



Malignant wounds in patients with advanced stage cancer

**A randomized controlled intervention study -
quantitative and qualitative findings**

PhD. Dissertation
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Malignant wounds in patients with advanced stage cancer. A randomized controlled intervention study – quantitative and qualitative findings.

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København, den 31. marts 2011

Resumé af afhandlingen: Kræftsår hos patienter med avanceret kræftsygdom

Et randomiseret interventionsstudium – kvantitative og kvalitative fund

Denne afhandling præsenterer resultaterne fra to studier, hvor formålet var, at forbedre behandlingen af kræftsår hos patienter med avanceret kræftsygdom.

Afhandlingen består dels af resultater fra et pilotstudie (feasibility study), som inkluderede kvinder med kræftsår og avanceret brystkræft (n=12). Pilotstudiet undersøgte effekten af sårbehandling med kul-sølvbandager, gel og skumbandager suppleret med psykosociale samtaler. Pilotstudiet undersøger endvidere patienternes oplevelse af at leve med et kræftsår.

Afhandlingen består endvidere af resultater fra et kombineret kvantitativt og kvalitativt studie som inkluderede 75 patienter med kræftsår, og avanceret kræftsygdom. I det randomiserede kliniske interventionsstudie undersøges intervention med honningbandager versus sølvbandager begge suppleret med cognitive samtaler samt afspændingstræning. De kvalitative fund afdækker fænomenet 'Health Care Avoidance' blandt kvinder med brystkræft, som havde ignoreret deres kræftsår.

Abstract

Baggrund: 5-10% af alle kræftpatienter udvikler kræftsår, hvor en underliggende tumor infiltrerer hud og væv resulterende i væskende og ildelugtende sår, som påvirker patienternes psykosociale situation og livskvalitet. Såvel sølv- som honningbandager har ved non-maligne sår vist positiv effekt på sårheling, lugt, eksudation og infektion, men er ikke undersøgt ved kræftsår.

Formål og design: I et hypotesetestende, randomiseret, klinisk interventionsstudie (n=75) sammenlignes effekten af to sårbehandlinger gennemført i patienternes hjem af specialuddannede sårsygeplejersker to gange ugentlig i en fire ugers interventionsperiode:

Honningbandage versus Sølvbandage - begge suppleret med kognitive samtaler og afspændingstræning.

Hypotese: intervention med honningbandager viser større effekt end sølvbandager på:

Primary outcome: sårstørrelse

Secondary outcome:

1. *Sårrelaterede:* Renhedsgrad, infektion, lugtgener, eksudation, sårsmertes.

2. *Patientrelaterede:* angst og depression, mestring og livskvalitet.

Endvidere belyses, via kvalitative data, patienternes erfaringer med at have kræftsår samt patientens perspektiv på fænomenet Health Care Avoidance i relation til ignorering af kræftsår hos brystkræftpatienter.

Metoder: foto med software-program Quantify-Image-Central, sårpodninger, sårmorfologiregistrering, VAS-score (smerter, eksudation, lugt). Psykometriske test (EORTC-QLQ-C30, HADS, mini-MAC), samt interviews.

Resultater: 69 patienter med kræftsår og avanceret kræftsygdom, alder 47-90 (median 65.6) indgik i studiet. Der var ingen statistisk signifikant forskel på sårstørrelse, renhedsgrad, eksudation, lugt, smerte og bakteriologi imellem grupperne. Hverken den antineoplastiske eller den antibiotiske behandling havde indflydelse på antallet af bakteriegrupper. Den mediane sårreduktion var 15 cm²/8 cm² for henholdsvis honning/sølvgruppen (p=0.63).

Efter pooling af data fra honning- og sølvgrupperne sås en forbedring fra baseline til post intervention på: sårstørrelsesreduktion hos 62% og øget renhedsgrad hos 58% (n=69).

Der var statistisk signifikant forbedring af patienternes vurdering af lugt (p=0.007) og eksudation (p<0.0001) samt af

angst ($p=0.007$) og depression ($p=0.049$), men ingen signifikant forskel på livskvalitet (HRQoL) og mestring (mini-MAC) ($n=69$).

Patienter med en reduceret sårstørrelse havde en median overlevelse på 387 dage sammenlignet med 134 dage for patienter, der ikke havde en reduktion i sårstørrelse ($p=0.003$).

Interview med patienterne indikerede, at de fandt interventionen gunstig og effektiv. Interviewundersøgelsen afdækkede fænomenet Health Care Avoidance i forbindelse med kræftsår hos kvinder med brystkræft ($n=17$). Kvinderne oplyste, at de bevidst undgik at søge lægehjælp i 24 måneder (median) (range 3 - 84 måneder), og de først søgte lægehjælp ved alvorlige kropslige symptomer som spontan knoglefraktur, dyspnoe (lungemetastaser) eller sårblødninger.

Konklusion:

Kræftsår er kroniske sår som medfører lugtgener, eksudation og psykosociale problemer.

Der fandtes ingen statistisk signifikant forskel mellem sølv- og honninggrupperne på sårstørrelse, renhedsgrad eksudation, lugt og bakteriologi.

En sårstørrelsesreduktion hos 62% og øget renhedsgrad hos 58% af den samlede population fra baseline til post intervention indikerer en forbedret sårhelingsproces. En statistisk signifikant reduktion af lugt, eksudation, angst og depression ved begge behandlinger forbedrede patienternes velbefindende og deres samlede situation.

Resultaterne indikerede, at en intervention med sølv- eller honningbandager suppleret med kognitive samtaler og afspændingstræning må overvejes som fremtidigt behandlingstilbud til patienter med kræftsår og avanceret sygdom.

Summary of the Ph.D.-thesis:

Malignant wounds in patients with advanced stage cancer.

A randomized clinical intervention study - quantitative and qualitative findings.

This Ph.D. thesis dissertation presents the results of two studies that aimed to improve treatment of malignant wounds in patients with advanced stage cancer.

The thesis comprises the results of a pilot study that included women with malignant wounds and advanced breast cancer (n=12). The pilot study investigated the effect of wound care using charcoal-silver bandages, gel as well as psychosocial conversations. The study also investigated the patients' experiences living with malignant wounds.

The thesis furthermore includes the results of a combined quantitative and qualitative study that drew in 75 patients with malignant wounds and advanced stage cancer. In the randomized study an intervention comprising honey dressings vs. silver dressings both in combination with cognitive conversations and relaxation training were investigated. The qualitative study researched the phenomenon of 'Health Care Avoidance' in relation to ignoring of malignant wounds in breast cancer patients.

Abstract

Background: 5-10% of all cancer patients develop malignant wounds. These wounds form from underlying tumors that penetrate the skin and result in exudation and in malodorous wounds that affect patients' psychosocial conditions. Silver- and honey-coated bandages shows positive effects on malodor, exudation and infection in non-malignant wounds but have not been tested in malignant wounds.

Aim and design: The effects of two wound treatments are compared in a randomized clinical intervention study (n=75). The intervention were carried out in the patients' own homes by specialized wound care nurses, twice weekly over a four-week period:

Honey-coated versus silver-coated bandages - both treatments are supplemented with cognitive conversations and relaxation training.

Hypothesis: The effects of honey-coated bandages are superior to silver-coated bandages on:
Primary outcome: wound size.

Secondary outcome:

- 1. Wound related aspects:* cleanliness, infection, malodor, exudation, wound pain.
- 2. Patient related aspects:* anxiety, depression, coping and quality of life.

Qualitative data highlights patient experiences living with malignant wounds and the patient's perspectives on Health Care Avoidance in relation to ignoring of malignant wounds.

Methodology: Photography using Quantify-Image-Central software, wound swabbing, wound morphology registration, VAS scoring (pain, exudation, malodor), psychometric testing (EORTC-QLQ-C30, HADS, mini-MAC) and interviewing.

Results: 69 patients with malignant wounds and advanced stage cancer, aged 47-90 (median 65.6) were included in the study.

There was no statistically significant difference in wound size, cleanliness, exudation, malodor, pain and bacteriology between the groups.

Neither the antineoplastic nor the antibacterial treatment influenced the number of bacteria types.

The median reduction in wound size was 15 cm²/8 cm² respectively for the group using honey-coated bandages and the group using silver-coated bandages (p=0.63).

Pooled data analysis from the two groups showed an improvement from baseline to post-intervention with respect to diminished wound size in 62% of patients and increased cleanliness 58% of patients (n=69).

There was statistically significant improvement in the patients' estimation of malodor ($p=0.007$), exudation ($p<0.0001$), anxiety ($p=0.007$) and depression ($p=0.049$) but no significant difference in quality of life (HRQoL) and mastering skills (mini-MAC) ($n=69$).

Patients with reduced wound size had a median survival time of 387 days compared with 134 days for patients with no reduction in wound size ($p = 0.003$).

Interview with patients indicated that they found the intervention beneficial.

The interview study uncovered the 'phenomenon' of Health Care Avoidance in connection with malignant wounds in women with breast cancer ($n=17$). The women informed consciously avoiding seeking medical assistance for 24 months (median) (range 3-84 months) and they did not seek assistance until faced with serious physical symptoms such as spontaneous bone fracturing, dyspnoea (lung metastases) or wound bleeding.

Conclusion: Malignant wounds are chronic wounds that lead to malodor, exudation and psychosocial problems.

There were no statistically significant differences between the groups either using silver-coated bandages or honey-coated bandages in terms of diminished wound size, cleanliness, exudation, malodor and bacteriology.

Reduced wound size in 62% of the population and increased cleanliness in 58% from baseline to post-intervention were indicative of improved healing. A statistically significant reduction in malodor, anxiety and depression with both treatments improved the patients' wellbeing and overall situation.

The results indicate that an intervention using silver-coated or honey-coated bandages, supplemented with cognitive dialogue and relaxation training should be considered as a future treatment option for patients with malignant wounds and advanced stage cancer.

Original papers

This dissertation is based on the following papers:

- I. Lund-Nielsen, B; Müller, K; Adamsen, L. Qualitative and quantitative evaluation of a new regimen for malignant wounds in women with advanced breast cancer. *Journal of Wound Care* 2005, 14; 2:69 – 73

- II. Lund-Nielsen, B; Müller, K; Adamsen, L. Malignant wounds in women with breast cancer: feminine and sexual perspectives. *Journal of Clinical Nursing* 2005, 14:56 – 64

- III. Lund-Nielsen B; Adamsen L; Kolmos HJ; Rørth M; Tolver A, Gottrup F. The effect of honey-coated bandages compared with silver-coated bandages on treatment of malignant wounds — a randomized study. *Wound Repair and Regeneration* 2011 (Accepted for publication)

- IV. Lund-Nielsen B; Adamsen L; Gottrup F; Rørth M; Tolver A, Kolmos HJ. Qualitative Bacteriology in Malignant Wounds — A Prospective, Randomized, Clinical Study to Compare the Effect of Honey and Silver Dressings. *Ostomy Wound Management* 2011; 57 (7):28-36

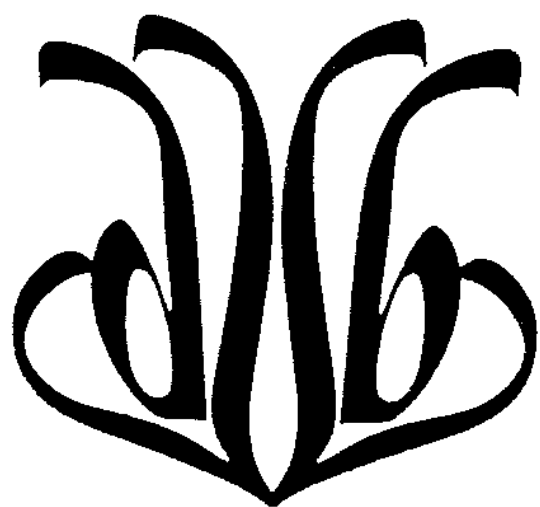
- V. Lund-Nielsen B, Midtgaard J, Rørth M, Gottrup F, Adamsen L. An Avalanche of Ignoring: a Qualitative Study of Health Care Avoidance in Women with Malignant Breast Cancer Wounds. *Cancer Nurs* 2011; 34 (4):277-285

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1. Malignant wounds: introduction

1.1. Cancer in Denmark

In Denmark, 35.500 people are diagnosed with cancer annually which means that every third Danish citizen/resident will receive this diagnosis during his/her lifetime (1). Cancer treatment over recent years has improved due to more specialized surgery and new developments in antineoplastic treatment in the form of, for example, chemotherapy, irradiation, antibody and antihormonal treatment. This has led to an increase in the one-year survival prognosis in eight large cancer groups (lung, breast, ovarian, uterus, cervical, prostate, rectal and colon) during the period 1997-2008 (2), an increase in the number of patients cured and more cancer patients living longer with the disease (3).

1.2. Terminology

Some patients will develop malignant wounds during their illness. The wounds stem from underlying tumours that infiltrate the skin, capillaries, lymph nodes and tissue (4-8). There is no agreement in the literature about what terminology to use when diagnosing a malignant wound. The terms 'fungating wounds' or 'malignant cutaneous lesions' are used and both terms can be misleading as 'fungating' refers to the structure of the wound and is not present in all malignant wounds while 'cutaneous lesions' refer to a condition when an open wound is not always present (9). Since the wounds develop as a result of the cancer process, the term 'malignant wounds' will be used in this thesis dissertation.

1.3. Literature review

A literature search on CINAHL, Dissertation Abstracts Online, EMBASE, Medline (PubMed), Science Citation Index Expanded, Social Sciences Citation Index, used the following descriptors: Malignant wound(s), Cancer Wound(s), Fungating Wound(s), Malignant Cutaneous Wound(s), Neoplastic Wound(s), and identified 260 English language articles on malignant wounds during the period 1980 to 2010 of which 198 were relevant, including three randomized studies in small populations, all of which focused on malignant wounds and malodour (10-12). The majority of the literature concerning malignant wounds is case studies. Most guidelines on malignant wounds are developed based on experience rather than on clinical intervention research. The articles focus on patho-physiological consequences of malignant wounds; including malodour (4;13-15), exudation and bleeding (16-18), infection (11) and pain (19). Only a few studies highlight the influence of malignant wounds on patients' psychosocial status, their quality of life and experiences with malignant wounds (20-23).

1.4. Incidence, prevalence and prognosis

A 2007 Cochrane Review by Addeley & Smith (24) suggests that a 5-10% incidence rate of malignant wounds is considered uncertain as malignant wounds are not classified by an independent diagnosis code and since the incidence of ma-

lignant wounds is not listed in international cancer registries. Uncertainty about the incidence rate is further compounded by discrepancy in the literature regarding the definition of the term 'malignant wound' and further discrepancy about the extent to which wounds stemming from melanomas should be included in the incidence count. Lokkingbill et al 1990 (25) reviewed journals from over a 10-year period in Pennsylvania and 5% of these journals involved cutaneous aspects, did not include melanomas and no differentiation was made between intact or damaged skin. Alvarez et al 2007 (26) found a prevalence rate of 7% at the Calvary Hospital, New York but did not specify the inclusion criteria used. Krathen et al 2003 (27) showed a prevalence rate of 5% for cutaneous lesions, where lesions with intact or damaged skin were included but lesions from melanomas were excluded. The above data indicate that approximately 5-7% of all cancer patients will develop malignant wounds. The wounds are most prevalent in patients over 60 years of age who have advanced cancer (5). The occurrence of malignant wounds is associated with a poor prognosis (median survival of approx 6 months). Saeed et al 2004 (28), after reviewing 77 cases of cutaneous tumor metastases over a 10 year period (1993-2003), found that 29% of the patients died within the first month of being diagnosed with cutaneous lesions, 66% died within the first six months and 75% within the first year.

1.5. Wound characteristics

Malignant wounds are most common in breast cancer and head-neck cancer. Malignant wounds vary considerably in size and presentation – from being only a few cm² to spanning the entire thorax surface, arms or back. The wounds can occur in connection with an initial operation for cancer (29), in cutaneous metastases (5) or by growth of a tumour through the skin (30). Typically, malignant wounds are classified as chronic and often lifelong since wound healing stagnates in the inflammatory phase instead of advancing to the granulation and epithelialization phase. This is possibly due to the underlying cancer (8;31) (see the wound healing process 3.2.).

1.6. Treatment of malignant wounds

The aim of treating malignant wounds is to reduce issues of malodour, exudation, pain and infection while healing is often considered an unrealistic aim due to the presence of tumour tissue at the base of the wound (6;30). Petrek et al 1983 (32) describes three of 19 smaller wounds (1-8 cm) in patients with breast cancer that healed as an effect of radiation therapy, and Lo et al 2007 (33) reported similar healing in superficial and smaller malignant wounds (6x7x1 cm). Furthermore, a single malignant wound was observed to have healed in own study during a 4-week intervention with silver-charcoal and foam bandages (34).

There is general agreement that patients with malignant wounds should be offered surgery if possible, and radiation and/or antineoplastic therapy. In complement, wound care that focuses on healing principles and reduces wound related problems like malodour, exudation, infection and wound pain is recommended (6;19;30). It is further recommended that patients are offered psychosocial care and that issues associated with having a malignant wound (e.g. depression, shame and changed appearance) are captured in the treatment plan in order to support and sustain the patient's quality of life (6;29;35).

1.7. Authors experiences from clinical practice and the pilot study (paper I and II)

It became evident while meeting the patients with malignant wounds that they had various physiological and psychosocial problems. It was therefore decided to run a pilot study with a four-week intervention, involving 16 consecutively selected breast cancer patients with advanced stage disease and malignant wounds. The aim of the study was to gain knowledge about the extent to which an intervention that uses modern wound care products (amongst which were silver-charcoal bandages and foam bandages) in supplement to psychosocial support in the form of conversations with patients could improve wound healing, reduce malodour, exudation and pain and positively influence the patients' wellbeing (34;36).

The key action areas in the four-week intervention in the pilot study included:

1. Systematic and structured wound treatment based on and existing knowledge about treatment of exudation, odour, bleeding, and wound pain in malignant wounds – and based on continuity. The author administered wound care as well as wound evaluation for each patient at home once weekly and a wound care nurse administered care up to twice weekly depending on how often the bandage required changing.
2. Wound care was administered using modern healing principles and modern wound care products; Alginate (Algisite M®), a hydrocellular bandage (Allevyn Adhesive®), a hydrogel (Intrasite Gel®) and carbon-silver bandage (Actisorp Plus®).
3. In connection with the weekly evaluation of wound care, psychosocial conversations were held between the participants and the author and focused on the malignant fungating wound's influence on their daily lives, self-image, sexuality, femininity and social relationships.

Twelve of the 16 women with advanced breast cancer as well as malignant wounds (75%) accepted to be included in the study and these women completed the intervention without any adverse reactions (attrition rate 100%).

The pilot project demonstrated that the wound care intervention was feasible.

The size of malignant wounds in women with advanced breast cancer can vary considerably. In this pilot study the wound size varied from 2 cm² to 240 cm² (15cm x16cm on the thorax surface). The wounds were exuding, malodorous and painful which were factors that limited the patients'

daily life and social interaction.

The pilot study indicated that the intervention could improve the wound's physiological status in 9 of the 12 patients and could support the patients' wellbeing in 5 of the 12 patients.

The wound care component of the intervention proved feasible and there were no adverse reactions (skin problems, increased wound pain, malodour or exudation) (34;36).

The pilot study indicated promising results, but had also some weaknesses: it focused on a single diagnostic group (breast cancer patients) and involved a smaller population (n=12). There was no control group in the study and as such it was not possible to conclude whether results were due to the intervention or from other effects. It should be noted that the pilot project participants are seen to have been 'their own control' prior to the intervention as they were responsible for their own wound care that involved applying paper towel, handkerchiefs, sanitary pads or at best some form of gauze to the wound. The pilot study looked at the effect of 'professional' wound care in combination with psychosocial support in contrast with the patients' earlier 'own' wound care.

The malignant wounds in three of the patients worsened during the intervention period on par with the progression of their disease. They experienced nausea, weight loss, fatigue, and low haemoglobin levels and compromised wound healing.

The pilot project indicated that the tested intervention could positively impact wound healing and wellbeing when used in complement to antineoplastic clinical treatment in 75% of the patients. It furthermore indicated that malodour, exudation, wound pain, impacted body image, anxiety and feelings of stigmatization continued to be problematic despite the intervention.

1.7.1. Conclusion from the literature review and the pilot study

In the pilot study as well as in the literature on malignant wounds, it is underscored that exudation and malodour due to the colonization of bacteria are the most burdensome wound related problems. Since carrying out the pilot project, new antiseptic wound care products have been developed.

Topical use of silver and honey wound bandages in chronic non-malignant wounds, including leg wounds, for example, have shown antiseptic, antimicrobial and anti-inflammatory properties and have proven to be effective in the healing process and in relation to malodour and exudation (37-40). Neither silver nor honey dressings have been tested on malignant wounds.

In the pilot study a silver-charcoal bandages, gel and foam bandages were used in supplement to a psychosocial component. In order to meet the challenge of malodour and exudation continuing to be problematic post-intervention, attempts were made in the subsequent randomized study to intensify the treatment of malodour and exudation by using a silver product with a higher silver content and comparing that with the effect of newly developed honey bandages.

2. Aims and hypotheses

This Randomized Clinical Trial (RCT) included men and women with different cancer diagnoses, and who were at advanced stages of the disease and had malignant wounds. The patients were in clinical antineoplastic treatment or in a control process. To gain knowledge about the extent to which malignant wound treatment options could improve, the aim of the trial was to compare the effect of two types of interventions, and both being carried out over a four week intervention period:

Honey bandages + cognitive conversations + relaxation training compared to
Silver bandages + cognitive conversations + relaxation training

Hypothesis: Intervention with honey bandages has a larger effect than silver bandage on:

Primary outcome:

Wound size (as a sign of wound healing)

Secondary outcome:

Wound related:

- Degree of cleanliness
- Colonization/infection in the wound
- Malodour
- Exudation
- Wound pain

Patient related:

- Anxiety and depression, mastering skills and quality of life

A further goal was to highlight, through the qualitative data, the patients' perspectives of the overall intervention and their experiences with their malignant wounds. More specifically the study investigated what impact malignant wounds have on body image, femininity/masculinity and sexuality. A final aspect of the study was to investigate the impact of the intervention as a whole on experienced well-being.

3. Theoretical frameworks and the intervention literature

3.1. Choice of intervention

The intervention in both the pilot study and the RTC study was a modified version of the bio-psychosocial model first described by a North American psychiatrist, George Engel, in 1977 (41). The principal assumption supporting the model is that health and illness cannot simply be understood from a biological perspective but is optimally under-

stood when combining biological, psychological and social factors. The model is partially derived from the social cognitive theory, in which it is claimed that there is interaction between the mind and the body.

The intervention in the current study was developed with focus on both the wound and cancer related problem (biological aspects) and furthermore focused on the consequences of the disease on feelings, thoughts, reactions and social interaction (psychosocial). A modified version of the model, however, meant that the author deemed it important to broaden the focus to include the patient's existential situation as rooted in advanced stage cancer, as well as the practical dimension comprising contact with further health experts, including the district nurse, hospital personnel, dietician, social worker, physiotherapist, psychologist or priest. Furthermore, the patient's perspective was essential and was drawn from direct contact with the patient.

The pilot study's intervention was, inspired by wound care approaches that related to malodour, exudation, wound pain and infection; one approach being the use of charcoal-silver bandages in combinations with psychosocial supportive conversations and continuity. It was agreed that wound care for the 12 included patients would be administered by the author in collaboration with three wound care nurses. Each patient would only have contact with the author and one of the wound care nurses. Should their bandage require only one change each week, the patients would have contact with only the author. The author carried out the psychosocial conversations during the pilot study.

Since malodour and exudation were issues highlighted in the pilot study, two antiseptic wound bandages were selected for comparison in the RCT-study – silver bandages versus honey bandages. The wound care intervention was supplemented with relaxation training and conversation based on the cognitive therapy framework in all patients. This cognitive dimension was added because literature had shown effect of cognitive therapy on anxiety and depression, and because the author has a fundamental belief that by shifting thought it is possible to change mental reactions, body image perception and wellbeing. As the geographic breadth of the study was expanded to include the entire country, i.e. 69 patients in total, three out of every five conversations held were conducted by the author, with the remaining conversations conducted by the wound care nurses.

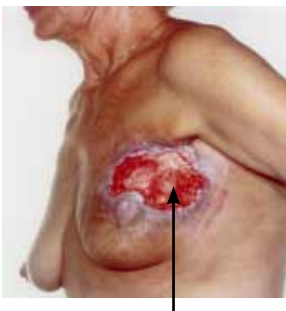
The literature and definitions used in the intervention are presented below. More specifically, the literature identified below concerns wound care; silver and honey bandages; cognitive behavioural therapy (in the form of conversation and relaxation training); and anxiety and depression, including a brief description of phenomenology which is the conceptual framework that forms the basis of the qualitative studies in this thesis.

3.2. Wound care

The wound care process in the case of acute wounds is carried out in three phases:



1) *Inflammation phase* is characterized by bleeding, tenderness, heat, exudation, yellow/black necrosis, non-vital tissue and infection/colonization with micro organisms. The wound is typically painful and malodorous.



2) *Granulation phase*, characterized by red vital tissue, with substantial bleeding and clean and free of necrosis and infection. The wound is barely exuding and mixed with blood.



3) *Epithelization phase*, characterized by epithelization. Fibrin and lymph can cause small scabs. The tissue is pale, almost translucent until completely healed (31;42).

The above-mentioned wound healing process for malignant wounds has stopped for some reason. The wounds remain at the inflammation phase for months up to a year, unless the healing process is positively affected.

Modern wound care principles ensure *moist wound healing* in contrast to conservative treatment with, for example, gauze. In 1962, GD. Winter (43) found that the speed of epithelization doubles if scab formation is prevented and moisture is retained in the wound. Today, wound care principles are built on this principle and include rinsing the wound with tap water, using bandages that promote moist wound healing here (honey, silver, and foam bandages),

providing an acidic environment (ph-level 4,5-5,7) and maintaining a constant wound temperature. Wound care is here administered together with **antineoplastic treatment** (chemotherapy, anti-hormonal treatment, antibody treatment, etc.) (44) which is used in advanced stage cancer, a situation whereby, beyond the existing malignant wound, there is 'evidence of disease' (in the lungs, bones, brain and/or disease that is spread outside of the local tumorous region) (45).

3.2.1. Silver bandages

In the pilot project, malodour proved to be a considerable problem and persisted after the intervention. The literature highlights that odour in malignant wounds results in nausea and loss of appetite. This can affect overall status, wound healing and quality of life (11;46). Furthermore, the odour from a malignant wound can lead to depression and anxiety (13;46). Finally, the odour can affect a patient's sexuality and can cause patients to become socially isolated (4). The studies show that the odour is the result of necrotic tissue and colonization of bacteria (4;15;46) which is why removal of necrotic tissue through mechanical wound rinsing is recommended (4;47). Investigations related to malodour and infection in malignant wounds has shown that bandages containing active silver can reduce the odour. Over recent years, silver bandages have been commonly used against wound infection (48), as the silver ions interact with the bacteria's DNA and prevent replication (49). Despite its widespread use, there are very few randomized studies on the use of silver on *people* with wounds (38). The majority of evidence on the effect of silver is from animal and in vitro studies (50;51), and Bergin & Wraight 2006 (52) report in their Cochrane review that randomized, clinical trials are needed in this area. Fong & Wood 2006 (37) state in their review that silver can have antiseptic, antimicrobial and anti-inflammatory properties, and Hampton 2003 (13) describes in her evaluation of bandages for malodour, that bandages with active silver are odour reducing, which ascribes to an antibacterial effect.

3.2.2. Honey bandages

Honey has been used for wound infection over centuries. Hippocrates, around 400 BC used it to cleanse wounds and cracked lips, and Celsus, around 50 BC recommended a mixture containing honey for application on wounds with scabs (40). More recently, honey bandages have become commercially available and contain honey with a special antibacterial effect (Manuka-honey) (53-59) that meets the basic requirements for modern wound care, amongst these being the requirement of moist wound care and low pH level. The studies document that honey bandages can promote wound healing, wound cleansing and have antimicrobial, odour, exudation and wound pain reducing properties (60-65). Amongst the different honey products, honey from the New Zealand tea tree *Leptospermum scoparium* (Manuka honey) is claimed to have the greatest antibacterial effect,

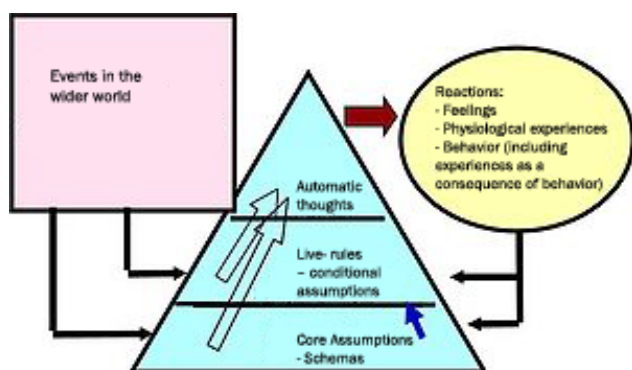
which, amongst other aspects, is due to the honey’s osmotic impact, low pH-level and hydrogen peroxide content (66). The nectar of honey from *Leptospermum scoparium* is further described as having an additional antibacterial component that is as yet unidentified. Documentation on the honey’s antibacterial effect is offered primarily from in vitro and animal studies. The honey’s antibacterial effect and wound healing properties are further documented in relation burn wounds, decubitus and Fournier’s gangrene (67), infected surgical wounds (68), diabetic wounds (69) and chronic leg wounds (61;70). Furthermore, honey has been found to be effective in radiation induced mucositis, radiation induced skin reactions and ‘hand and foot skin’ reactions in chemotherapy (71). Most of the studies are case series or un-blinded RCTs with small population groups. Honey has shown an antibacterial effect in in-vitro studies against *Staphylococcus aureus*, including methicillin-resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa*, streptococci, vancomycinresistant enterococci (72-74) as well as in combating yeasts and fungi (75).

3.3. Cognitive behavioural therapy

Cognitive conversations and relaxation training, both of which are anchored in cognitive behavioural therapy, were used in the current study in an attempt to reduce anxiety and depression levels.

3.3.1. Cognitive conversations based on the cognitive therapy framework

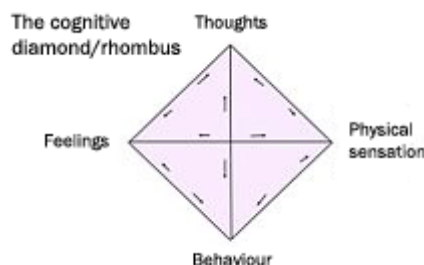
Cognitive therapy was originally developed by the psychiatrist, Aaron Beck, and its approach considers what a person thinks of him/herself and the world, feelings and behaviour patterns as well as their physical signs and symptoms. This is illustrated in ‘The Cognitive Model’ (76).



(Diagram by Christian A. Stewart Ferrer)¹

The model shows that thoughts rise from three levels that are influenced by broader world events, opinions, and upbringing.

1. Schemas – core assumptions is the law of nature or accepted persuasions about how we see the world (e.g. ‘the earth is round’ or ‘we will all die’).
2. *Life-rules – conditional assumptions* are the rules that we follow in order to remain in the world (e.g. ‘If I help others, I will be accepted’). Thoughts that arise from levels 1 and 2 are normally unproven – they simply exist without further consideration.
3. *Automatic thoughts* arise based on our life rules and schemas. A person who thinks negatively about him/herself and the world will typically ‘produce’ negative thoughts when a stressful event presents itself. He/she will react to the event from the worst possible perspective and ‘thinking errors’ like, for example, negative predictions, over generalizations, taking information out of context and labelling are common (77). Being negative to ‘reality’ results in difficulty managing feelings, uncomfortable physical sensations and inappropriate behaviour. A positive attitude about oneself and the world, in contrast, will result in positive thoughts, physical sensations and behaviour, which is why cognitive therapy works to identify and challenge negative automatic thoughts and draw in alternative constructive thoughts (76). In this thesis dissertation, the ‘Cognitive Diamond’ (see model below), originally developed by Beck 1979 (78), is used to disseminate the above-mentioned knowledge to the patients.



(Diagram by Christian A. Stewart Ferrer)²

3.3.2. Anxiety and Depression

A cancer diagnosis is claimed to result in **anxiety and depression** in 15-40% of all cancer patients (79;80), and as such are amongst the most frequently noted symptoms related to cancer (81-84). The prevalence of anxiety and depression in *advanced stage cancer* is claimed to be significantly higher than in curable cancer (85). In addition, having a malignant wound will most likely increase feelings of anxiety and depression due to, for example, social isolation that results from having a malodorous and exuding wound. Depression is described as being an independent predictor of poor survival in advanced cancer due to reduced self-care and non-compliance with anti-cancer treatment (86;87). The degree of anxiety and depression is measured in the current study, using the Hospital Anxiety and Depression Scale (HADS) (88-90).

¹⁺² http://da..wikipedia.org/wiki/Kognitiv_terapi den 28.01.11

Anxiety is defined here as ‘*an unpleasant subjective experience associated with the perception of real or imagined threat*’ (91). This thesis focuses on generalized anxiety that is a more sustained state of anxiety filled with tension and worry (92). According to the authors of the HADS questionnaire generalized anxiety covers: the state of anxious mood, restlessness and anxious thoughts (89). The use of the term **Depression** in relation to cancer patients with advanced stage disease remains unclear in the literature. The term *depression* is used both as a *category* (such as a diagnosis/disorder) and as a *dimension* that includes depressive symptoms that are not necessarily seen as a diagnosis/disorder (93). In a psychiatric context, symptoms such as appetite loss, weight loss, fatigue, sleeping disorders, difficulty concentrating and sadness are classified under the depression diagnosis that, if seen in an oncology context, would be recognized simply as symptoms of advanced stage cancer. This is also reflected in the frequency variation of depression in cancer patients and in studies concerning depression in cancer patients that seldom define the term ‘depression’ (93). ‘Depression’ in this thesis dissertation refers to the term ‘anhedonia’ and which the authors of the HADS questionnaire, Snaith & Zigmond 1994, p.2 (89) describe as ‘*the state of loss of interest and diminished pleasure response*’. Anhedonia refers to the depressed person’s characteristic inability to feel happy. Anhedonia is seen to be an appropriate criterion to differentiate pathological signs and symptoms of depression on the one hand and normal reactions to grief and hopelessness on the other hand.

3.3.3. Cognitive conversations – anxiety and depression

Cognitive therapy is primarily used in the treatment of clinical depression, anxiety, personality disorders and psychoses (94). It is also used in the cancer field under the assumption that since cognitive therapy has shown to be effective on clinical depression and anxiety, its therapeutic form could hypothetically have an effect on generalized anxiety and depression (anhedonia measured by HADS) in cancer patients (95). In a RCT study, cognitive therapy (group-based conversations in conjunction with weekly relaxation training over a 20 week period) has shown an effect on anxiety and depression in women with breast cancer (96). A meta analysis by Osborn et al (97), involving 1,492 cancer survivors with various cancer diagnoses (60% breast cancer) showed an effect of cognitive therapy on anxiety, depression and quality of life (intervention period was 4-55 weeks; weekly conversations of one-hour duration; relaxation training; instruction or problem-solving). The authors concluded that one-on-one interventions had a more sustainable effect than a group-based intervention. In their RCT study, Kissane et al 2007 (87) showed positive effects with 90-minute weekly, group-based cognitive conversations over a 12-month period on depression (anhedonia) in breast cancer patients with advanced stage cancer.

The majority of studies combine cognitive therapies such as conversation and relaxation training and the interventions are typically offered as group therapy (98). Only a few studies have tested cognitive conversations as an isolated intervention (99;100). A questionnaire study by Semple et al 2005 (101) shows, that 28 patients with head-neck cancer preferred one-on-one cognitive therapy to group therapy. Bottomley 1998 (98) found that patients with new diagnosed cancer, who have participated in a cognitive behavioural therapy intervention (weekly, group-based cognitive conversations and relaxation training for 90 min., over 8 weeks), learned the skills required to challenge and resolve issues – and learned to use the cognitive model.

3.3.4. Relaxation training – anxiety, depression and pain

Progressive relaxation training takes its origin from neuromuscular relaxation. The aim is to provide transparent rest and control of the body muscles by teaching the patient to relax the large muscle groups. By systematically guiding the patient to flex and relax different parts of the body from the feet to the head, the patient will reach a relaxed stance. The method was developed by Joseph Wolpe, psychiatrist and professor in cognitive behaviour therapy during the 1950s (102). Progressive relaxation (whereby the muscles are actively flexed) as well as passive relaxation (whereby focus is placed through the thought process alone to relax the muscles) trigger what Benson 2000 (103) calls an automatic ‘relaxation response’ which is a series of physiological reactions that disengage the automatic ‘fight or flight’ system. This results in a cascade of physiological reactions that lower the heart rate, respiration and blood pressure (103). Relaxation training is rarely used as an isolated intervention (104) but is typically combined with other cognitive interventions such as conversation or guided imagery. In the present study the intervention uses a combination of relaxation training and cognitive conversations to investigate the extent to which these components have an effect on wound pain, anxiety and depression in cancer patients with malignant wounds and advanced stage disease. The literature primarily presents studies in which relaxation training is used to counteract anxiety and depression in cancer patients. Cheung et al 2003 (104) showed a significant effect on anxiety and quality of life in their randomized study of 59 patients with colon-rectal cancer (after stoma surgery) versus a control group, in a 10 week intervention with progressive relaxation training (2-3 times weekly, home-based). And Baider et al 2001 (105) showed in their randomized study of newly diagnosed cancer patients (n=116) with various types of cancer when compared with the control group, that relaxation training and guided imagery (60 minute group sessions, once weekly over 6 weeks) increased psychological and physical health and improved body-mind control. Based on this we decided to include one-to-one cognitive therapy and relaxation in the therapeutic approach to all the patients.

3.4. A phenomenological approach

An existential phenomenological approach was used in the qualitative investigations discussed in this dissertation. Existential phenomenology emanated from a philosophical tradition developed by, amongst others, Martin Heidegger (1889-1976) and is characterized by its ability to analyze people's experiences (106). From this perspective, man is seen as a being that 'already' has and always will have a relationship with our common world; this includes what Heidegger calls man's special manner of *being-in-the-world*. Man's *being-in-the-world* is understood as man involuntarily having a relationship with the world – we think, see, hear, feel and are made aware through our activities, language and body interaction with other people and with the world. From a phenomenological viewpoint, man's existence in the world is purposeful and the most prevailing question in relation to phenomenology is what the essence is of a given phenomenon experienced by man (107). In the current qualitative investigations, the essence researched is living with a malignant wound and ignoring the fact that one has cancer. A North American professor in psychology, Amadeo Giorgi, describes existential phenomenology as inspired by the French philosopher, Maurice Merleau-Ponty (1908-1961), who believed that phenomenology can best be understood in light of its phenomenological methodology, that he claims, '*has four principal characteristics: it is descriptive, it uses the reduction, it searches for essences, and it is focused on the intentionality*' (108) p. 49. Giorgi uses these characteristics as a basis for his approach to analyzing interview data. The stages of Giorgi's analytical methodology are the first to achieve a general and detailed sense of the material as a whole. Next, to discriminate what Giorgi calls 'meaning units (109), these 'meaning units' relate to a specific research question. In the current study, the 'meaning units' were the experience of having a malignant wound and health care avoidance. The final stage of the methodology provides a synthesis of transformed 'meaning units', which allow the description of aspects of the studied phenomenon, referred to as 'the essence'. This analytical method was used in qualitative studies in this dissertation, however, in a modified version as described by Malterud 2001 (110).

4. Materials and methods

4.1. Design

The pilot study was a prospective and explorative study with a quantitative and a qualitative component. The intervention was tested on 12 consecutively selected women with progressive breast cancer, who also have malignant, fungating wounds and were undergoing treatment or control check-ups. The following study project is organized as a prospective, randomized, clinical intervention study and in addition an exploratory qualitative interview study. The study compares the effect of two types of interventions (honey bandages compared with silver bandages both in combination with relaxation training and cognitive conversations) from baseline through a 4-week intervention period.

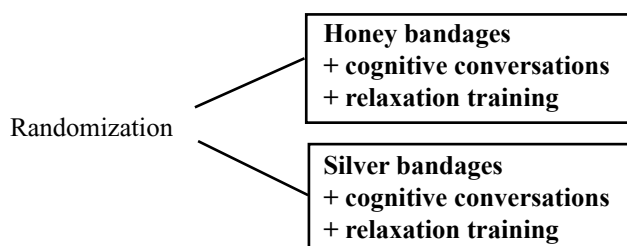
After the patients provided written consent they were allocated to one of the two interventions. The Clinical Research Unit (KFE), in the Oncology Clinic of Copenhagen University hospital (Rigshospitalet), managed the randomization using a computer-based process via the Clinical International Trial Management System (CITMAS) (111). Stratification for gender, cancer diagnosis (+/- breast cancer) and treatment (+/- antineoplastic treatment) was carried out. No control group was included. Blinding participants in the allocation process was not possible.

4.2. Sample size

The pilot study (34;36), which captured data from 12 patients (18 wounds), used standard deviation on the change in wound size between 'own' wound care and 'professional' wound care using, amongst other products, silver bandages (before and after the intervention on the same patients) 8,0 +/- 36,6 cm² (mean +/- standard deviation). It was assumed that the change had the same standard deviation when using either the honey or the silver wound bandages. A quick calculation showed that a sample size of 70 patients would be required, i.e. 35 in each group, in order to establish a sum difference of 24,8 cm² between the two treatment groups and with a significance of 5% and strength of 80% in a two-sided, unpaired t-test. As no relevant literature could be found regarding the effect of wound care on size of malignant wounds the pilot study results were used in the calculation. The results of the pilot study were positive considering that this was a patient group with advanced cancer. Its further anticipated effect in the RTC study was therefore considered to be optimistic.

4.3. Sample

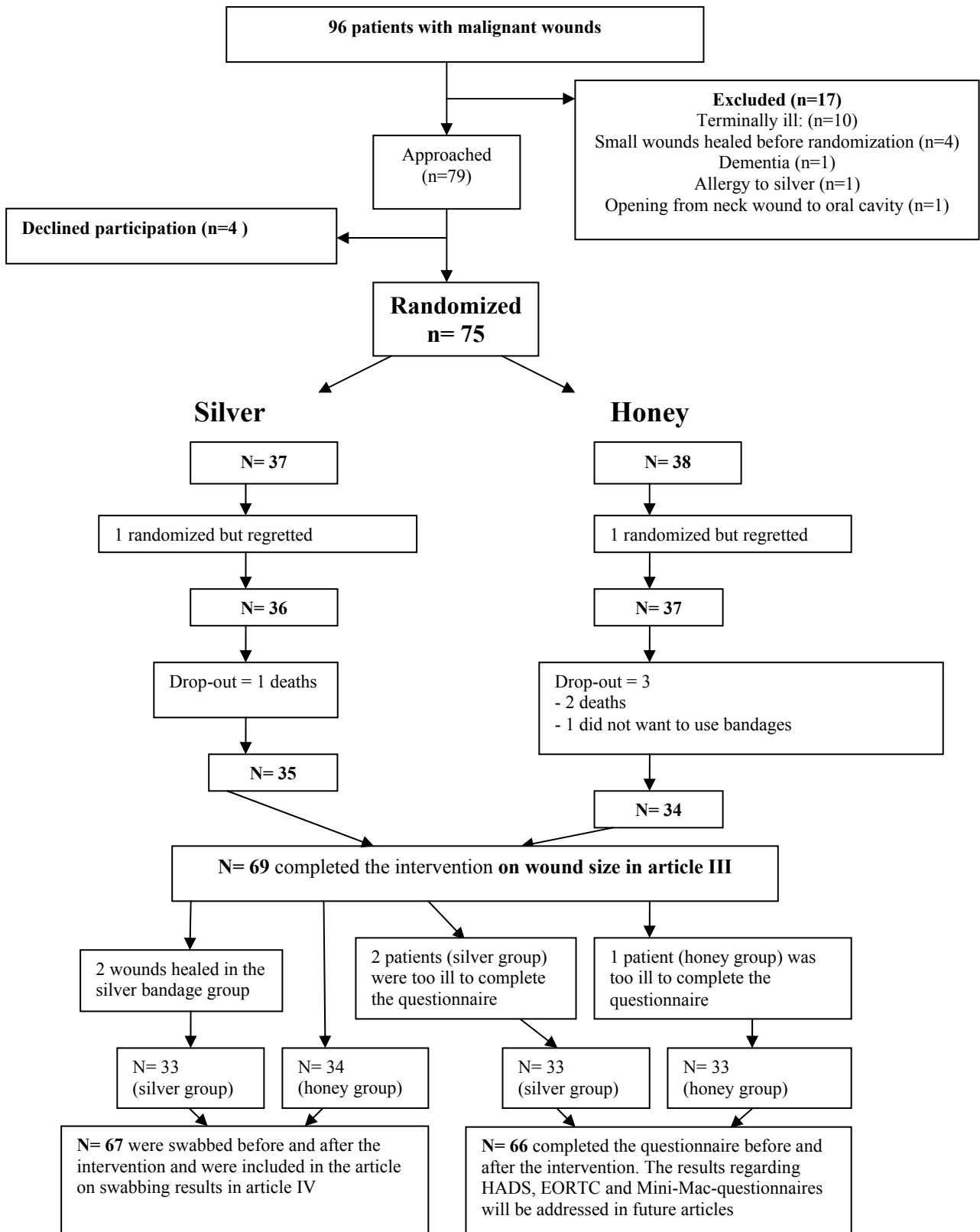
In total, 75 patients were randomly selected during the period from March 2007 to August 2009.



Danish speaking cancer patients who met the following criteria were included in the study: over 18 years old, had malignant wounds and advanced stage cancer (metastases to the lungs, bones, liver or cancer outside of the localized region of the tumour), Wound size >1,5 cm² a survival prognosis of 3+ months, and who had not received radiation therapy to the wound region over the past three months. Patients undergoing antineoplastic treatment (e.g. chemotherapy, anti-hormonal treatment) as well as systemic antibiotic treatment were also included in the study.

Assessment of whether a wound could be characterized as malignant was made based on clinical signs and not by means of biopsies. The clinical diagnosis was: a non-healing wound that developed from the growth of a tumour that erupted through the skin or occurred in connection with metastases. Patients from oncology departments in 10 municipality hospitals (e.g. Herlev, Hillerød, Roskilde, Næstved, Odense, Vejle, Sønderborg, Esbjerg, Århus and from Rigshospitalet) and from the wound department in Viborg, Odense Hospice and head-neck-department at Køge hospital were included in the study. During the 2.5-year data collection period, 96 patients were offered participation in the project. Of those 21 patients were not included in the randomization process: 10 patients were too ill and died before the randomization began. Four patients were not interested in joining the study, as they were satisfied with their current wound care/were signed up to another intervention. In four patients, superficial and smaller wounds (<1 cm in diameter) healed by means of another treatment prior to randomization. One patient was excluded from the study since his head/neck wound developed an opening into the oral cavity and this condition did not allow the wound bandage to remain free from food or drink. Two further patients were excluded, i.e. one patient due to dementia and another who was allergic to silver. Following the randomization process, two patients were dismissed from the intervention prior to its start – one patient was dismissed because she wanted to try a gel containing morphine before joining the current intervention. She used the gel up to her death a few weeks later. The other patient did not join as she was offered surgery and the wound was removed during the mastectomy. Finally, one patient did not wish to use bandages and three further patients died during the intervention period. Sixty-nine patients are therefore included in paper III, and 67 patients in paper IV, as two of the patients' wounds healed during the intervention period and it was not possible to take swabs from them after the intervention. Sixty-six patients completed the questionnaire before and after the intervention. The results regarding HADS, EORTC and Mini-MAC-questionnaires will be addressed in future articles (see figure 1).

Figure 1: Patient Flow-Chart



4.4. The overall intervention

The patients had advanced stage disease with burdensome symptoms and short lifespan. It was therefore important that the intervention be carried out avoiding any additional burden on the patients which is why treatment was home-based and done by experts (oncology, wound care, cognitive conversations). The author has worked with cancer patients over 18 years and for 10 years with people with malignant wounds, in addition to one year's training in cognitive therapy. The three employed care providers were experienced nurses with continuing education in wound care

and were further trained in the intervention by the author through counselling and guidelines. As such, the patients were provided with the state-of-the-art know-how, competence and expertise in relation to wound care and psychosocial aspects. Furthermore, the basic principles for the treatment of patients by the nurses included ensured time, a calm atmosphere, engagement and presence. Finally, the fact that the care providers assumed a listening attitude toward the patients allowed a trusting alliance to form in the patients' own environment.

Table 1. Intervention

Intervention	The Intervention period (28 days)
<p>1. Modern wound healing principles:</p> <ul style="list-style-type: none"> - Cleansing with faucet water and liquid medicinal soap (PH factor 4,5) and continued with the aid of tweezers, Mezenbaum scissors, and non-woven pads - Wound treatment with modern wound care products: Group A: Manuka honey bandages (<i>Algivon[®]/Activon Tulle[®] UMF 12+</i>) + <i>Absorbent bandage</i> + (<i>Sorbion[®]/Drymax[®]</i>) + <i>Skin-prep[®]</i>. + <i>Foam bandages (Allevyn Adhesive[®])</i> <p style="text-align: center;">Or</p> Group B: Nanocrystalline silver (<i>Acticoat[®]/Acticoat Absorbent[®]</i>) + <i>Skin-prep[®]</i> + <i>Foam bandages (Allevyn Adhesive[®])</i> <p>2. Cognitive conversations about coping with the illness and particularly with a malignant wound</p> <p>3. Relaxation training: pre-recorded CDs with relaxation exercises</p>	<ul style="list-style-type: none"> - Wound care took place in the patient's homes, on average every 2-3 days with approximately 1½-hours per visit. - The author and the patient collaborated with the wound care nurse/district nurse to complete the procedure. - Wound evaluation and wound swabbing was carried out once weekly by the author. - The patients received one-hour cognitive conversations held weekly with the author, structured in accordance with the cognitive therapy model. - The patients underwent 20 minutes of progressive relaxation training at least once every other day.

4.4.1. Wound care

The intervention was carried out over a 4-week period, during which wound care was administered, with an interval of 2-3 days on average. Wound care was carried out in collaboration with the patient, the wound care nurses and district nurses. The patient was instructed on how to manage a seeping bandage, based on a checklist for wound care that ensures the highest level of safety and security. The aim of the instruction was to relay relevant knowledge about the wound and its care and treatment, in order to impact and support cognitive functions (attitude, experience of control). Wound care: see table 1.

how the symptoms and side effects could best be managed. The conversations also concentrated on psychological issues such as existential, social, physiological and practical aspects. They covered wound related problems, e.g. exudation and malodour, social isolation, choice of clothing, sexuality and closeness, anger, anxiety, thoughts of death and impotence to win over the cancer's visible destruction of the body. The conversation structure: 1. Thoughts on a specific issue. 2. Possible mental shift to constructive thoughts, and 3. Practical help with symptoms such as nausea, fatigue and pain, or contact on behalf of the patient with the municipality regarding district nursing or other service to enhance the patient's daily life.

4.4.2. Cognitive conversations – use in practice

Five problem-focused, self-supporting, individual one-on-one cognitive conversations lasting approximately one hour (45-90 minutes) were held weekly over the 4-week intervention period. During the conversations, focus was placed on what was possible [for the patient to experience] 'despite' having problems related to cancer and malignant wounds, and

Conversation process: Since the initial contact between the author (or the wound care nurse) and the patient was by telephone, we seen as 'strangers' when making the initial home visit. That is why the visit was structured in a way that we and the patient discussed more practical wound related problems, after which wound care was administered and, in closing, a cognitive conversation took place. The wound acted as the entry point to conversing about the patient's life, thoughts and feelings and the wound related procedure

became the turning point in the relationship. By focusing initially on the wound we were able to form a basic evaluation of the patient, his/her thoughts about immediate surroundings, basic thinking and managing patterns as well as the psychological stance that could be used in the cognitive conversation (i.e. we observed how the patient referred to the wound, what feelings and reactions the patient showed in relation to the wound, and the patient's eventual interaction with the author during treatment of the wound). During the conversation, we explained and provided a diagram of the cognitive model and explained how thoughts, feelings, physical reactions and behaviour interact. The patient was initially asked 'What is your most pressing problem today', and the consequent conversation would focus on that problem. The aim of the conversation was to trigger cognitive, emotional and behavioural changes (see example of a cognitive conversation).

Example of a cognitive conversation

A woman with a malignant wound to the breast informs that she had been at a dinner party. She noticed that one of the guests was glaring at her and the patient felt 'uncomfortable' and left the party.

Using the Cognitive Diamond methodology, the situation was reviewed with the patient.

What were you thinking at that moment: 'Everyone is glaring at me because I have a huge, oozing and smelly malignant wound'.

What did you feel at that moment: 'I was panic struck and upset'

How did your body react at that moment: 'I got a stomach ache; my hands were shaking and I was blushing'

What did you do then: 'I excused myself and rushed back home. There, I promised myself that I would never go to another dinner party'.

Through Socratic dialogue, the thoughts were challenged:

- *What evidence do you have that everyone could see that you had a malignant wound?*
- *Are you able to see the situation from another perspective?*
- *How would you feel if this alternative perspective was the right one?*
- *What advantage/disadvantage would there be in sticking to the negative version?*
- *What advantage/disadvantage would there be if you gave up the negative thoughts?*

An alternative positive thought is launched. *How would it feel if the dinner guest was simply thinking that you looked charming and wished to speak with you?* 'I would be happy and it would feel great - and I would probably have stayed at the party'.

By use of this process negative thoughts can be restructured to more positive ones that, in this example, could have prevented social isolation. The patient, via the Cognitive Diamond methodology grasps an insight into and understanding that thoughts are steered by feelings, reactions and behav-

our that in this case resulted in further pain for the patient. The conversation would be summarized at the end. Often, the patient would be left with the task of remaining conscious of any thoughts/situations about the topic under discussion as well as to try and shift thoughts towards more positive, rewarding ones. At the close of each conversation, the patient would be asked if there were any practical matters with which we could assist. At a consequent meeting the following week, the conversation would begin with a summary of how matters have progressed since the last visit and new problems the patient may be facing were then identified and tackled.

4.4.3. Relaxation training – use in practice

The patient was expected to undertake relaxation training every other day for 20 minutes guided by instructions from a CD that contained two relaxation processes both with dialogue and music (Relaxation 1 & 2 by Christina Maria Melskens, Danske Afspændingspædagoger). If the patients were not in possession of a CD player, one was provided to them on loan by the author. The CD format was selected as it responded to the collective needs of the patients, including those who were physically weak. The patient could choose between progressive relaxation-training (Relaxation 1: 20 minutes) whereby they were expected to flex and then relax all of the muscles in the body or alternatively to select a form of relaxation that would draw in thought, beyond movement, to focus on relaxing the body (Relaxation 2: 17 minutes). The patients were instructed to listen and concentrate on the guidance provided on the CD. They were advised to lie down comfortably in an environment that had a suitable temperature and where it was quiet. The patients were guided through the process of relaxation, followed by piano music and at which time the patient was expected to simply remain lying down, listen and feel the benefits of relaxation. Finally, the patient was instructed to do light stretching movements and return to an upright position.

4.5. Data collection

Well-known and validated data collection methods were used in addition to own developed methods. Quantitative methods gained insight into the effect of the intervention on physiological parameters. Questionnaires investigated the effect of psychosocial aspects while qualitative methods were used to gain an understanding of the patients' experiences of living with a malignant wound and advanced stage cancer, including their perspectives on the intervention itself.

4.5.1. Registration record – demographic and disease related data

Information on gender, age, civil status, education, employment and social relations were collected from own devel-

oped registration records on the first day as well as disease data including diagnosis, time of diagnosis, time of wound identification, and time of the wound's antineoplastic treatments and medications.

4.5.2. Quantitative data collection related to primary Outcome: wound size

4.5.2.1 Digital images – wound size

Digital image capturing is a valid method to *evaluate wound healing and size* (112). A centimetre-measuring tool is placed next to the wound and in the pilot study this proved to be a durable method to evaluate the stage and size of the wound (34;36). The method is sensitive in accuracy to distance and lighting when capturing the image. That is why the method was considered to qualify for use in the current study and involved the transfer of images to the software program *Quantify Image Central*[®] that would then run a precise calculation of the wound size within 1 mm² accuracy (113). Image capturing took place on day 1 and day 28.

4.5.3. Quantitative data collection related to secondary Outcome

4.5.3.1. Digital images: Cleanliness of the malignant wound

Cleanliness of malignant wounds was also evaluated based on these captured images.

Definition of improved cleanliness: a wound that after intervention shows less necrosis, fibrin and increased vascularity and granulation tissue. The degree to which the wounds improved in cleanliness was estimated by four specialized wound care nurses on the basis of the images over time. These nurses were blinded to the treatments provided. The wounds were categorized as 'more clean', 'less clean' or 'unchanged cleanliness' compared to pre-intervention images. Agreement was reached when three out of the four or all four observers scored the same in each case. If two out of the four observers were not in agreement, the images were evaluated again, which occurred in four cases. Agreement between the four observers was evaluated using Cohen's Kappa score (114;115) after merging the group 'unchanged cleanliness' with the 'less clean' grouping.

4.5.3.2. Wound Morphology Record

Own record was developed and used weekly to describe wound morphology: *wound size, colour, stage, infection, odour, exudation and pain*.

4.5.3.3. Verbal rating scales- malodour and exudation

Malodour was evaluated at baseline and following the intervention period, based on a verbal rating scale (4-step) defined by Haughton and Young 1995 (116): 1) no malodour; 2) slight malodour; 3) moderate malodour; and 4) strong malodour. *Exudation* was evaluated prior to and following the intervention period, based on a verbal rating scale (4-

step scale): 1) Dry (no bandage change in a week); 2) Slight fluidity (bandage change once weekly); 3) Moderate fluidity (bandage change every 2-3 days); and 4) Heavy fluidity (bandage change daily or every second day).

4.5.3.4. VAS scales- malodour, exudation and wound pain

Malodour and exudation were also evaluated at baseline and following the intervention by the patients on a 100 mm graduated mechanical VAS-scale, as was the case with *Wound pain*.

4.5.3.5. Swabs- infection/colonization

Infection/colonization by bacteria was measured through weekly wound swabbing to determine primarily wound pathogenic bacteria including haemolytic streptococci, *Staphylococcus aureus* and *Pseudomonas aeruginosa* as well as anaerobic bacteria and enterobacteria. Swabs were found to be reliable in detecting bacteria in wounds (117).

4.5.3.6. Quality-of-Life Questionnaire C30 (QLQ-C30 – quality of life)

The European Organization for Research Treatment of Cancer (EORTC) Quality-of-Life Questionnaire C30 (QLQ-C30) was used to measure *health related quality of life* (118-120). The survey comprised 30 questions, divided into six functional scales (physical, role, cognitive, emotional, social and global) as well as symptoms scales that measured fatigue, nausea/vomiting, sleeps disturbance, constipation, diarrhoea, appetite loss and dyspnoea. The raw data was transformed linearly to a scale ranging from 0 –100. The survey was used at baseline and post-intervention.

4.5.3.7. Hospital Anxiety and Depression Scale (HADS) – anxiety and depression

Hospital Anxiety and Depression Scale (HADS) questionnaire was used at baseline and after the intervention to measure the degree of *self experienced anxiety and depression*. The HADS-scale, that comprises 14 questions, was developed by Zigmond & Snaith in 1983 to measure general self experienced anxiety and depression in connection with a physical illness (90). Since 1989, HADS is suggested as a valid method to measure symptoms of anxiety and depression in cancer patients (89).

4.5.3.8. Mini-Mental Adjustment to Cancer (Mini-MAC) – coping

The Mini-Mental Adjustment to Cancer (Mini-MAC) questionnaire is a valid survey tool comprising 29 questions in five areas: fighting spirit, helplessness/hopelessness, anxious preoccupation, fatalism and denial (Cognitive Avoidance). The questionnaire was used before and after the intervention to measure the degree of *mastering cancer* (121;122).

4.5.4. Qualitative data collection

4.5.4.1. Semi-structured interviews – the pilot study

Semi-structured interviews were used as this method is optimal for capturing details and for uniquely highlighting the women's experiences regarding the impact of malignant fungating wounds on their daily lives (123). Two semi-structured interview guides were used, one prior to the intervention (G1) and the other post-intervention (G2). These guides contained both closed [yes/no] and open-ended responses. G1 contained 47 questions (11 open-ended, 36 closed) while G2 had 41 questions (18 open-ended, 23 closed). The guides had three themes, with the exception of G1, which contained demographic information and G2 focused on perspectives of the impact of the intervention. Theme A focused on wound related questions (physiological factors, the wound's process of development, perception about wound care products). Theme B dealt with psychological and social issues, such as femininity and sexuality, the wound's influence on everyday living and emotions and feelings while with other people. Femininity includes aspects of appearance, choice of attire, feelings of well-being and being a woman in social relationships. The term 'sexuality' refers to intimate situations such as embracing, touching and close physical contact. Theme C focused on future wound care (responsibility for wound care, social assistance, the home care nurse).

All 12 women in the pilot study were interviewed. The interviews lasted 45 minutes duration and took place in an office located at The National University Hospital of Copenhagen or in the women's own homes.

4.5.4.2. Semi-structured interviews – the RCT-study

The author held semi-structured interviews, using interview guides in the randomised study. The aim was to gain insight into each patient's unique experience of the situation and the patient's perspective of the intervention.

The interviews, which took place in each patient's home, were tape-recorded and had an average duration of 70 minutes (min 30 – max 180). Semi-structured interview guides were used at baseline and post-intervention. The themes were inspired by existing literature, knowledge gained from the pilot study and inspiration from the current thesis dissertation's theoretical framework. The interview guide used at baseline focused on a) wound related questions (physiological factors such as exudation, odour and pain as well as the wound's development and views on wound care products), b) psychosocial issues, and c) the wound's influence on everyday living. The interview, post-intervention focused on: a) silver or honey bandages, b) bandage related well-being and security, c) symptoms/side-effects, d) the cognitive conversations and relaxation training (duration, content, benefits), e) benefits of the overall intervention (wound-related, mastering skills, wellbeing, physical aspects), f) perspectives on being treated at home, g) being involved in a research project (use of questionnaires, wound swabbing, images, interviews), and h) suggestions for improvement.

All patients (n=69) were interviewed at baseline and post-

intervention in the randomized study. Ten key respondents' interviews post-intervention were selected to describe and evaluate the intervention. The respondents were selected with maximum variation in age, gender, diagnosis and perception (positive/negative) of the intervention. The results from these interviews are briefly discussed in this thesis while the interview responses at baseline will be addressed in a future article.

During the interviews in the RCT-study, it became evident that some women with breast cancer had kept their wounds as a secret and avoided medical treatment for several months and often years. This led to a more in-depth study – 'Health Care Avoidance'- of 17 women with advanced breast cancer.

4.5.4.3. In-depth interviews

The interviews explored the experience of Health Care Avoidance in women with advanced breast cancer and malignant wounds who had avoided seeking medical treatment (n=17). Experience can be defined as immediate, pre-reflective of actual event, facts, self and surroundings (124). An interview guide covering different time periods and focus areas was used to structure the interview.

The initial interview guide was based on findings from own previous research on the femininity and sexuality perspectives of breast cancer wounds (125). The aim of the interview was to provide rich, detailed information about the phenomenon under study (126). The interviews which were tape-recorded, had an average duration was 70 minutes.

5. Data analyses and interpretation

5.1. Statistics (paper III and IV)

Mann-Whitney U-tests and Fisher's exact tests were used to compare the baseline characteristics of the treatment groups.

The change in wound size during the intervention period was analyzed using the Mann-Whitney U-test as well as linear regression. To meet the assumption of variance homogeneity, linear regression analysis was done on square root transformed data. The regression parameter described the size of the wound after the intervention, measured in percent of the wound size at baseline, and a test for the hypothesis that this parameter equals 100% was performed. Cohen's Kappa score was used to evaluate observer agreement between multiple inspections of wound cleanliness before and after the intervention.

Changes in subjective measures of malodor, exudation and pain, measured on a VAS scale was compared across treatment groups using a non-parametric Mann-Whitney U-test. Paired Wilcoxon tests were applied to detect changes over the intervention period. Due to a low number of patients in each response group for the measures of malodor and exudation, categories 'no'+ 'slight' - and 'moderate' + 'strong' were merged prior to the statistical analysis. The

resulting binary variables were analyzed using a logistic regression model taking into account the correlation between variables, which were analyzed using a logistic regression between observations on the same patients. Testing for the effect of an interaction between time and treatment as well as a marginal test for change over time is given in the presentation of the results.

The survival time of the patients after the intervention period is described by a Kaplan-Meier survival plotting, and a log-rank testing was used to assess whether there was a longer survival period among patients experiencing a reduction in wound size during the intervention period.

The binary outcomes measuring the prevalence of various bacterial groups were analyzed using a logistic regression model with treatment group and time (before/after completing of the intervention) as explanatory variables. A treatment effect during the intervention period corresponded to an interaction between treatment and time. Test for changes in the prevalence of a bacterial groups corresponded with a main effect of time. To take into account that matched observations on the same patient were present in the data set, all p-values were adjusted by including an over dispersion parameter in the logistic regression model. The paired outcomes recording the number of bacterial species present in each wound before and after intervention were compared using a Stuart-Maxwell test for marginal homogeneity. Finally, Fisher's exact test was used to explore if the microbiology of the wound after completion of the intervention depended on whether we observed a reduction in the wound size during the intervention period.

A 5% significance level was used throughout the study. The statistical analyses were made using "*R: A Language and Environment for Statistical Computing, version 2.10.1.*" (127).

5.2. Qualitative Data Analysis

5.2.1. Semi-structured interviews from the pilot study (paper I and II)

All interviews were conducted by the author, tape-recorded and later transcribed verbatim. The thematic analysis began in the field during data collection, using semi-structured interview guides. In the initial stage of data collection, two of the researchers reviewed the first two interviews to verify the reliability of the interview process. Contextual annotations were added and data were then categorized in relation to the pre-established themes in the interview guides. The data were sorted under different headings to identify expressions or phrases that could be seen to form features (107). Predominant themes and text passages served to identify and validate meaning related to the patient's experiences of living with malignant wounds (pilot study) and experiences with the given intervention (RTC). Investigator triangulation was used to minimize biases (128). Based on an analysis of each text, consideration was given to alternative explanations for the findings.

5.2.2. Interviews from the in-depth interview study 'Health Care Avoidance' (paper V)

All interviews were conducted by the author and transcribed in full using the *Microsoft WORD* application. During transcription, care was taken to transfer contextual annotations (i.e. emphasized words, use of capital letters, symbols, etc.). A data driven analytical format, described by Crabtree & Miller 1999 (129) as editing analysis style, was applied. Furthermore investigator triangulation was applied to minimize bias (129). A data driven, four-step analysis, based on the phenomenological philosophy recommended by Giorgi 1985 (109) and modified by Malterud 2001 (110) was carried out. The first step in the analytical process aimed at obtaining a general and comprehensive sense of the information gathered. This was ensured by each of the investigators responsible for the analysis listening to the interviews, and then reading through each interview transcript several times. Once we gained an overall sense of the material, the next task was to discriminate what Giorgi calls 'meaning units', which are understood as different units or blocks that express a self-contained meaning (109). This was ensured by carefully searching for the different key terms, aspects, attitudes or values that highlighted the interviewees' lived experiences.

The next step involved relating each of these meaning units to the specific research question under study (i.e. *lived experiences of Health Care Avoidance in women with breast cancer who have developed malignant wounds*) and assembling them into specifically revealing categories. At this point in the analysis, the investigators met several times to discuss the meaning of each of these categories and to rewrite, transform and condense them further. The final step involved summarizing the sense of each category into a single general analysis, which integrated and synthesized the transformed meaning units in order to describe the common and essential aspects of the studied phenomenon - referred to as the 'essence'. In this last step of the analysis, the investigators began the process of free imaginative variation, whereby aspects of the concrete phenomenon are varied until its essential or invariant characteristics show themselves (130). Giorgi (109) suggested that 'essence' could be defined as the most invariant and unchangeable characteristics of the particular phenomenon under study. Discussion and adjustment of the essence was carried out in continuous collaboration between the investigators and continued until unanimity could be attained.

5.2.3. Semi-structured interviews from the RCT-study concerning the intervention

The interviews that focused on the patients' experience in relation to the intervention are yet to be analyzed. The results section of this thesis dissertation presents only a general summary of the patients' statements regarding the intervention.

Presentation of data and further discussion of the results from the interviews will be addressed in a future article.

6. Ethical considerations

Patients with malignant wounds find themselves in a burdensome situation in that the majority of them have symptoms of advancing disease. The intervention was therefore carried out in the patients' own homes as it would prove to be an unnecessary burden to have them travel from around the country to be treated at Rigshospitalet.

The patients were first verbally informed via telephone about the project. If they showed interest in participating in it, they were then forwarded written information. The patients were given seven days to consider their decision to be included in the project and were then contacted by telephone about their decision. Those who accepted the offer signed a consent form and were included in the randomization process.

At the close of the project, the district nurse to each participant was contacted regarding product ordering and assistance with changing bandages and was provided with wound care products for three bandage changes.

The study was registered under the identification no. NCT00435474 at <http://www.clinicaltrials.gov>. Approval was granted from the National Data Inspectorate (2006110013A). The study adheres to guidelines set by the Ethical Research Committee for Copenhagen and Frederiksberg municipalities ((KF) 01 2006-5491).

7. Results

7.1. Demographic data in the pilot study – paper I and II

Twelve women with advanced breast cancer participated. The mean age of the women was 68.5 years (range: 57–85). They had had breast cancer for a mean of 8.2 years (range: 0.1–28). The mean duration of the wounds was 1.8 years (range: 0.1–4). At the start of the intervention, nine women were receiving anti-neoplasm treatment for their cancer (five chemo therapy and four anti-hormonal). The remaining three women had stopped taking this treatment as they had reached the end stage of the disease.

7.2. Paper I (pilot). Qualitative and quantitative evaluation of a new regimen for malignant wounds in women with advanced breast cancer

Prior to the intervention, the 12 participants were anxious about seepage, bleeding and odour originating from the wounds and were concerned these might be obvious to others. Following the intervention, nine wounds (75%) showed improvement with increased granulation and epithelialization and complete wound healing in one participant. Seepage was considerably reduced in 83% of cases and there was an average 75% reduction in the number of bandage changes. The women's sense of wellbeing improved, as did their independence and self-confidence.

7.3. Paper II (pilot). Malignant wounds in women with breast cancer: femininity and sexuality perspectives

The 12 women described how malodorous and exuding wounds trigger anxiety about seepage, prevent them from wearing feminine attire and cause them to suppress the need for physical closeness and sexual activity. The results showed that by using modern wound care products, the patients could be secured against seepage and odour. The women experienced a sense of comfort, were able to dress again as they wished, no longer felt caged in and isolated and were given a sense of freedom which they had not felt for a long time.

The intervention succeeded in increasing breast cancer patients' psychosocial well-being and reducing social isolation.

7.4. Demographic data in the RTC-study – paper III

Demographic and medical characteristics of the 69 patients are presented in Table 2.

88% of the participants were women. 80% had breast cancer, 12% had head- and neck cancer and 8% had other cancer diagnoses (sarcoma, bladder cancer, Merkel cell carcinoma, malignant melanoma). 81% of the patients were undertaking antineoplastic treatment with chemotherapy; anti-hormonal treatment, etc., and 16% were simultaneously undergoing antibiotic treatment.

The median of data at baseline for the patients (n=69) were: age: 65.6 years; wound duration: 7 month; wound size: 130.9 cm². (See photographs: examples of malignant wounds in paper II; III, V).

Two malignant wounds healed during the intervention period. Characteristic for these wounds was that they were superficial and small (2.44cm² and 1.98cm²).

Social: 55% of the patients were married and 29% were widowed; 30% did not have basic education after grade school, 45% had basic/secondary school education after grade school (<3 years), 25% university level/continuing education after grade school (3-5 years/>5 years). 78% were retirees.

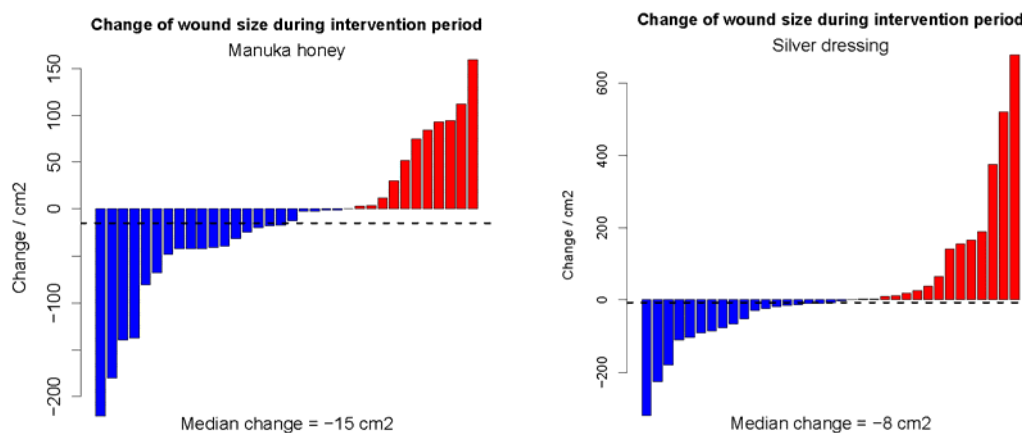
Table 2. Demographic and clinical characteristics of patients entering the RCT study

Variable		Group A Honey (n=34)	Group B Silver (n=35)	p-value
Sex	Female	30	31	1.000
	Male	4	4	
Age (Years)	Median	66.1	60.7	0.355
	Range	50.9 – 86.8	47.4 – 89.6	
Cancer diagnosis	Breast	27	28	0.619
	Head/Neck	5	3	
	Others	2	4	
Antineoplastic Treatment	Yes	28	28	1.000
	No	6	7	
Antibiotic Treatment	Yes	4	7	0.513
	No	30	28	
Wound duration (Month)	Median	7.5	6.0	0.834
	Range	1 – 86	1 – 48	
Civil status	Married/co-habitats	16	22	0.377
	separated/divorced/lives alone	7	4	
	Widow/other	11	9	
Education/training*	None	9	12	0.701
	Short (<3 years)	16	15	
	Medium-term 3-5 years/Long-term >5 years	9	7	
Employment status	Invalid status	7	5	0.490
	Other (retired, home-maker)	27	30	

* One missing from the silver group (education/training)

7.5. Paper III. The effect of honey-coated bandages compared with silver-coated bandages on treatment of malignant wounds - a randomized study

No statistically significant difference was noted in wound size, degree of cleanliness, exudation, malodour and pain *between* the honey and silver groups (group A and B). There was a median decrease of 15 cm²/8 cm² for the honey group and silver group, respectively (p=0.63) (see figure 2).

Figure 2

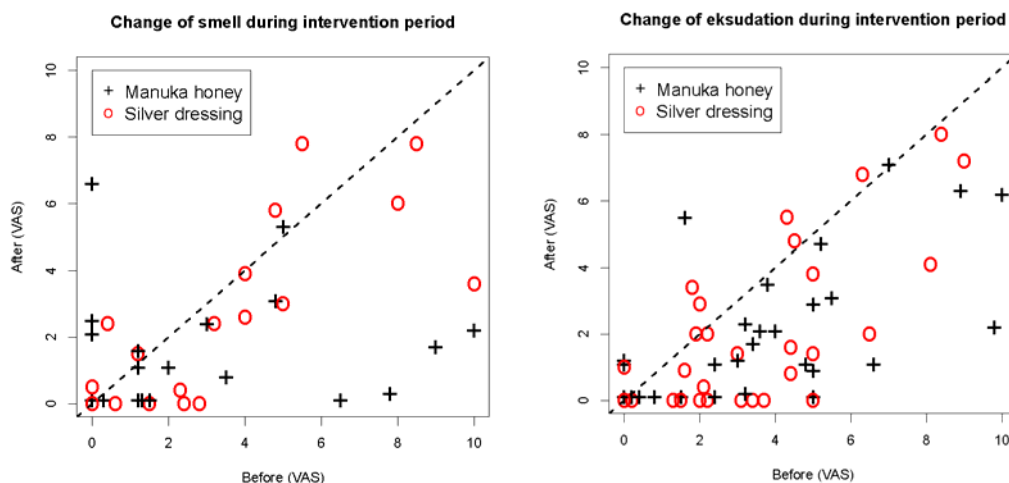
‘Waterfall diagrams’ displaying the change of wound size during the 4-week intervention period for the Manuka honey group (left) and the Silver bandage group (right).

As there was no difference between the effect of the honey and silver bandages the two treatment groups A and B were therefore pooled in a subsequent analysis to investigate whether treatments from the pooled group showed any effect over time.

After pooling data from group A (honey) and B (silver) post intervention data showed that there was improvement in: wound size for 62% and cleanliness for 58% of the patients (n=69).

VAS rating score for malodour (p=0.007) and exudation (p<0.0001) improved significantly post intervention (see figure 3).

Figure 3.



The figure displays the change of smell (left) and exudation (right) over the intervention period reported by the patients on a VAS scale ranging from 0 to 10. Patients below the dashed line experienced a decrease over the intervention period.

Patients with reduced wound size had a median survival time of 387 days compared with 134 days for patients with no reduction in wound size (p = 0.003). (See Kaplan-Meier survival plot – paper III – figure 3.)

7.6. Paper IV. Qualitative Bacteriology in Malignant Wounds - A Prospective, Randomized, Clinical Study to Compare the Effect of Honey and Silver Dressing

The honey group (group A) and the silver group (group B) were comparable at baseline.

There was no statistically significant difference between the bacteria found over time or between Group-A and Group-B. Neither antineoplastic nor antibiotic treatment influenced the occurrence of wound pathogens.

Staphylococci were found in 43%, enteric bacteria in 39% and pseudomonads in 22%. In total 25 bacterial species were identified.

7.7. Paper V. 'An avalanche of Ignoring'– A qualitative study of Healthcare Avoidance in women with malignant breast cancer wounds

Out of the 55 patients with malignant wounds and advanced breast cancer who were included in the RTC, 17 of them (31%) deliberately avoided health care for a median of 24 months (min.3; max.84). Despite being aware of the development of a malignant wound from a breast lump, the women avoided health care due to negative health care experiences and burdening life situations. The women did not seek health care up to the point when the situation became unmanageable.

7.8. Quality of life

Quality of life was measured using the EORTC-QLQ-C30 questionnaire. There was no difference observed in the global score and the subscales between treatment groups at any point during the intervention period. *The results will be published separately.*

7.9. Anxiety and depression

No significant differences *between groups* were reported for anxiety and depression (HADS).

There seemed to be a decrease in depression ($p = 0.048$) and in anxiety ($p = 0.007$) during the intervention period.

11% of the patients had moderate to severe anxiety and 15 % had moderate to severe depression.

The results will be published separately.

7.10. Coping

There was no statistical significance in difference between the groups in relation to coping strategies throughout the intervention period.

Presentation of data and further discussion of the results from the questionnaires (EORTC-QLQ-C30, HADS and Mini-MAC) will be addressed in future articles.

7.11. Statements from the qualitative interviews about the intervention

Since the interview component analysis has not been completed, a summary of the statements regarding the intervention is presented below.

Collectively, the patients expressed that intervention and its components were meaningful for them. Wound care, the cognitive conversations and relaxation training were considered to be important constituents of the treatment. It was important to the patients that the intervention was carried out at home and with a high level of know-how, experience and consistency.

Several of the patients stated that they felt more energetic, had more personal resources and more hope about the future following the intervention.

Wound care. The patients expressed that the bandages that were used were effective in absorbing exuding fluids and malodour and that they were comfortable, soft and flexible (not tight –fitting) and looked 'professional'. The form and size of the bandages, however, were difficult to match with the form and size of head and neck wounds on some of the patients.

The majority of the patients experienced a reduced frequency in bandage change, which resulted in the practical and psychological relief of not having to deal with the wound and its treatment.

Cognitive conversations. Overall, the patients stated that the conversations held were important to them. They did not want to speak with a psychologist but that since the author was visiting them at home anyway for the wound treatment, it was relevant to discuss their issues. Several of the patients expressed that the conversation about thoughts of death was meaningful to them as that subject was often difficult to tackle with their own family members.

It was important for the patients to gain more knowledge about the wound, while they often were in a situation where the nurses needed to be supervised. It gave them a sense of security and a higher sense of managing their situation and independence in relation to the wound care.

Some of the patients expressed that the conversations trig-

gered further reflection and a broader understanding and insight into their mental reactions and well-being. Furthermore, some of them experienced the ability to shift negative thoughts to more positive ones.

Relaxation training: The patients indicated that the relaxation training gave them an opportunity to completely relax. Several patients informed that they fell asleep during the sessions but that their bodies were more relaxed before falling asleep and that their sleep was more regular and tranquil. Some of them stated that the relaxation training caused 'the body and mind' to relax and that relaxation provided them with an escape from pain and thoughts.

Several of the patients undertook both the progressive and the passive relaxation training. The progressive relaxation component was characterized as 'calming' because it provided an opportunity for them to feel in a relaxed state in comparison with a tense state. The passive relaxation component was considered the better of the two when the patient was feeling tired.

Presentation of data and further discussion of the results from the interview will be addressed in a future article.

8. Discussion

8.1. Introduction

The Ph.D. thesis dissertation presents the results of a study that aimed to improve treatment of malignant wounds in patients with advanced stage cancer.

The thesis comprises the results of a pilot study that included women with malignant wounds and advanced breast cancer ($n=12$). The pilot study investigated the effect of wound care using charcoal-silver bandages, gel as well as psychosocial conversations.

The thesis furthermore includes the results of a randomised, clinical study that drew in 75 patients with malignant wounds and advanced stage cancer. The overall intervention in the RCT-study involved the use of honey versus silver bandages, both bandages applications being supplemented with cognitive conversations and relaxation training in all patients. The purpose of the RCT was thus to compare two types of wound bandages with regard to effects on the wounds - and to corroborate the results from the pilot study. The study investigated effects of healing, cleanliness, malodour, exudation, pain and bacteriology. Furthermore, the intervention investigated the impact of its components on quality of life, anxiety, depression and mastering skills- these data will be published separately. The thesis also includes the results of two qualitative studies, one of which investigated the patients' experiences with having malignant wounds, and the other researched the phenomenon of 'Health Care Avoidance' in relation to malignant wounds.

8.2. Results achieved - summary

The results of the pilot study showed that the wound size and degree of cleanliness were reduced in 75% of the participants. This is not a significant difference from what was achieved in the RTC, where pooled data analysis from the two groups showed an improvement from baseline to post-intervention with respect to diminished wound size in 62% of patients and increased cleanliness 58% of patients (n=69).

The pooled data analysis showed, that there was statistically significant improvement in the patients' estimation of malodour (p=0.007), exudation (p<0.0001), anxiety (p=0.007) and depression (p=0.049) but no significant difference in quality of life (HRQoL) and mastering skills (mini-MAC) (n=69).

The results showed a significant correlation between wound size and survival. Patients with reduced wound size had a median survival time of 387 days compared with 134 days for patients with no reduction in wound size (p = 0.003)

We found no statistically significant difference in wound size, cleanliness, exudation, malodour, pain and bacteriology between the groups. Neither the antineoplastic nor the antibacterial treatments influenced the number of bacteria types. The median reduction in wound size was 15cm²/8 cm² respectively for the group using honey bandages and the group using silver bandages (p=0.63).

The qualitative interview results from the pilot study showed that the patients stated feeling shame and social isolation and their body image and sexuality were reported as negatively affected.

The interview study uncovered the 'phenomenon' of Health Care Avoidance in connection with malignant wounds in women with breast cancer (n=17). The women informed consciously avoiding medical assistance for 24 months (median) (range 3-84 months) and they did not seek assistance until faced with serious physical symptoms such as spontaneous bone fracturing, dyspnoea (lung metastases) or profuse wound bleeding.

8.3. Methodological considerations and limitations

8.3.1. Validity

To the author's knowledge, this was the first randomized study that included a larger population (n=75) of patients with malignant wounds and advanced cancer.

The strength of this RCT-study is that it was randomized and encompassed a national cohort in which patients with advanced stage cancer and malignant wounds were included from oncology departments nationwide. As such it was a representative group of patients in Denmark with malignant wounds.

Throughout the 2.5-year data collection period, wound care products remained the same, and procedures were carried out in relation to the comparative design by the author and the trained nurses who were supervised by the author.

The weakness of this RTC study is its lack of a control

group. Our previous research (the pilot study) (34) showed that the women did not have professional help with their malignant wounds prior to the intervention but used paper towels, handkerchiefs, sanitary napkins and at best, gauze. The pilot study therefore explored active treatment versus 'non-active treatment'. The results following the intervention showed promising results this made it unethical to include a control group without active wound care/treatment in the current RCT-study. Since the pilot study, developments have led to, that the majority of the patients used the modern bandages (typically foam bandages, alginate and gel) before entering the study. It was therefore not seen as either responsible or practical to allow a control group to be treated, for example, with the use of paper towels or handkerchiefs.

The study called for insight into further aspects than a measurement method could highlight. Therefore we used quantitative as well as qualitative methods. Method triangulation allowed increased insight of the subject under investigation and drew a coherent picture of the patients' situations (126). It indicates that the use of known and well-validated methods can increase the quality level of research (131). Some dimensions could only be highlighted using quantitative methods (e.g. wound size and degree of cleanliness through imaging) while the experience of having a malignant wound was best investigated through interviewing. Furthermore, there was a desire to measure the level of anxiety, depression and quality of life in the patients and that was done through well-validated questionnaires selected to highlight these dimensions. The interview investigation from the RTC study, which included the patients' perspectives on the overall intervention, was carried out; however, the data is yet to be published.

The results from the quantitative and qualitative investigations show that there is an effect of the overall intervention on, for example, cleanliness, malodour and exudation – and that the patients' experiences of these factors are in agreement. The methods used can therefore be said to have ensured internal validity. The term 'internal validity' describes the degree to which the study was designed and carried out in order to avoid systematic errors from occurring, whether the study investigated what it set out to do, and whether the results surfaced as a consequence of the intervention and not from other factors (110;126).

Since the patients all had advanced stage disease, it could not be expected that the patients attain improved illness status (including the malignant wound) during the four-week intervention period. The best scenario could have been that the cancer remained stable with antineoplastic treatment, however, in more realistic terms, in some cases the cancer progressed. This increases the belief that a positive effect in wound related variables and degree of anxiety and depression were the reason for the intervention and not other factors.

It would be relevant in this study to consider to what degree the study results were impacted by the author's relations to the patients as well as the author's background as a nurse having worked 10 years with patients who had malignant wounds. Without a blinding option, it is difficult in inter-

vention studies to dismiss the personal impact of the researcher on the effect. However, it should be noted that the principles of the intervention and the relations between the nurses and the patients remained the same for all of the patients over the 2.5-years data collection period, regardless of treatment group. An eventual effect cannot be dismissed; however, the effect would be the same for all of the patients.

8.3.2. External validity

External validity in quantitative studies considers in which context the results could be applied and the opportunity for generalizing them to a broader population (110). Polit&Beck 2004 (126) state that lacking external validity is the reason for small sample size in studies being performed at one location. In the current study, the patients were included collectively from oncology departments around the country, which proved to be strength as it is a representative group of patients in Denmark with malignant wounds.

The study's size (n=75) can be seen both as strength and as a limitation. With respect to the study of interventions on malignant wounds, a population of 75 cancer patients is considered as strength. This is justified both in the incidence of malignant wounds, and difficulty in including cancer patients with advanced disease who have a serious symptoms burden and the complexity of care and treatment needs. With respect to the randomized design, a population of 75 patients should be seen as a smaller sample size. Despite the small sample size and basis for this representative group, it is reasonable to assume that the results of this study can be reproduced and generalized to a broader population of patients with malignant wounds.

8.3.3. Bias

Bias is described as a systematic error that can result in the researcher erroneously concluding an effect of the intervention. To increase the study's quality any existing bias should be eliminated from the design, in the process of the study, in its reporting and in its analysis (132).

Randomization minimizes bias by establishing similar groups with equal distribution of known and unknown prognostic factors. Randomization can also minimize selection bias. In the current study, the patients were selected based on inclusion and exclusion criteria. Following informed consent, the patients were then randomly distributed into two groups using the software program CITMAS (111) and then stratified by gender, diagnosis and +/- treatment in order to reach a balance in both groups.

It was not possible to blind either the researchers or the patients in testing of the honey and silver bandages, especially since the honey bandages with respect to odour, colour and consistency could not be hidden. It should be indicated that it is strength that the bacteriology investigation (article IV) had a blinded laboratory component.

It can be seen either as strength or a limitation, that the evaluation of the wounds' status and the bandages role at baseline and post-intervention were the responsibility of

the author herself. It is considered as strength in respect to the fact that there was a higher degree of uniformity in the assessment. It can simultaneously be seen to carry a risk for bias, e.g. if the author had been biased towards one of the two treatments. An attempt was made to keep this bias at a minimum by using quantitative methods (images, swabbing and rating scales) and assistance of four blinded observers in the assessment of cleanliness based on the images (see Outcome measure considerations 8.4.).

8.3.4. Validity of the qualitative studies

The quality of interview investigations depend on several factors, including the sample, the extent of saturation and achieved transferability. The selection affects whether the informants have a wealth of information that the formulated issue can highlight. The term 'saturation' regards whether the selection is sufficient in quantity to achieve a sufficiently nuanced description and enough data to evaluate alternative interpretations. The term 'transferability' is covered in qualitative studies and regards the opportunities, limitations and considerations for the validity of the results and whether they can be transferred to similar contexts other than the one in which the study is implemented (133).

8.3.4.1. The pilot study interviews

During clinical practice in the oncology clinic, the author became aware that some of the women with breast cancer also had malignant wounds. On the basis of this fact, the author designed a pilot study with the aim to carry out a wound care intervention over a four-week period and to highlight the participants' experiences of living with a malignant wound. The author had one year to collect the data and during that period 12 women with malignant wounds and advanced breast cancer were consecutively included in the study (eight women from Rigshospitalet and four women from Naestved Hospital's oncology department). Under the given conditions (financial, time wise and geographically) it was possible to interview these 12 women before and following the four week wound care intervention period.

A convenience sampling strategy was used, since the study included all participants that were possible to access in the given period. At the same time, it could be argued that a purposeful intensity sampling strategy was used, which Crabtree and Miller (129) defines as interviewing of 'Information-rich cases that manifest the phenomenon intensely', since the women met the inclusion criteria of having a malignant wound, advanced breast cancer and required wound care. Collectively, the informants had sufficient experience with and knowledge of how malignant wounds affect their lives to pass this information along during the interviews.

The participants were grateful that someone was interested in their problems and experiences and they were eager to share their stories. The author conducted the intervention and also pre- and post-intervention interviews in connection with the pilot study. This can create uniformity in interpretation and risk bias, especially if the patients are asked to evaluate the overall intervention. It should be not-

ed, however, that the specific themes (e.g. femininity, sexuality, clothing, social isolation, shame, etc.) as they related to the unique situation of having a malignant wound, did not interfere with the assessment of the intervention, the author or any interaction between them. In order to minimize unilateralism in interpretation, researcher triangulation was used in the analysis of the interviews. From the themes related to sexuality and femininity nuances and detailed descriptions surfaced that were consistent with each other. No further new aspects or description of the phenomenon following the interviews with the 12 women was surfaced. This was probably due to the fact of the limited issue formulation, and saturation therefore, was considered as having been met within the theme areas. At the same time, it cannot be ignored that when interviewing, 25 women, for example, on other themes could have surfaced further aspects of living with a malignant wound, which could then have been further unfolded.

The results regarding femininity and sexuality in the current study are linked to the context of having a malignant wound and being diagnosed with breast cancer. The results can therefore only be transferable to future breast cancer patients that find themselves in similar circumstances in Denmark and other countries, since it is likely that the impact of a malignant wound on femininity and sexuality will be the same around the world.

8.3.4.2. The RTC study interviews

The initial intention in the RTC study was to interview 20 participants pre- and post-intervention. During the course of the project, however, the author experienced that the interviews had a therapeutic impact on the patients. These patients often felt that they were an overlooked patient group that did not capture the interest of the health staff. The fact that the author came to their home and expressed sincere interest in each patient's story proved valuable to the patients. The author received invaluable insight into and understanding of the general life situation and concrete story of each patient.

Sixty-nine patients were included in the RCT study and were interviewed at baseline and post-intervention. A combination of convenience sampling and purposeful intensity sampling were used since all possible participants were interviewed, and they all had the unique characteristic of having malignant wounds and advanced stage cancer (metastases to the lungs, bones, liver or cancer outside of the localized region of the tumor) as well as a survival prognosis of 3+ months. As such, the participants had deep enough knowledge to be able to express them regarding the malignant wound, treatment and experiences of living with a malignant wound. This interview material will be subsequently fully analyzed.

In order to grasp an impression first hand of what perspectives the patients had regarding the overall intervention, after transcribing the interviews the author selected ten of them that reflected the maximum variation in age, gender, diagnosis and perception (positive/negative). This sampling strategy can be seen to have selected key informants that

could provide the broadest possible evaluation of the intervention. From these 10 interviews the author could gain an impression of the extent to which there were consensus of the perspectives regarding the intervention. It must be stated, however, that only preliminary analysis has been carried out, and the content of these interviews can change in the future analysis process.

The author conducted the RCT study intervention as well as the interviews. It could have proven difficult for the patients to differentiate between assessing the intervention and assessing the author as a person. This posed the risk that a positive opinion about the author could have led to a positive opinion about the intervention while a negative opinion could have impacted negatively (107). It should furthermore be noted that impact on the patients could not have been avoided after four weeks of wound care and cognitive conversations. It would have been optimal if a researcher, who was not associated with the intervention, had instead interviewed the patients post-intervention. This proved to be impractical and financially difficult since the patients were drawn into the study from around the country and were too ill to travel to Rigshospitalet to be interviewed. Researcher triangulation will be used in the final analysis in such a way that researchers who do not have any connection with the study participants will analyze the interviews.

The results regarding the wound related intervention could be transferred to other patients with malignant wounds. There is no indication from the study that patients with malignant wounds and advanced cancer will react differently to relaxation training and cognitive conversations than patients who simply have advanced cancer. The extent, to which these results are transferrable to cancer patients with advanced disease in general, is dependent on the analyses and as such it is not possible at this time to come to a conclusion on this point in this dissertation.

8.3.4.3. In-depth interviews

During the RCT study interviews, it became evident that some women with breast cancer had kept their wounds a secret and avoided medical treatment for several months and often years. This led to a more in-depth study of 'Health Care Avoidance' that targeted 17 women with advanced breast cancer.

The interviews in that study showed that some of the participants responded differently than expected about avoiding medical assistance when they discovered their malignant wound. This astonished the author who pursued the phenomenon in the following patients to be interviewed. Each time that a new patient showed the same phenomenon, the interview frame intuitively broadened to include questions about the patients' choice of keeping the wound hidden, their life situation in relation to the malignant wound's appearance and avoidance of seeking medical assistance. A further developed interview guide was then created that resulted in deep insights into these reactions that deviated in comparison from the other patients who opted for contact with their doctor.

In accordance with the study's purpose, those participants

who had substantial experience with advanced breast cancer neglected their malignant breast cancer wounds and whom had deferred seeking medical treatment participated in the in-depth interviews.

The saturation point was reached after interviewing 11-12 women, i.e. the responses began to be repetitive and redundant and no new aspects surfaced. The author decided anyway to interview all of the patients (17 out of the 69 who were included in the RCT study) to gain an insight into how many breast cancer patients reacted by ignoring their wound, which turned out to be a striking number of them. One third of all women with breast cancer in the study had reacted by ignoring. Furthermore, all of the women who had ignored their malignant wounds were interviewed as it became apparent that the interview process had therapeutic value for them. These women felt shame and guilt for having decided to avoid medical assistance and which resulted in a life full of secrets and concealment of information to their closest relatives from months to years. After having decided to visit their doctor, the women felt the need to openly share their stories. By telling their story to the author, they had an opportunity to elaborate their experiences while the author was able to inform them of similar reactions from other women in the same situation. As such, they received confirmation that they were not the only ones who reacted by ignoring their circumstance and were able to come to terms then with accepting their poor choice, which relieved their feelings of guilt. The women's openness resulted in high quality interviews.

The validity of the study is supported by the use of researcher triangulation. The analysis was done by two investigators, which represented two different disciplines (nursing and psychology). The aim was not to obtain agreement among the researchers to confirm validity but rather to ensure transparency and share assumptions (110). During the interview, the author fed back to each participant the descriptions she had heard and asked the participant to confirm whether she had understood them correctly. Participant descriptions referred to thoughts and feelings that in some instances may have dated back seven years and as such could have been subject to recall bias. Health Care Avoidance should be viewed as a process that evolves over time and ends at the instance of first medical contact (i.e. a few weeks prior to the interview).

It is known in cancer literature that patients avoid contact with their doctor at any signs of cancer, e.g. bloody stools in the case of colon cancer or continuous coughing and fatigue in the case of lung cancer. What is specific to malignant wounds in comparison with other signs of cancer is that it requires exceptional action and efforts to hide and camouflage a bleeding and malodorous wound. That is why this can be considered as a group of patients that is in a difficult and extreme situation. Overall, the results of this study are transferable conceptually and theoretically to clinical settings where patients deliberately neglect bodily changes and physical symptoms in order to avoid health care that could issue them with a poor prognosis.

8.4. Outcome measurement considerations

8.4.1. Primary outcome – wounds size

The software program *Quantify Image Central* (113) was used in this RCT study to estimate the size of wounds within 1mm² accuracy rate. In the pilot study, wound size was measured by placing a measuring tape next to the wound. The wound size was then measured from the widest point from one side to the other side. The increase in accuracy in estimation of the wound size could have influenced the fact that we did not achieve the same improvement rate as in the pilot study. However, the increased accuracy did provide a more precise result of the effect of the intervention and furthermore an image of variation of wound sizes in malignant wounds, which had not yet been described in the literature.

8.4.2. Secondary outcome

8.4.2.1. Cleanliness

Using four observers instead of one to evaluate cleanliness based on images could also have influenced the fact that we did not achieve the same level of improvement in the wound healing process in the pilot study. In 62% of the patients in the current study, a reduction in wound size and an increase in cleanliness in 58% were noted while 75% improvement in wound size and cleanliness were achieved in the pilot study. This should be seen in light of the fact that there was a small population of patients (n=12) in the pilot study compared with the larger number (n=69) in the RCT study.

8.4.2.2. Colonization /infection

We used a standard *swabbing technique* routine, that was primarily qualitative, i.e. we registered whether a bacteria species was present or not, but not in quantity. A quantitative cultivation technique, e.g. biopsy, could have provided more detail and as such a more precise measure of the effect of the intervention. However, this would have required an invasive and much more complicated sampling technique, which was not possible under the given circumstances. Pellizzer et al. 2001 (134) showed in their study on deep tissue biopsy vs. superficial swab culture monitoring in the microbiological assessment in diabetic foot infection that there are no statistical differences between the two procedures in detecting bacteria. The mean number of isolates per patient was 2.34 using swabbing and 2.07 by tissue biopsy (134). As such, the swabs provided a reliable picture of which bacterial species were present, which can be interpreted as a significant and relevant measure of the effect of the intervention. The advantage of the method used is that it complies with the routine that is used in most microbiological laboratories and the results are therefore directly correlated with clinical practice.

8.4.2.3. *Odour, exudation and pain*

Malodour and exudation were partially measured by the author using *rating scales*, and by the patients using the *VAS-scale*. Wound pain was measured as well on the VAS-scale by the patients. Rating scales such as the VAS-scale are dependent on the assessment of the person measuring, which in itself can be sensitive. As the author's sense of smell, for example, cannot be validated, we chose to use identified methods from the literature. VAS was found valid to provide a measurement of subjective conditions (135) and valid status in cancer patients (136).

8.4.2.4. *Femininity, sexuality, health care avoidance, experience from the intervention*

Qualitative interviews were used in both in the pilot study and in the RCT study. Furthermore, the interviews were used in the sample of women with breast cancer and malignant wounds (n=17) in order to gain more knowledge about their experiences in relation to health care avoidance.

We used the qualitative data to obtain knowledge required about the patients' experiences of having a malignant wound and their perspectives on the extent to which the intervention was feasible, safe and effective in order to gain clarity over whether a similar intervention could be recommended for future patients with malignant wounds.

The value of the qualitative studies, which examined the patients' experiences, were that they provided an introspective lens through which data (positive and negative) to validate the effect of the wound care intervention could be collected. Interviews were useful in examining attitudes, processes and experiences and especially as these related to interactions and activity (128). As such they thereby related to core components of clinical knowledge as argued by Malterud 2001 (110). The interview method was developed and used with the intention of highlighting nuanced (unique) knowledge from the study's subjects (123).

Qualitative methods are described in the literature as being beneficial in combination with quantitative methods (137). Since, for example, standardized questionnaires are rarely sensitive enough in question form to gain an insight specifically of living with a malignant wounds, the combination of qualitative interviews allowed an insight into and understanding of the unique and nuances in living with a malignant wound and experiences with the intervention.

8.5. Discussion of the results

No studies have been found that investigated a combined intervention comprising wound care and a psychosocial component in patients with malignant wounds. As such, the study is unique.

The following includes findings from related areas. With respect to wound care, literature on chronic non-malignant wounds was consulted. In relation to the psychosocial component, literature that focuses on cancer patients with advanced stage disease was also identified.

The psychosocial components of the intervention are probably functioning by creating a therapeutic atmosphere of trust and professionalism, provided by the expertise of the caregivers. This could ostensibly improve the direct outcome of wound care by improving compliance – but of course also positively influence factors as psychosocial well-being.

8.5.1. *Wound size and degree of cleanliness (paper I (pilot) and paper III (RCT))*

There was a reduction in wound size and degree of cleanliness in 75% of the participants in the pilot study. This was not significantly different from the results of the pooled data in the RCT study. These results can be interpreted as an expression of what can be achieved with malignant wounds. In this group of patients with advanced stage cancer, impressive effects were documented in the combined group (pooled data from 69 patients) with a wound size reduction in 62% of patients and improvement in wound cleanliness in 58% of patients. In the literature, healing of malignant wounds is described as an unrealistic goal due to the underlying cancer (9). In the current study, two malignant wounds *did* heal during the intervention period and one wound healed during the pilot study. Characteristics of the wounds in the RCT study were that they were superficial and small (2.44 cm² and 1.98 cm²). There was a larger amount of healthy tissue in the superficial and small wounds that allowed for administering concomitant anti-neoplastic therapy in combination with optimal wound care.

Malignant wounds contain tumour tissue in the wound bed and as such it is expected that they remain chronic and non-healing and for the majority of the patients will be life-lasting. This is reflected in the significant association between wound size and survival. We found that patients with reduced wound size had a median survival period of 387 days compared with 134 days for patients with no reduction in wound size. This indicates that when the malignant wound worsens there is a parallel worsening effect on the patient's overall health and survival status. A malignant wound that responded to care was probably the combined effect of the antineoplastic treatment and wound care and can be seen as an indicator for improved survival prognosis. Malignant wounds are associated with poor prognosis (28).

8.5.2. *Colonization/wound infection (paper IV)*

There was no statistically significant difference between the bacteria found over time or between honey and silver-bandages.

In other types of chronic wounds it has been possible to impact the bacteriology by use of honey-coated or silver-coated bandage treatment (37;39;49;57) however we were unable to reproduce this with malignant wounds in the RCT study. Contrary to other chronic wounds, malignant wounds are under the continuous influence of the cancer's general progressive character and possible effects of the systemic treatment. This can lead to continuous production of deteriorating tissue with a large volume of necrosis and slough. Our investigation indicates that anti-neoplastic treatment with, for example, chemotherapy and anti-hormonal treatment, will not change these circumstances based on the culture results. As such, the bacteria had optimal growth conditions and a continuous colonization of malignant wounds should be expected. This is also reflected in the study results; 97% of the wounds were colonized with between 1-4 bacteria species (median=2).

Some cancer patients received antibiotics (e.g. metronidazol, doxycycline) regularly in order to diminish the odour while other patients received antibiotics based on positive swab results with no obvious signs of clinical infection. Our results suggest that antibiotic treatment has little impact on the presence of bacteria in the wounds and that bacteria flora is therefore not suited for monitoring the clinical effect of treatment.

8.5.3. Malodour, exudation and wound pain (paper III)

In the RCT study, the wounds showed increased granulation tissue and vascularity; they had less necrosis, and reduced malodour and exudation. This result is further confirmed by the fact that both malodour and exudation were statistically significantly diminished following the intervention than at baseline in both treatments, as rated by the patients' VAS scores.

Malodour and exudation are described in the literature as debilitating problems that have consequences for a patient's general well-being, causing anxiety, depression, shame, affected sexuality and social isolation (14;18;138). Since an essential and positive result was achieved using honey and silver bandages, it can be stated that these treatments may be effective in increasing patients' well-being.

Honey and silver bandages used in chronic non-malignant wounds have shown to be effective in combating malodour, exudation and pain (139). This study confirms the previous findings with the exception of wound pain. Less favourable results in our study with respect to wound pain can be explained by the fact that not only the skin, tissue and nerve paths were affected as is the case in non-malignant chronic wounds but the growing tumour tissue in malignant wounds also affects the underlying tissue and organs. Furthermore, malignant wounds are typically larger, deeper and localized within a substantially larger diameter compared with other types of chronic wounds, which can add to an increased pain burden. Furthermore it can also be difficult for patients to distinguish wound pain from other types of pain.

8.5.4. Femininity and sexuality (paper II)

The results of the study showed that malignant wounds

had consequences on the women's sense of femininity. The quotes showed that the women's self-esteem suffered and they lost their self-respect. This is consistent with a study by Wilmoth 2001 (140) involving 18 women's experiences following diagnosis with breast cancer, where women felt a partial loss of femininity. The results of the present study concur and provide more detail about feelings of loss in femininity because the women suffered a double stigma as each had a breast removed as well as experiencing an odorous and seeping malignant wound on her chest. In order not to expose themselves or others to situations that were uncontrollable, the women opted for a safe and secure home environment. What concerned the women the most was their anxiety that the wound would smell or that others would notice it. Many of the women chose, therefore, to isolate themselves from their social circles by remaining at home and not participating in social events.

The results of the study indicated that the wound was seen as the reason why sexual activity was no longer possible. The wound was perceived as disgusting and took away the desire for sexual activity because of its odour and exudation. Prior to the intervention, the participants in this study gave the impression that they did not miss having a sex life. Other more general studies on breast cancer patients describe, in contrast, the importance of continuing to have a sex life as this strengthens the woman's feelings of being attractive and 'normal' (140-142). The women in this study already suffered from symptoms of progressive breast cancer, e.g. fatigue, nausea and reduced mobility as well as having a malignant wound. Sexual activity under these circumstances required rethinking and using alternative sexual positions for which the women may not always have had the energy or knowledge. The odour from the wound gave the women the impression that their bodies were rotting, leading to feelings of powerlessness and shame and gave the women negative feelings about their own bodies (143). Thus, not missing having a sex life can be interpreted as the woman's desire to protect herself as well as her partner from the constant life threatening and visual reminder that the wound was the symbol of a progressive illness and expected premature death.

An important result of the study indicated that femininity and sexuality can be strengthened, and social isolation might be prevented, by using modern wound care products that could reduce seepage and odour and improve comfort. These actions, combined with the counselling during conversations with the author, meant an increased desire for close physical contact for most of the participants. Studies have shown that simply having a dialogue with a breast cancer patient about changed body image or sexual activities can be effective in allowing the individual to resolve these issues (144;145). These dialogues legitimized articulation of sexual problems and gave the woman the possibility to share their problems rather than dealing with them alone.

8.5.5. Health Care Avoidance (paper V)

The study revealed that 17 women (25%) out of the population in the RCT study had attempted to hide their malignant

wound and cancer prior to diagnosis. A possible scenario of the process over time and possible reasons for Health Care Avoidance are specified in model 1. (see last page of this thesis). This study provides insight into the women's choice not to seek medical care despite oozing, malodorous and bleeding wounds to their breasts. This breach from normality and the women's deviant behaviour from what are typical give an indication of what can be expected in the general community, and some women require special attention in order to maintain some focus on their own health. Insight was gained into this complex phenomenon, which may be interpreted as an escalating destructive process initiated by feelings of disbelief and over time of shame and thus reinforces their inability to take action. The essence - 'An avalanche of ignoring' - points to the escalating, powerful development of destructive feelings behind Health Care Avoidance. The term *avoidance*, as used in this study, is understood as a deliberate and conscious action anchored in the experience of powerlessness, lacking resources, fear of cancer diagnosis and lack of belief that cancer treatment is beneficial. It is a complex and multifaceted phenomenon and cannot be explained by a single theory or in a cause-effect context. Health Care Avoidance may be a way of coping both for women who are primary and/or bereaved caregivers.

Health Care Avoidance, delay and subsequent development of malignant wounds in women who are primary, and often bereaved caregivers, may be prevented if doctors and nurses in the oncology settings, general practitioners and district nurses are aware of the need for special attention to this group of women. By means of information about the early signs of cancer, these women may become conscious of the need to react to possible own symptoms.

In a preventative perspective it seems advantageous to bring into focus the health of primary and bereaved caregivers, thereby potentially reducing patient delay and ultimately improving survival. This could imply development of information concerning awareness of stress-related symptoms and bodily alterations in caregivers that can be distributed through the primary and hospital sectors as well as in patient organizations and by the media.

8.5.6. The patient's perspective of the overall RTC study intervention

During the interviews, the patients informed that prior to entering into the project they felt isolated in their responsibility of caring for their malignant wound. They informed that their doctors and nurses equated the statement that 'malignant wounds could not be healed' with 'there is nothing more to do about it'. As such, the patients' felt like they were written off and their needs were not met as no efforts were made by the caregivers to investigate whether inconveniences of the wound (including odor, exudation, pain, etc.) could be reduced through wound care.

The patients expressed gratitude for the opportunity to participate in the project and moreover, for the fact that there was finally someone who took interest in intensify-

ing care for them as patients with malignant wounds. This finding is consistent with qualitative studies on experiences with wound care in three patients, one family member and 14 nurses (20). In that study, the patients: '*expressed appreciation for the opportunity to discuss matters that few people had been willing to listen to previously*' (20) p 3. Patients with malignant wounds continue to be an overlooked group, which is on par with the sparse international literature found on this subject.

The interview with the patients in the current study shows that they experienced that the wound care, cognitive conversations and relaxation training to be effective and meaningful. They strongly suggested that the entire intervention be offered in the future to treat patients with malignant wounds. This can be interpreted as the patients' preference for a bio-psychosocial approach to supporting their situation. This interpretation supports the patients' critique of general wound care provided today both in the hospital system and by the district nursing service. They complained of the lack of continuity, time and know-how by district nurses and that the hospital personnel did not show interest in either the wound or the limitations that the wound imposed on their daily lives. This finding is consistent with those of other studies carried out in Denmark which also point to the patients' desire for an improved treatment dimension as well as an integrated component that supports improved quality of daily life for those living with cancer (146;147).

8.5.7. The overall intervention – opportunities and limitations

8.5.7.1. Wound treatment

Collectively, the 69 patients completed the intervention (completion rate 100%), and simultaneously completed the wound treatment offered by the nurses. This can be interpreted as positive, considering the patients' advanced stage of disease. A completion rate of 100% indicates that the patients found the intervention to be meaningful and not burdensome. The intervention was carried out in the patient's own home; a factor, which several patients claimed, was a pre-requisite desire to joining the study. This way the patients could handle the treatment and limit themselves to as few caregivers as possible, which gave them a sense of security. Continuity furthermore led to uniformity in evaluating and treating the wound, which was a core consideration. A further reason for the high completion rate could possibly be found in the fact that nurses who had substantial wound care expertise and were knowledgeable in oncology administered treatment. This provided the patients with a sense of security. Several warn that malignant wounds bleed easily and this calls for an assessment of whether cleansing is necessary (148). It is recommended that wound cleansing be approached with caution and be done using gels instead of tweezers and Metzenbaum scissors. In the current study, bleeding was not a major issue for the patients, which are why the recommendation of avoiding wound cleansing would have been directly harmful to these patients. A wound that is not cleansed or cared for will al-

low the growth of bacteria in the necrotic tissue and will lead to malodor, exudation and in the worse case, wound infection. Silver as well as honey bandages are effective in cleansing the wound but are not sufficient in themselves. If the wound is characterized by clusters of necrotic tissue, these must be mechanically removed or else it will not be possible to reduce malodor and exudation. *Cleansing of the wound with tweezers and scissors should always be done with great care.*

In the author's collaborative efforts with district nurses around the country she often experienced that the district nurses were anxious about the possibility of the malignant wound bleed and the discomfort that they felt in removing dead tissue. Their attitude often resulted in lacking wound cleansing. Alexander 2010, p. 6 (20) also describes in an article about 14 nurses' experiences with care for people with malignant wounds that they were anxious about being witness to patients' body parts falling away. She describes that it was particularly traumatic; *'when body parts fell away while the nurses were bandage the malignant wound'*.

In the pilot study interviews, the patients informed that they felt disgust and were powerless in relation to the wound, its malodor and appearance. Just in observing a photograph of a malignant wound (see photos in paper I, III and V), most people would be shocked and possibly feel nauseous and powerless in treating this group of patients with advanced cancer and malignant wounds. As such it is relevant to discuss how personnel experience the treatment of these patients. Several articles describe the difficulty of treating patients with malignant wounds (149;150), but only two studies describe the personnel's experiences with it. Wilkes et al 2003 (150) investigated the experiences of nurses caring for patients with malignant wounds. The study found that the nurses felt it difficult to deal with this patient group; they felt powerless and inadequate if the patient felt that the wound care was insufficient. The nurses in the study were psychologically impacted by the responsibility of administering care, and required counseling. Alexander 2010 (20), p. 6 described the experiences of 14 nurses in the treatment of patients with malignant wounds and their feelings as *'extraordinarily impactful, confronting and emotionally draining'*. The malodor from the wounds was the greatest problem. They described how the odor was that of 'rotting flesh' and 'the smell of death' penetrated their clothing and skin and that they attempted to eliminate the smell by frequently washing and changing uniforms several times a day. The informants in that study experienced a sense of hopelessness, frustration, sadness and guilt – and one informant expressed anxiety that she may have been developing a malignant wound and often went to the doctor for check-ups. From the results of these two studies, it is clear that malignant wounds also impact the personnel who administer care. To diminish the inconveniences of malignant wounds for the patient, family members and personnel, it is essential that these wounds are cleansed and that the patients are offered wound care with bandages that best ensure against malodor, exudation and colonization of bacteria (e.g. silver or honey bandages in combination with foam bandages). It takes expertise, experience and cour-

age to work with patients with malignant wounds and it is important to remain aware that personnel need counseling when treating patients with malignant wounds.

8.5.7.2. Cognitive conversations

It was possible to carry out the cognitive conversations following the planned approach, i.e. structured using the 'Diamond' model with 54% of the patients. It was not possible to use the structure in the model with 39% of the patients due to difficulties with concentration, fatigue or activity in the home (visitors, etc.). In these patients, cognitive conversations were held in a modified format and with the entry point being 'what is the biggest problem you are facing today' as well as attempting to draw these patients' attention to the connection with their thoughts, feelings, physical reactions and wellbeing. In 7% of the patients a structured conversation was not carried out due to physiological issues with their wound that affected speech (n=2), dyspnoea and coughing (n=1) and severe fatigue due to terminal illness (n=1).

The patient participated actively in the cognitive conversations that demanded their energy, willingness and not least working with thought patterns, feelings and reactions. Considering that this patient group with advanced stage cancer typically has symptoms such as fatigue, dyspnoea, nausea and difficulty concentrating, it can be considered a positive result that 93% of them completed the cognitive conversations. During these conversations, the patients had the opportunity to discuss important questions which, seen from the perspective of the completion rate, indicates that the conversations were meaningful to them.

The structure of the cognitive model was difficult for some patients to understand. It was furthermore difficult for some of them to learn how to recognize negative thoughts and to reframe them to become more positive within the four-week period. Some of the patients otherwise expressed that simply focusing on how thoughts, feelings, physical reactions and wellbeing interact allowed them to become aware of the substantial difference they could make for themselves by focusing on something constructive instead of focusing on their limitations. By using this method they could avoid suffering from self-induced negative thoughts. This finding is consistent with a smaller study Bottomley 1998, p. 27 (98), that included seven women with newly diagnosed cancer (breast and ovarian cancer) who learned to use the cognitive technique as well as relaxation training as methods of coping positively with the situation. One participant informed: *'thinking a negative thought, I could push it around the other way and think something positive. So it made me train my mind more to not think of the negative aspects of things'*. In contrast with the patients in the current study, the participants in the Bottemley study were younger (mean age 50,4) and newly diagnosed and as such did not carry the degree of disease burden experienced by patients with advanced cancer and malignant wounds – which is why the latter included a cognitive component in parallel in their studies. The patients in the current study expressed satisfaction and felt secure about the conversa-

tions being conducted as one-on-one conversations. This approach was also used in a two-pronged randomised study by Hellbom et al 1998 (100) involving 527 newly diagnosed patients with breast cancer, colorectal cancer, ventricular and prostate cancer. In that study, 265 patients in contrast to the control group received individual psychological support in the form of cognitive conversations with a psychologist in addition to relaxation training. The study showed that individual conversations, designed on the basis of individual needs, were effective in reducing anxiety and depression and that the biggest benefit achieved for the patients was in coping with negative thoughts, concerns about the disease and depressive symptoms. The patients in the Hellbom study had their one-on-one conversations at the hospital whereas the intervention in the current study took place in the patient's home. Again, consideration was given to the degree of burden faced by the patients with advanced disease.

During the interviews, the patients expressed that the conversations allowed them the opportunity to express the taboo subjects such as sexuality and thoughts about death. Again, this process requires knowledge, courage and experience by the nurses to dare to bring these subjects into dialogue. This is problematic for some caregivers. Alexander 2010 (20), p. 6 describes this difficulty in a citation by a nurse who had to conduct a difficult conversation with a patient: *'It's draining. I find that exhausting ... my heart's in my throat when I'm having a conversation which is so confronting... it's awful'*. Continuity is essential if one is to hold conversations on these subjects. It requires that the patient knows the caregiver and that there is an opportunity to create a sense of trust and security in the patient. Furthermore, the caregiver must have knowledge of malignant wounds, oncologic psychosocial aspects, knowledge about palliative units, hospices, and not least knowledge about transfer options to, for example, a psychologist, social worker or priest.

8.5.7.3. Relaxation training

78% of the patients chose the progressive relaxation mode as they could clearly feel the difference between the flexed and relaxed muscle groups. The weakest patients (13%) who faced mobilization problems, pain, fatigue, nausea, dyspnoea, movement restrictions, lymphoedema, etc., informed that they felt best when they undertook the passive relaxation modality. 9% of the patients participated only partially in the relaxation training (1-3 times during the intervention period). Two of the male patients thought that the relaxation training 'wasn't for them', one female patient thought that the music was depressing, another female patient could not hear the instructions on the relaxation CD and two of the women could not grip the CD player.

91% of the patients undertook the relaxation training, which again, from the perspective of this patient group's profile indicates a positive result. The relaxation-training component was also seen as such to be meaningful to the patients. This is consistent with Kwekkeboom 2010 (151) who shows in a study of 30 patients with advanced disease

from lung, colorectal, prostate and gynecological cancer, that 90% undertook an intervention with relaxation training, guided imagery and nature sound recording. Kwekkeboom concluded that the patients in that study enjoyed the intervention, learned useful skills and perceived improvement in their symptoms (pain, fatigue, and sleep disturbance). The patients in the current study also expressed more sound sleep and the results showed that the levels of anxiety and depression were reduced following the intervention. This result must be credited to the overall intervention including wound treatment, cognitive conversations and relaxation training, since the effect of the intervention components cannot be evaluated separately.

9. Conclusion and recommendations

Malignant wounds are chronic wounds that lead to malodor, exudation and psychosocial problems. The quantitative results show that there is no statistically significant difference in wound size, degree of cleanliness, exudation, malodor and bacteriology *between* the patient group using silver and the patient group using honey bandages, and as such both bandage types are recommended.

A reduction in wound size in 62% of the patients and an increased degree of cleanliness in 58% of the collective population from baseline to post-intervention indicates an improved wound healing process when using both honey and silver bandages. This is seen as a positive result in patients with advanced cancer. A statistically significant reduction in malodor, exudation, anxiety and depression with both treatment types improved the patients' wellbeing and their overall situation.

The Study showed that patients who had reduced wound size during the trial period had a median survival time of 387 days compared with 134 days for patients with no reduction in wound size ($p = 0.003$). No improvement in wound size during the trial period therefore indicated poor survival.

There is no indication for taking qualitative swabs from malignant wounds unless there are clinical signs of infection or if there is suspicion of infection with MRSA.

The results from published qualitative studies show that patients with malignant wounds and advanced disease experience powerlessness and shame and that the wound poses consequences for femininity, sexuality and social interaction and result in social isolation, anxiety and depression. The results indicate that conversations about taboo subjects such as sexuality and death are important to the patients as they find it difficult to speak about these subjects with their family members.

The qualitative studies furthermore indicate that patients with malignant wounds and advanced cancer are heavily burdened and that they desire treatment and care that is administered by professionals who show interest, have the expertise and required knowledge, and that these caregivers should assume responsibility for treatment. The patients want the treatment to take place at home, which is why it is recommended that this be considered in future planning for patients with malignant wounds.

It is important to note that some patients with malignant wounds choose to ignore signs of cancer for reasons of Health Care Avoidance. A special effort targeting family members of the patient is recommended in order to reduce patient delay and as such results of a poor prognosis.

The general conclusion is that an intervention with silver or honey bandages supplemented by cognitive conversations should be considered in any future treatment service for patients with malignant wounds and advanced disease.

Recommendations

The results show that treatment of patients with malignant wounds requires continuity, oncology and wound care expertise and experience, time needed to administer wound care, an empathetic and listening attitude and fluency in making a psychosocial intervention (conversations and relaxation training). As wound care with honey bandages has the same effect as with silver bandages, both types are recommended and should be seen to provide the satisfactory results and a better treatment outcome. From the percentage of relaxation training undertaken, it is recommended that this form of training be provided to patients for use at home.

Not all of the patients were able to participate in the cognitive conversations and it should be considered whether future conversations should simply build on the cognitive theory instead of structurally carrying them out in accordance with the model. In this connection there is an important further question of whether one can attribute the effect to the cognitive conversations or whether it was simply the effect of having the same caregiver that had oncology expertise and knowledge of wound care, that during one hour weekly in the patient's home, listened to and discussed problems and was helpful in responding to practical questions and referrals to other experts. This requires further investigation since a cognitive conversation requires more expertise from the personnel than an unstructured conversation that builds on continuity, empathy and knowledge.

Since malignant wounds are a symptom of the patient's cancer status, it appears to be most logical and optimal that the personnel in oncology wards who already possess oncologic expertise also gain knowledge and experience with treating malignant wounds. This would allow them to control and evaluate the wounds and collaborate and suggest treatment options and offer the assistance of district nurses knowledgeable in wound care. As few patients experience malignant wounds, it is important that wound care is delegated to one/a few caregivers in order to achieve optimal continuity, expertise and experience in treating patients with malignant wounds. The patients are meanwhile still not receiving that expertise within hospitals and the results of this study show that patients prefer to be treated at home. One option that could tackle both aspects would be to establish a 'wound function' whereby an oncology nurse who is knowledgeable in wound care could initiate treatment and evaluate the wound and wound treatment at the hospital, and also have an 'outbound' function, where evaluation and treatment could take place in the patient's home in close collaboration with the district nurse who would be charged with the daily wound care. This would require continuity by the district nurse and furthermore that each district home care unit house district nurses that have been trained in wound care, are knowledgeable in oncology issues and have the ability to hold psychosocial conversations.

10. Future research

Due to tumorous tissue located at the base of the wound, it is difficult to suggest any new treatment methodologies to improve malignant wound healing. New treatment would probably require the development of antineoplastic means that impact both the underlying cancer as well as the malignant wound.

But it is important in the future to be oriented toward potential new treatment options for malignant wounds. This includes treatments that emanate from technological developments within the cancer field as well as newly developed wound care interventions. It is as important to consider testing new options for diminishing malodor, exudation, pain and infection through newly developed wound care products.

In this study, we found no difference in effect between the honey-coated and the silver-coated bandages on the malignant wounds. These bandage types were used following recommendations made by product companies. In other studies, honey proved to have an effect on wound healing and bacteriology. Molan 2000 (56) described that by applying a consistent volume of honey to the wound this will suffice until the next bandage change (typically, 20 ml. of honey for 10 cm² bandages). Future research could therefore consider testing the extent to which honey could have a greater effect if it was applied in daily bandage changes instead of changing the bandage every 2-3 days.

The current study found no effect of the bandages on the bacteriological pattern of the wounds. As such it would be relevant to investigate whether more intensive and effective bacteria-killing efforts (e.g. more honey, increased frequency of bandage changes, etc.) could provide better results.

A drawback of this study could be that the primary outcome was wound size. While healing of malignant wounds cannot be expected, and because the most important issues for the patients are malodour and amount of exudation and cleanliness, we recommend that future research also focus on these issues and not wound size alone. These recommendations are in line with a recent publication on outcomes to use in wound healing and care (152).

In the literature, bleeding is described as an overshadowing issue in malignant wounds, which was not the case in the current study. It would therefore be relevant to establish a nationwide database whereby malignant wound related problems could be registered so that updated knowledge can be centrally located in the future in response to factual issues and their prevalence.

Only one small population study investigated barriers faced by caregivers when treating patients with malignant wounds (20). It will be important to investigate the extent to which these barriers are contributing factors for the caregivers' avoidance behavior and ignoring of malignant wounds.

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Original papers

This dissertation is based on the following papers:

- I. Lund-Nielsen, B; Müller, K; Adamsen, L. Qualitative and quantitative evaluation of a new regimen for malignant wounds in women with advanced breast cancer. *Journal of Wound Care* 2005, 14; 2:69 – 73
- II. Lund-Nielsen, B; Müller, K; Adamsen, L. Malignant wounds in women with breast cancer: feminine and sexual perspectives. *Journal of Clinical Nursing* 2005, 14:56 – 64
- III. Lund-Nielsen B; Adamsen L; Kolmos HJ; Rørth M; Tolver A, Gottrup F. The effect of honey-coated bandages compared with silver-coated bandages on treatment of malignant wounds—a randomized study. *Wound Repair and Regeneration* 2011 (Accepted for publication)
- IV. Lund-Nielsen B; Adamsen L; Gottrup F; Rørth M; Tolver A, Kolmos HJ. Qualitative Bacteriology in Malignant Wounds — A Prospective, Randomized, Clinical Study to Compare the Effect of Honey and Silver Dressings. *Ostomy Wound Management* 2011; 57 (7):28-36
- V. Lund-Nielsen B, Midtgaard J, Rørth M, Gottrup F, Adamsen L. An Avalanche of Ignoring: a Qualitative Study of Health Care Avoidance in Women with Malignant Breast Cancer Wounds. *Cancer Nurs* 2011; 34 (4):277-285

Qualitative and quantitative evaluation of a new regimen for malignant wounds in women with advanced breast cancer

- **Objective:** To investigate the experience of women with advanced breast cancer who have a malignant fungating wound and to test the benefits of a structured, evidence-based, management regimen, combined with psychosocial support.
- **Method:** Twelve women with advanced breast cancer were consecutively selected for inclusion in a four-week intervention. The patients were interviewed and the condition of the wounds was recorded before and after the intervention.
- **Results:** Prior to the intervention, participants were anxious about seepage, bleeding and odour emanating from the wounds and were concerned these might be obvious to others. After the intervention, nine wounds (75%) showed an improvement, with increased granulation and epithelialisation and complete wound healing in one participant. Seepage was considerably reduced in 83% of cases and there was an average 75% reduction in dressing changes. The women's sense of well-being improved, as did their independence and self-confidence.
- **Conclusion:** A wound-care intervention built on evidence-based practice and psychosocial support resulted in an improvement in 75% of the wounds, and increased the women's sense of well-being, independence and security.
- **Declaration of interest:** This study was funded by the National University Hospital of Denmark's Corporation Fund and the Novo Nordisk Clinical Nursing Research Fund. Wound-care products were sponsored by Smith & Nephew A/S and Johnson & Johnson A/S.

breast cancer; malignant fungating wounds; wound management; female perspective; daily life

Malignant fungating wounds have physiological and psychosocial consequences, including seepage,¹ mal-odour,²⁻⁴ bleeding,⁵ pain,⁶ infection,⁷ depression and altered body image.⁸

The incidence in patients with breast cancer is low at 2–5%,^{6,9,10} and these wounds are generally neglected in terms of management guidelines,¹¹⁻¹³ with care and treatment being random and unstructured.¹⁴

A literature search of Medline, Cinahl and Cancerlit found only six relevant research-based studies^{2,15-19} and a smaller number of case reports or anecdotal evidence.²⁰⁻²² While some authors have described treatment principles,^{1,4,23} the literature lacks specific information, particularly on wound-care products that could facilitate optimal healing and meet the patient's physical and psychological needs. This study set out to investigate these issues.

The intervention

Over a four-week period we tested a specific intervention, which comprised:

- A systematic, unique and structured wound treatment, built on existing knowledge and continuity

of care.^{1,4,23} The wound-care treatments given are outlined in Box 1. Following the intervention period, responsibility for wound care was transferred to the home care nurse, who was informed about the patient via a nursing care report

- Dialogue between the women and the clinical nurse advisor — these focused on the impact of the wounds on the women's daily lives.

Method

Research design

The research intervention, which formed part of a larger study, was prospective and exploratory. The results presented here pertain to quantitative and qualitative aspects of the treatment studied.

Subjects and recruitment

Twelve women with advanced breast cancer receiving treatment at the oncology departments at the National University Hospital of Denmark and Naestved Hospital participated.

The mean age of the women was 68.5 years (range: 57–85). They had had breast cancer for a mean of 8.2 years (range: 0.1–28). The cancer had meta-

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- 1 Grocott, P. The palliative management of fungating malignant wounds. *J Wound Care* 2000; 9: 1, 4-9.
- 2 Houghton, W., Young, T. Common problems in wound care: malodorous wounds. *Br J Nurs* 1995; 4: 16, 959-963.

Box 1. Care of malignant fungating wounds**General wound care**

Rinse the wound with tap water, preferably under the shower. If there is exposed bone, use sterile water

Wash unclean wounds with liquid medicinal soap (pH level: 4.5–5.7) using a foam washcloth and then rinse the wound under the shower or using a 20ml syringe

Inspect the wound, noting its size, colour, phase, smell, bleeding, seepage, infection, and pain (as reported by the patient)

Select a wound-care product, based on the wound's phase, and the patient's wishes

In the case of seepage/skin irritation, protect the wound edges by applying a barrier cream/film

Place the new dressing on the wound

Selection of wound-care products**Wounds with necrosis**

Use a hydrogel to dissolve necrosis. Avoid surgical manipulation with scissors and tweezers as this often causes bleeding

Use a foam dressing as a secondary dressing

Seeping/bleeding wounds

Use an alginate product

Apply a foam dressing with an adhesive border

If moist necrosis is present, use an alginate product. If dry necrosis is present, use a hydrogel

Malodorous wounds

Place the charcoal dressing directly on the wound. If using a hydrogel or an alginate product, place them directly on the wound and then put the charcoal dressing over the top

Use a foam dressing with an adhesive border as a secondary bandage. If the patient's skin is sensitive to adhesive, use a foam dressing without an adhesive border and secure it in place with tube gauze or body netting

3 Price, E. Wound care: the stigma of smell. *Nurs Times* 1996; 92: 20, 70-72.

4 Mallett, J., Mulholland, J., Lavery, D. et al. An integrated approach to wound management. In *J Palliat Nurs* 1999; 5: 3, 124-132.

5 Haisfield-Wolfe, M.E., Rund, C. Malignant cutaneous wounds: a management protocol. *Ostomy/Wound Manage* 1997; 43: 1, 56-66.

6 Hallett, A. Fungating wounds. *Nurs Times* 1995; 91: 39, 81-85.

statised to the bones in five women, to the lung in two women, to the lung and liver in two women, to the lung and bones in one woman, to the lung and brain in one woman, and to the liver and bones in one woman. The mean duration of the wounds was 1.8 years (range: 0.1–4). At the start of the intervention, nine women were receiving antineoplasm treatment for their cancer (five chemotherapy and four antihormonal). The remaining three women had stopped taking this treatment as they had reached the end stage of the disease.

Wound recording

Wound morphology (wound size and its phase in the healing process), supplemented by photographs, was recorded before the study, then weekly through-

out the intervention period and finally at the end of the study. The extent of malodour, seepage and bleeding were also recorded.

The subsequent analysis involved a comparative evaluation of the wounds using the photographs and the morphology recordings (method triangulation) made before and after the intervention.

The intervention was considered effective if there were improvements in the following indicators:

- Wound size reduced by over 0.5cm, measured from the widest point from side to side
- The presence of granulation or epithelial tissue
- Reduced or no malodour (Box 2)
- Reduced or no bleeding (scale: no fresh bleeding; fresh bleeding at dressing change; continuous flow of fresh bleeding)
- Reduced or no seepage (scale: dry/low level of seepage [dressing dry/slightly moist]; moderate seepage [dressing saturated but seepage was contained]; heavy seepage [dressing and clothes soiled]).

The dressings

The project team recorded data on the functionality of the dressings and the frequency of dressing changes. This included patients' perceptions of the intervention dressings. Comfort and functionality of the dressing before and after the intervention were assessed using the following criteria:

- Dressing absorption — did the patient perceive that it completely, partially or did not contain the seepage and odour?
- Comfort — did the patient perceive that the dressing/bandage was completely, partially or not at all comfortable?

Patient interviews

The researchers conducted semi-structured interviews with the patients before and after the intervention, with the aim of establishing each woman's perspective on living with a malignant fungating wound.²⁴ Each interview lasted about 45 minutes and was audiotaped and later transcribed verbatim. Early on in the data-collection stage, two of the researchers reviewed the first two interviews to check the reliability of the procedure and to identify emerging themes.

The data were sorted under different headings to identify expressions that formed themes.²⁵ An analysis of the main themes, in the context of the subjective and objective information recorded, is considered in the results section below.

Ethical considerations

Approval was gained from the National Data Inspectorate. The study adhered to guidelines set by the Ethical Research Committee for Copenhagen and Frederiksberg municipalities.

As participants were likely to be in a state of

emotional distress, they were given a choice of place for the interview — the hospital (in connection with a photographic session) or at home.

Results

Wound size and phase

The intervention was observed to have had a positive effect in nine cases (75%) (Figs 1–3). After the intervention period, the wounds were smaller, and contained granulation and epithelial tissue. The wound of one patient (patient 9) healed completely over the study period (Fig 3).

In three patients (25%), the wounds increased in size and exhibited less vascularisation and granulation tissue and more fibrin, yellow and black necrosis and infection (Fig 4). This may have been because these three women were no longer receiving antineoplasm treatment.

Malodour

The following levels of malodour were observed at the end of the intervention period:

- Seven women (58%) had no malodour
- Two (17%) had a slight level of malodour
- One (8%) had the same level of malodour
- Two (17%) had worsening odour.

Before the intervention, more women (eight, 67%) perceived that their wounds had been malodorous than was recorded by the project group (five, 42%) using the assessment score in Box 2.

The women described two types of odours — the ‘ordinary smell of wound liquid’ and the ‘odour of decay’. Both were repulsive and offensive and the reason why most of them were afraid they would be labelled as smelling bad.

‘Offensive! I feel like vomiting because of the odour — it has become a nuisance for me. I’m thinking, my God, I hope it does not smell bad for others.’ (Patient 1)

Following the intervention, six women (50%) said they had experienced malodour, whereas the professionals only recorded this for three women (25%).

The remaining six women felt the new dressing had had a positive effect on malodour:

‘I feel better and it is more comfortable. I feel more secure. I can better mingle among others now, without being afraid that they will look at me oddly, or that the wound will smell.’ (Patient 6)

The dressing gave these women a sense of security and may have stimulated an increased desire for social contact.

Bleeding

In 11 of the 12 women (92%), no bleeding from the wound was registered either at the start or end of

Box 2. Malodour assessment²

Score	Assessment
No odour	No odour is evident, even at the patient’s bedside with the dressing removed
Slight	Odour is evident at close proximity to the patient when the dressing is removed
Moderate	Odour is evident on entering the room (6–10ft from the patient) with the dressing removed
Strong	Odour is evident on entering the room (6–10ft from the patient) with the dressing intact

the intervention period. In the twelfth woman (8%), bleeding had increased by the end of the intervention period.

Again, before the intervention, comparisons of the women’s comments at the interview and the recordings made by the project group showed discrepancies between the women’s perceptions of bleeding (67%) and the number recorded by the professionals (8%).

The women were shocked and anxious about their bleeding episodes, associating them with serious illness or death.

‘I am afraid of it. I always have to have some plastic [bags] and handkerchiefs ready. I was desperate before — I did not know how to stop it, it just started running down me.’

Respondents expressed anxiety about losing control, and a lack of knowledge on how to deal with the bleeding.

After the intervention, two women (17%) said they were experiencing bleeding, whereas the project team recorded bleeding in only one (8%).

There was relief the bleeding was under control:

‘It is not even bleeding today, while it did before [the project], so I feel much better.’ (Patient 1)

Through her participation in this project, patient 4 learnt how to prevent bleeding:

‘I used to tear off the dressing. Now I know that I should be careful and soak the dressings first. I have more control over the bleeding.’

Seepage/comfort

According to the observers, the intervention had a positive effect in 10 women (83%), in whom seepage reduced considerably or stopped completely. However, in two cases (17%) they observed heavy seepage, an increase in wound size and a deterioration in the wound phase, with less vascularisation of tissue, less granulation tissue, increased fibrin

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research

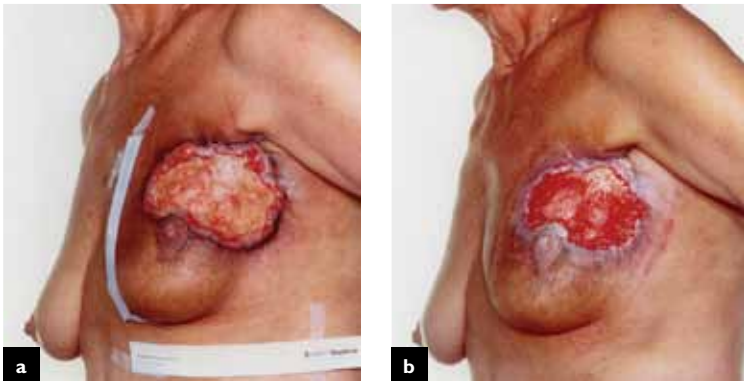


Fig 1. At baseline this wound measured 9.5 x 14cm (a) and reduced to 7.8 x 10.8cm by the end of the intervention period (b)

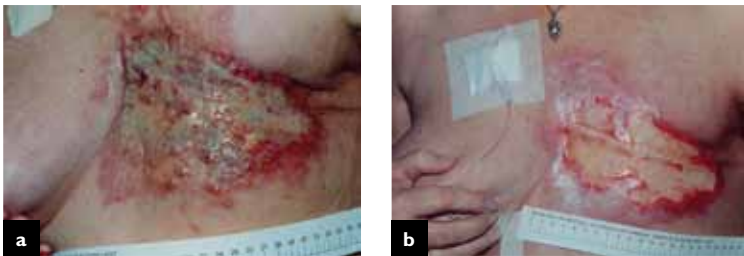


Fig 2. At baseline this wound measured 15 x 16cm (a) and reduced to 8 x 15cm by the end of the intervention period (b)

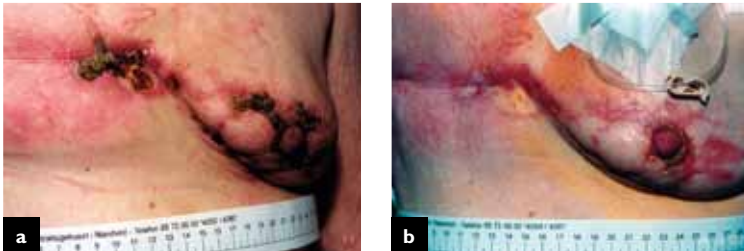


Fig 3. At baseline wound no. 1 measured 3 x 5.5cm (a) and healed completely during the intervention period (b); at baseline wound no. 2 measured 4 x 9cm (a) and also healed completely (b)

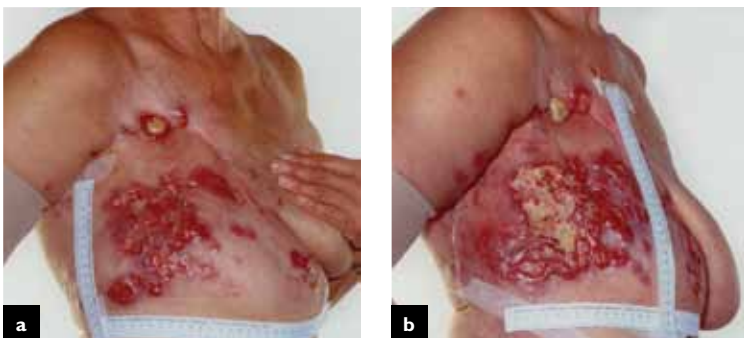


Fig 4. At baseline wound no. 1 measured 12 x 14 cm (a) and reduced to 16.4 x 14cm by the end of the intervention period (b); at baseline wound no. 2 measured 7 x 6cm at baseline (a), reducing to 9 x 8cm by the end of the intervention period

and yellow and black necrosis, and infection.

The frequency of dressing changes reduced for all participants. Before the intervention, the 12 women had 133 dressing changes per week. After the intervention, this fell to 34, with an average reduction of 75% (Fig 5).

Before the intervention respondents commented on seepage, comfort and functionality of the dressings. Seepage was a serious problem that had a major impact on their lives. The women also experienced limited movement due to poorly fitted dressings. This was caused by both poor dressing selection and poor application technique.

'I can't wear any decent clothes — it seeps right through. I have to constantly plan my wardrobe — the clothes must not pull over my head because that would dismantle the entire wound dressing. I am constantly afraid of blood seeping through and it's so difficult to clean. It is annoying with all that laundry to do. I feel so bound.' (Patient 4)

After the intervention, 10 women stated that the new bandages gave them a sense of security because they fitted better and contained the seepage.

'I feel much more secure now. One should actually have these things [bandages] — using gauze just doesn't work. I now have less laundry than before, when there was fluid and blood all over my undergarments and bedlinen. I can dress differently now — put on some decent clothes because the bandages fit better.' (Patient 5)

Overall, all the women felt that seepage was contained and eight (67%) perceived that malodour was controlled. They said the intervention dressing freed them from having to think about the wound all the time and from constantly checking that the bandage was still sealed.

Discussion

The results show that the intervention had a beneficial effect on the size and phase of the wounds in 75% of the participants. The wounds of the remaining 25%, who were no longer receiving antineoplasm treatment, deteriorated in both respects. This raises the question of whether the improvement in the 75% was due to the antineoplasm treatment. However, their wounds had, on average, been present for 1.8 years before the study and had not improved despite receiving antineoplasm treatment. Therefore, it is probable that the intervention alone contributed to the improvement.

The 25% with advanced breast cancer experienced loss of appetite, nausea, decreased food intake, weight loss, fatigue, infections and a lowered haemoglobin count. This may have compromised

healing and contributed to the increase in wound size, seepage and malodour.

Despite this, wound healing was observed during the intervention period, a finding not reported elsewhere, to our knowledge, in the literature. Bird,⁸ for example, stated that healing of malignant fungating wounds is an unrealistic goal, and that wound care is necessarily palliative. It is therefore important for us, as the research team, to state that, through this intervention, we were able to optimise healing, with increased vascularisation, granulation and epithelialisation, and a reduction in wound size.

Before the intervention the women were affected by malodour, which resulted in them avoiding social contact, as reported in other studies.^{2,3,5,26} In our study the descriptions of the two types of malodour appear to be unique — the 'ordinary smell of wound liquid' and the 'smell of decay'. The project group categorised only the 'decaying' smell as malodour (ignoring the 'ordinary smell of wound liquid', which would be expected in such cases). This may explain why more women than professionals reported malodour.

The use of charcoal dressings in combination with a foam dressing with an adhesive border made the women feel protected against malodour and encouraged them to resume social activities.

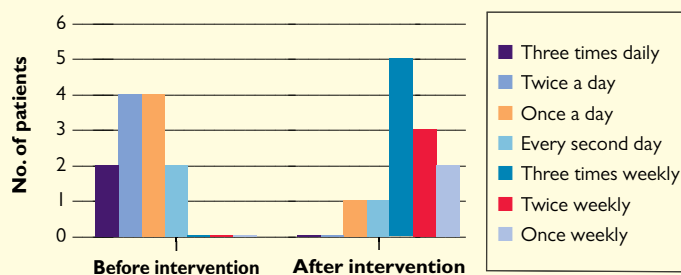
Bleeding was reported in only one woman (8%) both before and after the intervention. In a study by Haisfield-Wolfe and Baxendale-Cox¹⁸ 29% of 17 fungating wounds bled. While some studies showed bleeding to be an issue,^{1,5,8} none reported the extent of the problem.

In our study the women perceived bleeding to be a sign of serious illness, which triggered a fear of death and anxiety about losing control. The reason for the divergence in the women's experiences from that of the project group's assessment is that they perceived bleeding differently. The project group applied the described definition (scale: no fresh bleeding; fresh bleeding at dressing change; continuous flow of fresh bleeding), whereas the women defined bleeding as cases of fresh bleeding, blood serum secretion and seepage.

To avoid bleeding during wound treatment, a hydrogel and an alginate were used rather than surgical manipulation. Talking to the women, including discussion of practical actions to stop the bleeding, might have helped them to feel less anxious about uncontrolled bleeding.

Seepage was a major problem for most of the women, reflecting findings reported previously by Grocott.¹⁶ The intervention had a positive effect in 83%, resulting in less or no seepage and instigating a sense of increased freedom and independence. This may have been because the wounds moved to the proliferation phase, but could also have been a result of the dressing.

Fig 5. Frequency of dressing changes



The women stated that use of the foam bandages with the adhesive border, in combination with the alginate product (and often a charcoal dressing as well), was the best solution. All insisted on using the bordered dressing, even though they had sensitive skin following irradiation. A barrier film was therefore applied as protection between the skin and the dressing's adhesive border.

The morphology of the wounds worsened in three of the women (25%), and their cancer was progressive. Within 10 weeks of the end of the study, they had died. Despite the lack of improvement in their wounds, they experienced greater security, an improved sense of well-being and had a more positive experience in their final phase of life.

Limitations

The small number of patients and the absence of a control group meant that the study lacked statistical strength. A randomised study to evaluate the effects of the treatment would be the ideal objective of further research.

Conclusion and recommendations

The problems faced by women with malignant fungating wounds due to advanced breast cancer are broadly overlooked, with seepage and malodour being particularly incapacitating. A better understanding of the physical and psychosocial problems experienced by women with malignant fungating wounds would inform the management of this patient group.

The study intervention increased the women's sense of well-being and gave them independence and security. This was the result of applying evidence-based wound-care principles and of providing these women with both psychosocial support and care.

A recommendation for the future is that treatment of patients with malignant fungating wounds should become structured, and modern wound-care principles should be applied. Psychosocial support also should be provided. ■

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CANCER CARE

II

Malignant wounds in women with breast cancer: feminine and sexual perspectives

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Malignant wounds in women with breast cancer: feminine and sexual perspectives
Aims and objectives. The aim of this article is to investigate the way malignant fungating wounds affect femininity, sexuality and daily life in women with progressive breast cancer. Malignant wounds occur when the underlying localized tumour filtrates into the skin, blood capillaries and/or lymph vessels.

Design. The study was a prospective and exploratory intervention study. The intervention was tested on 12 consecutively selected women with progressive breast cancer and malignant fungating wounds.

Methods. The 12 women participated in a 4-week wound care intervention programme that comprised evidence-based wound care principles and psychosocial support. Data were generated by means of interviewing prior to and following the intervention period.

Results. The women described how malodorous and oozing wounds trigger anxiety about seepage, prevent them from wearing feminine attire and cause them to suppress the need for physical closeness and sexual activity. The results showed that by using modern wound care products, the patients could be secured against seepage and odour. The women experienced a sense of comfort, were able to dress again as they wished, no longer felt caged in and isolated and were given a sense of freedom which they had not felt for a long time.

Conclusions. The intervention succeeded in increasing breast cancer patients' psychosocial well-being and reducing social isolation.

Relevance to clinical practice. There is a lack of standard methods of practice for care of malignant wounds in women with breast cancer. This article describes an intervention for wound care which could improve daily life in women with progressive breast cancer.

Key words: breast cancer, female perspective, femininity and daily life, malignant fungating wounds, sexuality

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*Malignant wounds in women with breast cancer***Introduction**

Malignant fungating wounds in women with breast cancer occur when an underlying localized tumour infiltrates the skin, blood capillaries and lymph vessels. The wounds can be a result of cutaneous metastatic growths from a primary tumour (Mortimer 1998). The incidence of malignant wounds in patients with breast cancer is shown to be 2–5% (Fairbairn 1993, Haisfield-Wolfe & Rund 1997, Grocott 1999). The issue of malignant wounds in women with breast cancer is neglected nationally and internationally (Ivetic & Lyne 1990, Moody & Grocott 1993, Bauer *et al.* 2000).

A questionnaire survey carried out in 1999 amongst care personnel in Denmark showed that none of the 25 departments of oncology/outpatient clinics spread over 11 hospitals/hospices, had guidelines for the treatment of malignant fungating wounds (Lund-Nielsen 2002). Consequently, women with malignant wounds receive sporadic and unstructured wound care.

Through literature searches on MEDLINE, CINAHL and CANCERLIT, 33 articles were found which focused on treatment of people with malignant fungating wounds. The search used the following international descriptors: breast neoplasm; wounds and injuries; fungating; and nursing. Six research-based articles on malignant fungating wounds were found (Grocott, 1997 1998, Thomas *et al.* 1998, Haisfield-Wolfe & Baxendale-Cox 1999, Grocott 2000, Grocott & Cowley 2001), and showed that most guidelines on malignant fungating wounds were developed through experience rather than based on clinical intervention research. Ten were case studies that documented individual trials (Shutler *et al.* 1997, Jones 1998, Price 2000). The identified articles describe, primarily, the physiological consequences of living with a cancer-related wound, including wound related pain (Hallet 1995), exudation (Grocott 2000), infection (Morison *et al.* 1997), bleeding (Haisfield-Wolfe & Rund 1997) and malodour (Houghton & Young 1995, Price 1996, Mallett *et al.* 1999).

Wound care principles described by Young (1997), Mallett *et al.* (1999) and Grocott (2000), recommended that the patient should be offered surgery if possible, or anti-neoplasm treatment in the form of chemotherapy, irradiation or anti-hormonal treatment as long as these treatments proved effective. In parallel with the anti-neoplasm treatment, the literature recommends that wound care focuses not only on the wound itself, but also on the morphology of the wound and the dressings as part of patient education and documentation. It was highlighted that care and treatment should be adapted to the individual's needs and problems, and focus on physiological and psychosocial issues. Accord-

ing to the literature, malignant wounds are chronic, and healing is therefore not considered to be an expected goal. Rather, the aim is to create optimal wound conditions, and to support the woman in improving her quality of life and independence of assistance by family members, doctors and care personnel (Hallet 1995, Haisfield-Wolfe & Rund 1997, Bird 2000b).

Although several authors named quality of life as an element that should be considered an integral component of treatment, this was not clearly stated in the literature, just as psychosocial issues were described in general terms without any definition of how they should be transferred to clinical practice. Only one article mentioned that different types of dressings can influence patient's experience of exudate management. In the study by Grocott (1998), data from three out of 45 included patients were presented when an evaluation system, the 'Teler System', was used to describe the results and concluded that exudate management depends on dressing fit and optimum absorption and venting of excess fluid (Grocott 1998).

No studies were found which highlighted women's perspectives or experiences of living with a malignant wound and its impact on psychosocial issues such as femininity, sexuality and social relations. These are examined in this study.

The intervention

A wound care intervention was developed based on evidence in the literature and our personal experiences. Table 1 shows the elements within the intervention. *They were included a systematic, unique and structured wound treatment that built on continuity and existing knowledge* (Young 1997, Mallett *et al.* 1999, Grocott 2000). Three specially trained wound care nurses were involved in developing the intervention and were responsible for assigned patients. Wound care took place in the women's own homes, on average every three days, for approximately one hour per visit. Each intervention started with an examination of the morphology of the wound during which details were registered regarding size, stage, rate of exudation of the wound, and its influence on the woman's psychosocial life. Wound care was carried out using modern wound healing principles including cleansing routines, humid wound healing, acidic wound environment, constant wound temperature, protection of the surrounding areas, avoidance of contaminants and using modern wound care products such as alginate (Algisite M[®]); a hydrocellular dressing (Allevyn Adhesive[®]); a hydrogel (Intrasite Gel[®]) and a carbon dressing (Actisorp Plus[®]). Wound care was continuously documented and evaluated by using a checklist and preprinted clinical care plans. Following the 4-week inter-

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Table 1 The key elements of the intervention

1. Systematic, unique and structured wound treatment that built on continuity and in the literature existing knowledge	
<ul style="list-style-type: none"> • Three specially trained wound care nurses undertook the wound care in the women's own homes, and were responsible for assigned patients 	Size, stage, rate of exudation of the wound, smell and the wounds influence on the woman's psychosocial life
The intervention started with morphology of the wound	Cleansing routines, humid wound healing, acidic wound environment, constant wound temperature, protection of the surrounding areas, avoidance of contaminants
Wound care was carried out using modern healing principles	Alginate (Algisite M [®]), a hydrocellular dressing (Allevyn Adhesive [®]), a hydrogel (Intrasite Gel [®]) and a carbon dressing (Actisorp Plus [®])
Wound care was carried out using modern wound care products	
<ul style="list-style-type: none"> • Wound care was continuously documented and evaluated by using a checklist and pre-printed clinical care plans • Following the four-week intervention period, responsibility for wound care was transferred to the home care nurse 	
2. Dialogue between the women and the clinical nurse advisor	With focus on the malignant fungating wound's influence on the women's daily lives, self-image, sexuality, femininity, choice of attire and social relationships

vention period, responsibility for wound care was transferred to the home care nurse who was informed about the patient via a nursing care report.

Dialogue between the women and the clinical nurse advisor

This took place each week, for approximately one hour in conjunction with dressing changes. The dialogue focused on the malignant fungating wound's influence on the women's daily lives, and also on self-image, sexuality, femininity, choice of attire and social relationships.

Materials and methods

Research design

The study forms part of a larger study entitled 'Women with breast cancer suffering from malignant fungating wounds' and was prospective and exploratory. The intervention was tested on 12 consecutively selected women with progressive breast cancer, who also have malignant, fungating wounds and were undergoing treatment or control check-ups at The National University Hospital of Denmark or at the Naestved Hospital's Department of Oncology.

Subjects and recruitment

Sixteen women with progressive breast cancer were invited to enter the study. Three women declined participation as they felt too weak, one woman died and the 12 women were referred to the investigation by staff members of the oncology departments.

Table 2 shows the demographic characteristics of the sample. The 12 women were between 57 and 85 years of age, and had been diagnosed with breast cancer from between 0.1

and 28 years. The women had metastases to the lungs, liver, bones and/or brain, nine of the women during the intervention period undertook anti-neoplasm treatment, while the remaining three women no longer undertook treatment. The women had had malignant, fungating wounds from between 0.1 and four years prior to the intervention. In nine of the women, malignant wounds were localized to the left of the thorax, and in three women to the right and all of the women had arm lymphoedema on the same side where the malignant wound was located. Five women were married, and seven lived alone. Six months following termination of the data collection, eight of the women had died.

Data collection and methods

No validated methods of evaluation of malignant wounds were found, therefore we developed our own methods, which comprised: (1) objective methods: photographs and wound morphology registration (data will be published elsewhere) and (2) subjective methods: interviewing.

Semi-structured interviews

Semi-structured interviews were used as this method is optimal for capturing details, and for uniquely highlighting the women's experiences regarding the impact of malignant fungating wounds on their daily lives (Kirk & Miller 1986). Two semi-structured interview guides were used, one prior to the intervention (G1) and one at termination of the intervention (G2). These guides contained closed yes/no questions as well as open-ended responses. G1 contained 47 questions (11 open-ended, 36 closed) while G2 had 41 questions (18 open-ended, 23 closed). The guides had three themes, with the exception of G1, which contained demographic

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*Malignant wounds in women with breast cancer***Table 2** Study participants' demographic data

Patients (<i>n</i> = 12)	Median value*
Age	69 years* (57–85)
Time since diagnosis with breast cancer	8.2 years* (0.1–28)
Stage of the disease	
Advanced breast cancer (IV) with metastasis to	
Bones	5
Lung	2
Lung + liver	2
Lung + bones	1
Lung + brain	1
Liver + bones	1
Type of anti-neoplasm treatment (at start of intervention)	
Chemotherapy	5
Anti-hormonal treatment	4
No treatment	3
Time since development of the malignant fungating wound	1.8 years* (0.1–4)
Location of the malignant fungating wound	
Left side of chest	9
Right side of chest	3
Contemporary arm lymph oedema	12
Marital status	
Married	5
Single	7

information, and G2 focused on perspectives of the impact of the intervention.

Theme A focused on wound related questions (physiological factors, the wound's process of development, views about wound care products). Theme B dealt with psychological and social issues, such as femininity and sexuality, the wound's influence on everyday living and emotions and feelings while with other people. Femininity includes aspects of appearance, choice of attire, feelings of well-being and being a woman in social relationships. The term 'sexuality' refers to intimate situations such as embracing, touching and close physical contact. Theme C focused on future wound care (responsibility for wound care, social assistance, the home care nurse). This paper presents the results from investigation of Theme B. Some results from Theme A are mentioned, as these help to better understand results from Theme B.

The interviews lasted 45 minutes duration, and took place in an office located at The National University Hospital of Denmark, or in the women's homes.

Analysis and interpretation

All interviews were tape-recorded and later transcribed verbatim. The thematic analysis began in the field during data collection, using semi-structured interview guides. In the initial stage of data collection, two of the researchers reviewed the first two interviews to verify the reliability of

the interview process. Contextual annotations were added and data were then categorized in relation to the pre-established themes in the interview guides. The data were sorted under different headings to identify expressions or phrases that could be seen to form features, for example loss of femininity, social isolation, disregard for sexuality (Polit & Hungler 1999). Predominant themes and text passages served to identify and validate meaning related to the women's experiences of living with malignant, fungating wounds. Investigator triangulation was used to minimize biases (Denzin & Lincoln 2000). Based on an analysis of each text, consideration was given to alternative explanations for the findings.

Ethical considerations

The women's lives were negatively affected by having malignant, fungating wounds, coupled with the symptoms of the progressive disease. If they were unable to come to The National University Hospital of Denmark to be interviewed, this was carried out in the woman's home. As the interviews focused on emotions, the participants were given the opportunity to express these during the interviews. To participate in the study, each woman was requested to sign a consent form, in which the principles of confidentiality and informed consent were highlighted. The Data Directorate was informed about the study (Journal nr.

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2000-41-0275), and the Regional Ethical Committee for Copenhagen and Frederiksberg Municipalities approved the study (Journal nr. 01-288-00).

Results

Interview responses regarding the effectiveness of the dressings showed that the new wound care products were more satisfactory for most of the women with respect to exudation and odour, when compared with the dressings used prior to the intervention. The women stated that the new wound care products were more comfortable and provided increased quality of life (data will be published elsewhere).

The malignant, fungating wound's influence on the women's daily lives prior to the intervention

Odorous and seeping malignant fungating wounds reduce femininity and socialization

The women were asked if their wounds had influenced their femininity and 42% of the women claimed that their wounds had a negative influence. They stated that the wound was the reason for their change in self-image. The women understood the question of femininity as relating to their choice of attire, their appearance as well as their well-being and they described that, because of the wound, they could not wear the clothes they wanted to and that this issue was most problematic when invited to family gatherings or social events. The women did not feel comfortable because of the large dressings which prevented them from wearing a bra and tight clothing and had a negative effect on their feelings of femininity and as a consequence, they shunned others, leaving them with a sense of social isolation. One of the women interviewed (Patient no. 4) gave the following response to the question of whether the wound influenced her daily life: 'When we have to go out, I can never have decent clothes on, so I decline many invitations. I now have an inferiority complex about it (the wound)'. Regarding the issue of whether not being able to wear a bra compromised femininity, Patient no. 12 explained: 'It is horrible not wearing a bra. I can't have nice clothes on. It's a real handicap'. Patient no. 4 explained: 'I cannot have a bra on or nice clothes. I am constantly afraid of seepage, and it (the wound) smells now'.

The wound's impact on femininity and sexuality was related to the women's ages. Three women (25%) who were over 70 years of age had no substantial comments to give on the subject, while two of the women over the age of 70 believed that the older one is, the less meaningful femininity and sexuality becomes. Two of the interviewees gave the following comments about femininity and sexuality – Patient

no. 2: 'I got this wound in my old age so it has not mattered so much', and Patient no. 11: 'No, I think that I'm too old. If I were 40 or 50 years old it would have been terrible to have both breasts removed, and also have this wound'.

Thirty-three per cent of the women interviewed believed that the wound had a negative influence on their sex life. The smell and the seeping wound made proximity to someone impossible and the women's desire for sex disappeared. One participant (Patient no. 3, having had a malignant wound for three years) provided the following answer to the question of whether the wound had changed her desire for close physical contact with others – for example, hugging or sexual activity:

We (the woman and her husband) have not had sex for two years, – it is not possible. The wound is the reason why. Before the operation on the right breast we had sex, but we have not had sex since the wound appeared. We never speak about it. It is just an agreement we reached that sex is out of the question. My husband is not upset about it. I don't miss it because I know that it will not be a pleasant experience, with the wound seeping like it does. That takes all the joy away.

In general, the above quotations showed that the women had low self esteem and felt unfeminine, as the wound prevented them from wearing the clothes they wanted to. The wounds had a negative influence on the women's daily life, their sex life and their social relationships.

The malignant fungating wound's influence on the women's daily lives, after termination of the intervention

The impact of wound care on physical well-being, appearance and desire for socialization

The intervention proved to have a positive impact on the participants' sense of femininity. Thirty-three per cent of the interviewees indicated that the wound care intervention, and the concomitant dialogues were the main influences on their increased sense of femininity, and increase their desire for socialization. The women associated femininity and identity with socialization and it was important that they look feminine, and are seen, by their relatives, to be good looking. With the new dressings came the opportunity to wear a bra and feminine clothes and they felt secure and did not need to hide anymore.

In response to the question 'has the wound care project enabled you to change your perception of yourself as a woman?' responses included the following (Patient no. 8): 'I can wear different clothes now – nice clothes – because the dressing is better fitted to my body and this makes me feel more secure.' Patient no. 1 answered:

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To a certain degree. I can now wear a bra without feeling bothered by it. Before the project I had 'pads and the like' on (absorbent dressings, handkerchiefs, sanitary napkins, etc.). This was unacceptable to my husband. It looked awful. This new dressing is nice. It has also changed my choice of clothes – before I always wore black clothes because I was afraid of blood seeping through in blotches and discolouring my clothes. But now I can wear white clothes just like I used to do, before the wound appeared. So this is a big change. I have a sense of well-being and a desire to do more with my appearance. The other day, I wanted to make myself pretty and my husband said, 'Wow! You look so nice today'. I had dressed well. I hadn't a desire to do that kind of thing for a long while. So the project has helped me a lot.

The dressing gave them a sense of well-being, and a freedom because there was no leakage, odour, and they were not constantly reminded about their serious illness. One woman said that she had been afforded more time, where she could feel free to be outgoing and sociable. Patient no. 6 explained:

I have had friends over for lunch almost every day the last four weeks. Prior to the project, I didn't feel like doing this. Now I am able to move around because the dressing fits better. All of a sudden, I have been afforded more time. Four weeks during which I can move around, and not feel locked in because I feel disgusting.

Thirty-three per cent of the women experienced an increased desire for close physical contact after the wound care intervention. The women felt more secure with the new dressing, and it gave them a feeling of relief by finding a solution to their problem because it seems easier to talk about it and easier to look ahead to a life where also physical contact is an option. Two of the participants described (Patient no. 1): 'It has improved. Before, I kept him (husband) at a distance, but I don't do that any more – It has improved'. Another woman (Patient no. 12) stated: 'Perhaps it's become a little better after getting this (dressing). I think that it is the dressing that has made the difference'.

The above quotations show that when the women have experienced the freedom which the dressing can provide, the first step to socialization is contact with friends and people from the outside world. Secondly, close physical contact is possible when the women have a feeling of safety and self-confidence.

Discussion

Femininity can be strengthened and social isolation might be prevented

The results of the study showed that malignant, fungating wounds had consequences for approximately half of the

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participants in relation to their femininity. The quotes showed that the women's self esteem suffered and they lost their self-respect as the wound prevented them from wearing a bra and nice clothes. This is in line with a study by Wilmoth (2001), involving 18 women's experiences following diagnosis with breast cancer, where women felt a partial loss of femininity. The results of this study concur, and provide more detail about this loss of femininity, in particular, how both the loss of a breast, and the existence of a malignant fungating wound, influenced their daily lives. The participants described the difficulties of not being able to wear clothing that they desired, how the large dressings prevented them from wearing short shirts and dresses and how general cancer-related consequences, such as immobility, can affect their femininity. In a study by Bredin (1999), which described experiences of three women who had a breast removed, the women's body image was affected and they felt unfeminine primarily because they associated breasts with being feminine. In the present study, the women similarly experienced feelings of loss of femininity and suffered a double stigma as each woman had had a breast removed as well as experiencing a smelly and seeping malignant, fungating wound on her chest. In order not to expose themselves or others to situations that are uncontrollable, the women opted for safe and secure home surroundings. What concerned the women the most was their anxiety that the wound would smell, or that others would notice it. Many of the women chose, therefore, to isolate themselves from their social circles by remaining at home, and not participating in get-togethers and events, consequently being socially isolated.

An important result of the study showed that, by using modern wound care products, seepage could be prevented and comfort improved. The women were able to dress again as they wished. Many of the women no longer felt caged in and isolated, but rather were given a sense of freedom which they had not felt for a long time.

Renewed desire for physical contact and sexual activity

The results of the study showed that the participants' sexual activity had been affected by living with a malignant wound. The wound was seen as the reason why sexual activity was no longer possible, as it was perceived as disgusting and took away the desire for sexual activity, because of its smell and exudate. The participants in this study gave the impression, prior to the intervention, that they did not miss having a sex life. Other more general studies on breast cancer patients describe, in contrast, the importance of continuing to have a sex life, as this strengthens the woman's quality of life,

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feelings of being attractive and being loved, and feelings of being a 'normal' woman (Bruner & Boyd 1999, Hordern 2000, Wilmoth 2001). The women in this study already suffered from symptoms of progressive breast cancer, for example, fatigue, lack of appetite and nausea, as well as having a malignant wound, which is physically irritating, painful, malodorous, bleeding and reduced mobility. Sexual activity under these circumstances requires rethinking, and using alternative sexual positions, for which the women may not always have energy or knowledge. The odour from the wound gives women with breast cancer the impression that their bodies are rotting, leading to feelings of powerlessness and shame, and gives women negative feelings about their own bodies (Bird 2000a). Thus, not missing having a sex life can be interpreted as the woman's desire to protect herself as well as her partner from the constant life threatening and visual reminder, that the wound is the symbol of a progressive illness and expected premature death.

By using modern wound care products, it was possible to 'hide' the wound and reduce the odour. These actions, combined with the opportunities provided for counselling during the dialogues with the nurses, meant an increased desire for close physical contact for most of the participants. Studies have shown that simply having a dialogue with a breast cancer patient about, for example, changed body image or sexual activity, can be effective in allowing the individual to resolve these issues (Burbie & Polinsky 1992, Bredin 1999, Price 2000). Discussion regarding sexual problems had an influence on the participants' increase in desire for closer physical contact. These discussions legitimized articulation of sexual problems, while continuity of care allowed the development of a relationship with, and confidence in, the clinical nurse advisor during the four-week intervention period. Also, in most cases, the wound care took place in the women's own homes, in a safe and secure context, so she could more readily speak about issues which normally would belong to her own home world. It can be easier to confront difficult issues in a secure environment, rather than in a large, intimidating hospital, with many different and foreign health professionals. By having the dialogue take place in the woman's home, she could share the problems rather than dealing with them alone.

Femininity and sexuality in the older participants

Five of the participants over the age of 70 years stated that femininity and sexuality had less meaning for them than for their younger fellow sufferers. These five women had suffered from breast cancer on average 10.6 years, and from a malignant wound for on average of 2.5 years. They had

lived through years of suffering and a series of cancer treatments and, as such, were forced to master various burdensome situations. Possibly, over time they had adapted to the situation. The latest scientific literature on quality of life discusses the patient's experience of living with cancer from an age-related perspective. Sammarco (2001) describes how women with breast cancer, who are over the age of 60 years, have many more personal and emotional resources than women with breast cancer who are under the age of 40. The study suggested that women over 60 years have fewer episodes of depression, less anxiety and fewer reported sexual problems. Since the myth (Hordern 2000) still exists today that older women do not have sex lives, this could be the reason why the women in the study by Sammarco (2001) had not reported sexual problems to the same extent as their younger fellow sufferers. Four of the women in the present study, who were over 70 years of age, had lost their partners and lived alone and therefore, may have suppressed possible sexual needs. Another explanation could be that women who are 70 years old or older today, grew up at a time when talking about sex was taboo. These aspects may have had an influence on the older women's openness about sexuality. In contrast to the Sammarco study, the women in the present study did not have many emotional resources, nor did they experience less anxiety than their younger fellow sufferers. They all experienced progressive breast cancer and a malignant fungating wound, the presence of which was perceived to pose a constant threat of an early death. One can therefore say, as did Bird (2000a), that women who have breast cancer and a malignant wound, are threatened both by the wound's appearance, as well as by a suppression of their own femininity and sexuality, all of which creates anxiety, frustration and suffering.

Methodological considerations

The value of this part of the study, which examines the patients' experiences, is that it provides an introspective lens through which data (positive and negative) to validate the effect of the wound care intervention could be collected. Interviews were useful to examine attitudes, processes and experiences, especially as these related to interactions and activity (Denzin & Lincoln 2000) and thereby related to core components of clinical knowledge, as argued by Malterud (2001). The interview method was developed and used with the intention of highlighting nuance (unique) knowledge from the study's subjects (Kirk & Miller 1986).

Despite the low number of participants in the study, it is believed that making visible the existential and psychosocial problems of women with breast cancer suffering from

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malignant fungating wounds can provide new insight into the tabooed and overlooked concerns of this category of cancer patients.

Conclusion

Women with malignant fungating wounds experience painful physical and psychosocial symptoms, which are tied with feelings of frustration and loss of power. A wound care intervention, built on evidence-based practice and psychosocial support, can increase the women's sense of well-being and reduce difficult psychosocial problems, including loss of femininity, sexuality and social isolation.

The study provided valuable knowledge about 12 women's experiences of living with malignant, fungating wounds. Further research is needed to investigate in more detail those areas identified by this study. Femininity and sexuality in women with breast cancer, who additionally suffer from malignant fungating wounds, is an overseen issue in both the literature as well as in clinical practice. It is important that future research considers inclusion of a larger number of informants, so that more expanded knowledge about how women with this disease can best be assisted, as well as to test similar interventions.

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Contributions

Study design: LA, BL-N; data collection: BL-N, KM; data analysis: LA, BL-N, KM; manuscript preparation: BL-N, LA.

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The effect of honey-coated bandages compared with silver-coated bandages on treatment of malignant wounds—a randomized study

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ABSTRACT

Malignant wounds (MWs) occur in 5–10% of all cancer patients. Malodor and exudation are the most common side effects. The aim was to determine the influence of honey-coated compared with silver-coated bandages on treatment of MWs. Patients were randomly selected to enter either group A (honey-coated bandages) or group B (silver-coated bandages). Parameters were the following: wound size, cleanliness, malodor, exudation, and wound pain. Digital photographs, visual analog scales (VAS), and wound morphology registration were used for measurement at baseline and following the 4-week intervention. Sixty-nine patients with MWs and advanced cancer, aged 47–90 (median 65.6), were included. No statistically significant difference was noted between the groups with respect to wound size, degree of cleanliness, exudation, malodor, and wound pain. There was a median decrease in wound size of 15 cm² and 8 cm² in group A and B, respectively ($p = 0.63$). Based on post-intervention pooled data from the groups, improvement was seen in 62% of the participants with respect to wound size and in 58% ($n = 69$) with respect to cleanliness. The VAS score for malodor ($p = 0.007$) and exudation ($p < 0.0001$) improved significantly post-intervention.

Patients with reduced wound size had a median survival time of 387 days compared with 134 days in patients with no wound reduction ($p = 0.003$). The use of honey-coated and silver-coated bandages improved the outcome of MWs. No differences were found between the two regimens. Both types of bandages are recommended for use by patients with MWs containing tumor debris and necrosis.

In the literature, malignant wounds (MWs) are described as chronic wounds that occur in 5–10% of all cancer patients.¹ MWs are most often seen in connection with breast cancer, head and neck cancer, and in advanced cancer cases.² These wounds occur when a tumor penetrates the skin or via metastases.³ MWs are often located in a previously irradiated area and have a negative influence on wound healing.⁴ An MW typically remains inflamed due to the presence of tumor tissue in the wound bed. Malodor and exudation are the most common and burdensome problems for patients with MWs.^{5–7} Psychosocial problems are also evident such as changed body image, shame, depression, and social isolation.^{8–10}

Guidelines for treating MWs are usually developed based on experience rather than on evidence from randomized clinical trials (RCTs).¹ Research is lacking on treatment strategies and wound care products that facilitate healing and that meet the patient's physical and psychosocial needs.¹¹

The application of carbon–silver-coated bandages has shown increased tissue granulation and epithelialization in

nine of 12 women with MWs and advanced breast cancer. The women's sense of well-being improved as did their self-confidence due to the psychosocial support offered to them in parallel with the wound care.^{12,13} This regimen was "standard practice" for these patients; however, larger randomized studies are needed to confirm the effectiveness of this treatment compared with other regimens.

Silver-coated bandages have shown antiseptic, antimicrobial, and anti-inflammatory properties when applied to chronic non-MWs.^{14–16} Furthermore, honey-coated bandages have also shown pain-relieving properties in non-MWs beyond their effectiveness in cleansing, antimicrobial, antiodor, and anti-exudation.^{17–20} To our knowledge, research on the use of honey-coated bandages for MWs has not been previously published.

The aim of this RCT study is to test the effect of honey-coated bandages vs. silver-coated bandages on wound size, cleanliness, malodor, exudation, and wound pain in patients with MWs and advanced stage cancer.

MATERIALS AND METHODS

Design

This prospective, open-labeled, RCT investigates a 4-week intervention using two forms of wound bandaging:

- Group A: *Manuka honey-coated bandages* (Algivon/Activon Tulle UMF 12+, AdvaNordic Medical Group A/S, Soroe, Denmark) and absorbent dressing (Sorbion/Drymax, Mediq Danmark A/S, Broendby, Denmark) as well as foam bandages (Allevyn Adhesive, Smith&Nephew A/S, Hoersholm, Denmark).
- Group B: *nanocrystalline silver-coated bandages* (Acticoat/Acticoat Absorbent, Smith&Nephew A/S) and foam bandages (Allevyn Adhesive, Smith&Nephew A/S)—in cancer patients with advanced stage cancer and MWs.

Approval was gained from the National Data Inspectorate (2006110013A). The study adheres to guidelines set by the Ethical Research Committee for Copenhagen and Frederiksberg municipalities ([KF] 01 2006-5491) and was registered under identifiers NCT00435474 at <http://www.clinicaltrials.gov>.

Outcomes

The primary outcome was a change in wound size. Secondary outcome was cleanliness of the MWs, degree of exudation, malodor, wound pain, and a correlation between survival time and healing.

Patients

Seventy-five patients with advanced stage cancer and MWs were consecutively recruited nationwide from oncology units of 10 hospitals in Denmark (see Table 1). Estimation of whether a wound could be characterized as malignant was established on the basis of history and clinical signs. No biopsies were taken. The clinical diagnosis was a nonhealing wound that developed due to the growth of a tumor through the skin or occurred in connection with metastases. Inclusion criteria were Danish-speaking cancer patients, aged 18+ years, with advanced stage cancer (metastases to the lungs, bone, liver, or locally advanced cancer), a minimum wound size of 1.5 cm², and a survival prognosis of at least 3 months. Exclusion criterion was received radiation therapy to the wound area over the past 3 months.

Randomization was done by the Clinical Research Unit at the Oncology Department of Copenhagen University Hospital (Rigshospitalet). The randomization process was computer-based and was stratified for gender, cancer diagnosis (\pm breast cancer) and treatment (\pm antineoplastic treatment).

A total of 75 patients were included consecutively in the study, six of whom were excluded for reasons shown in Figure 1.

This article describes the condition of MWs in the 69 included cancer patients prior to and after the intervention.

Evaluation parameters

Wound size was determined based on digital photos taken by the first author (B.L.N.). Prior to and on completion of the

Table 1. Demographic and clinical characteristics of patients entering the study

Variable	Group A Honey (n = 34)	Group B Silver (n = 35)	p-value
Sex			
Female	30	31	1.000
Male	4	4	
Age (years)			
Median	66.1	60.7	0.355
Range	50.9–86.8	47.4–89.6	
Cancer diagnosis			
Breast	27	28	0.619
Head/neck	5	3	
Others	2	4	
Antineoplastic treatment			
Yes	28	28	1.000
No	6	7	
Antibiotic treatment			
Yes	4	7	0.513
No	30	28	
Wound duration (months)			
Median	7.5	6.0	0.834
Range	1–86	1–48	
Wound size cm ² (baseline)			
Median	137.76	128.95	0.448
Range	0.07–756.51	0.17–893.14	

The last column displays the p-value for testing for homogeneity before intervention.

intervention, the photos were standardized for light, area to be photographed, and distance from the camera to the wound. The photographs were loaded to the software program “Quantify Image,”²¹ and the images and sizes were recorded within 1 mm² precision.

Cleanliness of the MW was defined as the wound showing less necrosis and fibrin and increased vascularity and granulation tissue following the intervention. The degree of cleanliness of the wounds was estimated by four specialized wound care nurses based on the photographs taken over time. These four nurses were blinded to the type of treatment used. The nurses evaluated all the photos taken at baseline and after the intervention. The wounds were categorized as “cleaner,” “less clean,” or “unchanged cleanliness,” compared with pre-intervention. Agreement was reached if three of the four or all four nurses scored the same. If two of the four nurses were not in agreement, the photographs were reevaluated. This occurred in four cases. Agreement between the four nurses was reached using Cohen’s kappa score^{22,23} after merging the group “unchanged cleanliness” with the “less clean” group.

Malodor was evaluated by the first author (B.L.N.) at baseline and following the intervention using the Haughton and Young 1995²⁴ four-step verbal rating scale (VRS), i.e., (1) no malodor, (2) slight malodor, (3) moderate malodor, and (4) strong malodor.

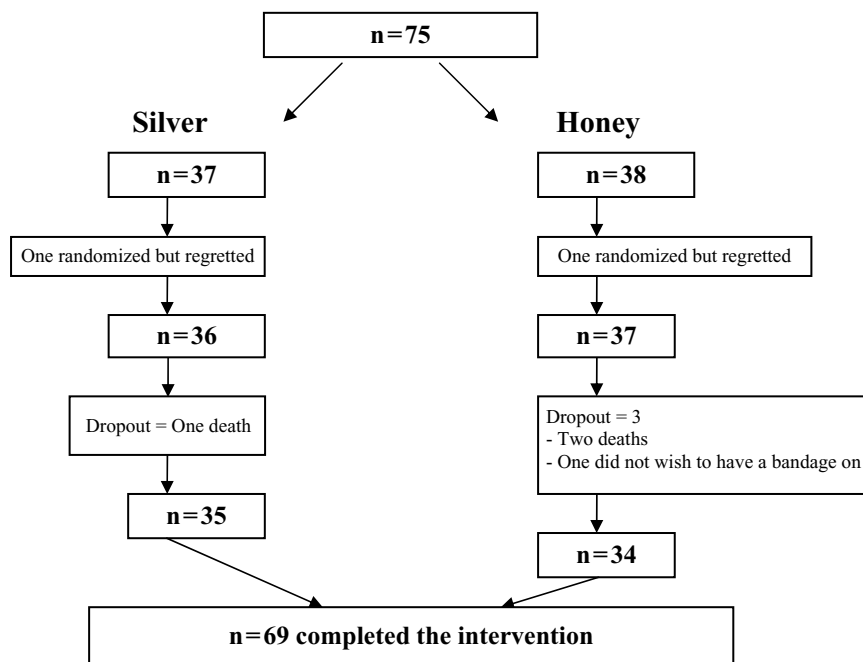


Figure 1. Patients’ flow chart. Description of patients included in the study.

Exudation was evaluated (B.L.N.) prior to and following the intervention and was based on a four-step VRS: (1) dry (no dressing change in a week); (2) slight fluidity (dressing change frequency once a week); (3) moderate fluidity (dressing change frequency every 2–3 days); and (4) heavy fluidity (dressing changed daily or every second day).

Malodor and exudation were evaluated by the patients at baseline and following the intervention using a 100 mm graduated mechanical visual analog scale (VAS). Wound pain was measured using the same methodology.

Malodor, exudation, and wound pain data measurements were documented using a morphology registration sheet.

Intervention

See Table 2.

Statistical analyses

Our pilot study,^{12,13} which captured data from 12 patients (18 wounds), showed a change in wound size of $8.0 \pm 36.6 \text{ cm}^2$

Table 2. The intervention

Intervention	The intervention period (28 days)
1. Modern wound healing principles: <ul style="list-style-type: none"> • Cleansing with faucet water and liquid medicinal soap (pH factor 4.5) and continued with the aid of tweezers, Metzenbaum scissors, and nonwoven pads • Wound treatment with modern wound care products: Group A: Manuka honey-coated bandages (Algivon/Activon Tulle UMF 12+), absorbent dressing (Sorbion/Drymax), and foam bandages (Allevyn Adhesive); or Group B: nanocrystalline silver-coated bandages (Acticoat/Acticoat Absorbent) and foam bandages (Allevyn Adhesive) 2. Psychosocial support: dialogues about coping with the illness and particularly with a malignant wound 3. Relaxation training: prerecorded CDs with relaxation exercises	<ul style="list-style-type: none"> • Both wound treatments took place in the patient’s homes, on average, every 2–3 days with approximately 1.5 hours per visit. Cleansing of the wounds was carried out in the same manner in both groups. • The primary author (B.L.N.) and the patient collaborated with the wound care nurse/district nurse to complete the procedure. Wound care was administered after training and guidelines were provided by the primary author. • Wound evaluation was carried out once weekly by the primary author. • The patients participated in 1-hour dialogues held weekly with the primary author, structured in accordance with the cognitive therapy model. • The patients underwent 20 minutes of progressive relaxation training at least once every other day.

Shows the contents of the 28 days intervention period. CD, compact disc.

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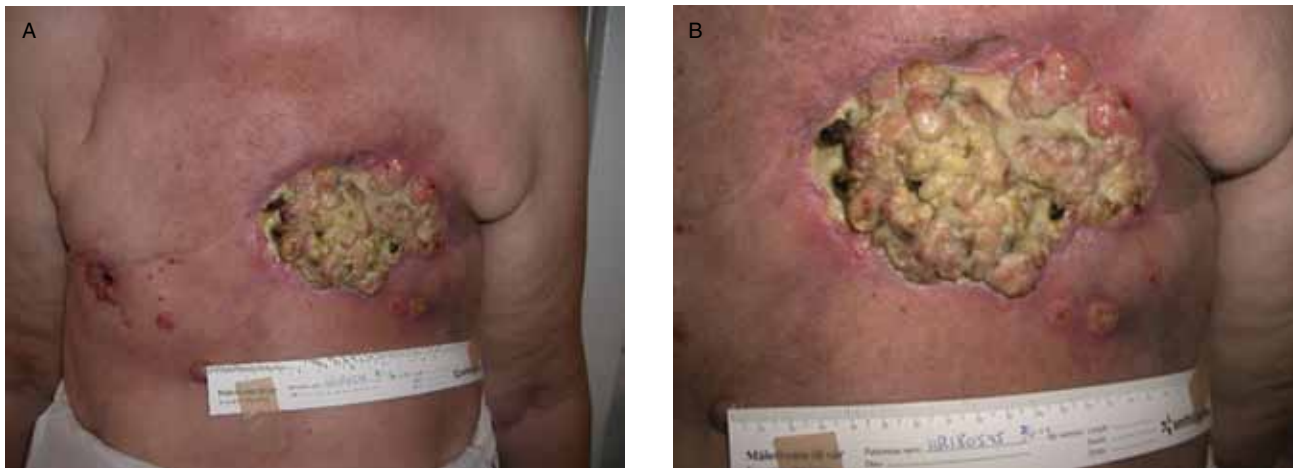


Figure 2. Photo samples: the wound size is measured by means of digital photography on the software program “Quantify Image Central.” The resulting measurement reflects the “open” area of the wound. The area with complete skin coverage is not included in the measurement of the wound size. Photo: woman with breast cancer. Wound size: 75.65 cm².

(mean \pm standard deviation) when “own” wound care was replaced by “professional” wound care using, among other products, silver bandages (before and after the intervention on the same patients). A standard deviation of 36.6 cm² for the change of wound size over the intervention period was used for power calculations in measuring the impact of the honey-coated and the silver-coated wound bandages. A sample size of 35 patients from each group was required to detect a difference of 24.8 cm² between the groups, with a power of 80% in a two-sided, unpaired *t*-test on a 5% significance level.

Mann–Whitney U-tests and Fisher’s exact tests were used to compare the baseline characteristics of the treatment groups.

The change in wound size during the intervention period was analyzed using the Mann–Whitney U-test as well as linear regression. To meet the assumption of variance homogeneity, linear regression analysis was done on square root transformed data. The regression parameter described the size of the wound after the intervention, measured in percent of the wound size at baseline, and a test was performed for the hypothesis that this parameter equals 100%.

Cohen’s kappa score was used to evaluate observer agreement between multiple inspections of wound cleanliness before and after the intervention.

Changes in subjective measures of malodor, exudation, and wound pain, measured on a VAS scale, were compared across treatment groups using a nonparametric Mann–Whitney U-test. Paired Wilcoxon tests were applied to detect changes over the intervention period. Due to the low number of patients in each response group for measures of malodor and exudation, categories “no” + “slight”—and “moderate” + “strong” were merged prior to statistical analysis. The resulting binary variables were analyzed using a logistic regression model, taking into account the correlation between variables analyzed using a logistic regression between observations on the same patients. Testing the effect of interaction between time and treatment as well as a marginal test for change over time is presented in the results.

The survival time for the patients following the intervention was described using Kaplan–Meier survival plotting, and log-rank testing was used to assess whether there was a longer survival period among patients experiencing a reduction in wound size during the intervention period. The survival rate was investigated in relation to change in wound size from baseline to post-intervention for all patients.

A 5% significance level was used throughout the study. The statistical analyses were made using “R: A Language and Environment for Statistical Computing, version 2.10.1.”²⁵

RESULTS

Baseline data

Demographic and clinical characteristics of the 69 patients are shown in Table 1. Groups A and B were comparable at baseline for age, gender, cancer diagnosis, duration of wound size. Similarly, subjective patient ratings for malodor, exudation, and wound pain using a VAS scale did not differ between the groups prior to the intervention.

Eighty-eight percent of the participants were women. Eighty percent had breast cancer, 12% had head and neck cancer, and 8% had other diagnoses. Eighty-one of the participants received antineoplastic treatment, and 16% were simultaneously undergoing antibiotic treatment. The median values were the following: age, 65.6 years; wound duration, 7 months; and wound size, 130.9 cm² (see photograph: example of MW, Figure 2).

Intervention data

No significant differences were found between the effects of the honey-coated and silver-coated bandages on wound size, degree of cleanliness, malodor, exudation, and wound pain. The two treatment groups A and B were therefore pooled in a subsequent analysis to investigate whether treatments from the pooled group showed any effect over time.

Table 3. *p*-Values for testing if the two treatments have the same effect over the intervention period

Variable	Scale	<i>p</i> -values: test for effect of: treatment time		Intervention (A + B): mean ± standard deviation	
		(A vs. B)	(A + B)	Before	After
Malodor	VRS	0.862*	0.036*		
Exudation	VRS	0.728*	0.926*		
Malodor	VAS 0–10	0.551	0.007	2.3 ± 3.0	1.4 ± 2.1
Exudation	VAS 0–10	0.730	<0.0001	3.5 ± 2.7	1.9 ± 2.2
Wound pain	VAS 0–10	0.733	0.202	2.1 ± 2.1	1.8 ± 2.4

The first column displays the *p*-values for testing for changing between treatment groups. The second column displays the *p*-values for testing if there is a change over the intervention period at all when data from the two treatment groups are pooled together. The last two columns show mean and standard deviation before and after intervention for the pooled data containing both treatment groups A and B. Due to the low number of patients in each category for the variables measured on a verbal rating scale (VRS), the *p*-values marked with a * were computed by merging the groups “no + slight” and “moderate + strong.”

Wound size

The median decrease in wound size in Group A (honey-coated bandages) was 15 cm² compared with 8 cm² in Group B (silver-coated bandages). This difference was not statistically significant (*p* = 0.563). There was no significant reduction in wound size for all patients (*p* = 0.388) in spite of the fact that 62% of the patients experienced a decrease in wound size. Two wounds healed during the intervention period.

Wound cleanliness

The average kappa score of agreement by the observers (Light's kappa) was 0.52, indicating moderate strength of agreement.^{23,26} The effect on cleanliness seems superior for the honey-coated bandages (23 of 34 improved) compared with the silver-coated bandages (17 of 35 improved). However, the proportion of wounds with improved cleanliness during the intervention did not differ *between* treatment groups (*p* = 0.145). This is calculated to be 58.0% (40 of 69 patients), with a 95% confidence interval (46.3%, 69.6%) for all patients.

Malodor and exudation

There was no significant difference between groups for the malodor variable when using a VRS (*p* = 0.862). However, a slightly significant reduction over time was detected for all patients (*p* = 0.036) (see Table 3).

There was no difference in exudation between the groups when using the VRS (*p* = 0.728) and no significant change over time (*p* = 0.926).

No significant differences *between* the treatment groups were found for malodor, exudation, and wound pain as reported by the patients when using a VAS scale of 0–10 (see Table 3, column 1).

A significant change during the intervention period was found in both treatment groups for malodor (*p*-value = 0.007) and exudation (*p*-value < 0.0001).

Wound size and survival time

A strong association during the intervention was seen between wound size change and patient survival time. Patients with

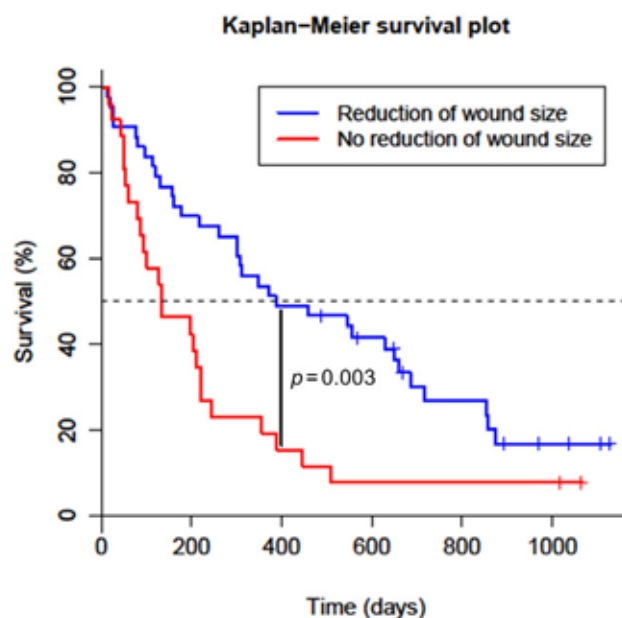


Figure 3. Kaplan–Meier survival plot. The figure shows the association between the change in wound size during the intervention period and survival time of the patients.

reduced wound size had a median survival time of 387 days compared with 134 days for patients with no reduction in wound size. The survival curves differed significantly (*p* = 0.003, log-rank test) (see Figure 3).

DISCUSSION

To our knowledge, the current RCT study is the first of its kind to describe the effects of using honey-coated bandages vs. silver-coated bandages on wound size, cleanliness, malodor, exudation, and wound pain in patients with MWs and advanced stage cancer.

Silver and honey for malignant wounds

Lund-Nielsen et al.

The strength of this study is its randomization and representation of a national cohort in which patients with MWs and advanced stage cancer are included from oncology departments from around Denmark.

The same wound care products were used throughout the 2.5-year data collection period, and procedures were carried out in the same manner by B.L.N. and the trained nurses under her supervision.

The weakness of this study is the absence of a control group. Our previous research (the pilot study)¹³ showed that women with MWs and breast cancer did not have professional help with their MWs but simply applied paper towels, handkerchiefs, sanitary napkins, and at best, gauze to their wounds. The 4-week wound care intervention for the pilot used carbon-silver dressings and was supplemented with psychosocial support. The pilot study therefore explored active treatment vs. "nonactive treatment." Following the intervention, nine wounds (75%) showed improvement with increased granulation and epithelialization and complete wound healing in one participant. Seepage was considerably reduced in 83% of cases, and there was an average 75% reduction in the number of bandage changes. As the results were promising, it was felt to be unethical to include a control group without active wound care/treatment in the current RCT study. In addition, developments since the pilot study led to the majority of the patients using modern bandaging (typically foam bandages, alginate, and gel) prior to joining the RCT study. It was therefore seen as irresponsible to allow a control group to be treated, e.g., with the use of paper towels or handkerchiefs.

Another drawback of the current study could be that the primary outcome was wound size. The scarcity of literature on healing MWs is probably due to the fact that healing MWs is an unrealistic goal due to the underlying cancer disease.¹ However, the most important issues for the patients with MWs include malodor, exudation, and cleanliness, and as such, we recommend that future research focus on these issues and not on wound size alone. These recommendations are in line with a recent publication on outcomes for wound healing and care.²⁷

Because MWs contain tumor tissue in the wound bed it is expected that the wounds will remain chronic, nonhealing, and lifelong for the majority of the patients. This is reflected by the association between wound size and survival time. We found that patients with reduced wound size had a median survival time of 387 days compared with 134 days for patients with no reduction in wound size. This indicates that when the MW worsens, there is a parallel worsening effect on the patient's overall health and survival status. Saeed et al. in 2004²⁸ informs that out of 77 patients with MWs, 66% died within the first 6 months and 75% died within the first 12 months following the appearance of the wound. MWs are associated with poor prognosis.

In the present study, two MWs *did* heal during the intervention period. The characteristics of these wounds were that they were superficial and small (2.44 cm² and 1.98 cm²). There was a larger amount of healthy tissue in the wounds, which allowed for administering concomitant antineoplastic therapy in combination with the optimal wound care procedure.

Despite the study's patient group members having advanced stage cancer, a wound size reduction for 62% of patients and improvement in wound cleanliness for 58% of patients were achieved when treated with honey-coated or

silver-coated bandages. Cleanliness evaluation by all four observers may have influenced not achieving the same level of improvement (75%) in the wound healing process as was done in the pilot study.

In the current study, the wounds that showed increased granulation tissue and vascularity had less necrosis, reduced malodor, and exudation. This result was further confirmed by the fact that both malodor and exudation were statistically significantly less following the intervention than at baseline in both treatments rated by the patients' VAS scores.

Malodor and exudation are described in the literature as debilitating problems that have consequences for the patient's general well-being, causing anxiety, depression, shame, affected sexuality, and social isolation.^{5,7} Because a positive result was achieved using honey-coated and silver-coated bandages, it can be expected that these treatments will increase patient well-being.

Honey-coated and silver-coated bandages used in chronic non-MWs have proven to be effective in combating malodor, exudation, and pain.²⁹ The current study confirms these findings with the exception of wound pain. Our study's less favorable results with wound pain can be explained by the fact that not only were the skin, tissue, and nerve paths affected (as is the case in nonmalignant chronic wounds), but the growing tumor tissue in MWs also affected the underlying tissue and organs. Furthermore, MWs are typically larger, deeper, and localized within a substantially larger diameter than other types of chronic wounds, which can add to increased pain burden. Furthermore, it can be difficult for patients to distinguish wound pain from other types of pain.

In this study, we could not show statistically significant differences in effect on the MW between use of honey-coated and silver-coated bandages. These bandage types were used following recommendations made by product companies. Honey-coated wound dressings, changed on a daily basis instead of every 2–3 days, should be tested for increased impact on MWs.

As honey-coated and silver-coated bandages showed effect on malodor and exudation, both treatments can be recommended in the care of MWs. The cost of using honey-coated or silver-coated bandages is comparable in Denmark. Silver-coated bandages are generally easy to handle, although they can cause discoloring due to the silver content and are difficult to rinse off. Honey-coated bandages smell of honey and are sticky to the touch. Patients and personnel should be prepared for these inconveniences. Honey-coated and silver-coated bandages can cause a slight stabbing pain for a 20- to 30-minute period following their application and primarily during the wound's stage of inflammation (the stage at which MWs seem to remain). Pain is triggered by the release of silver ions to the tissue when using silver-coated bandages. In the case of honey-coated bandages, pain is triggered by the acid content in the honey, which stimulates the nociceptors to pain response.^{30,31}

A drawback when using silver-coated bandages is that bacteria, e.g., *Enterobacter cloacae*,³² can become resistant, which has not been the case to date when using honey-coated bandages.³³ However, to ensure a low risk of resistant bacteria, it is recommended that the bandages are used only when MWs are at the stage of inflammation.

In conclusion, no difference was seen in the effect of using honey-coated and silver-coated bandages on MWs. In the current study, both treatments led to a reduction in wound size

in 62% of the patients and improved wound cleanliness in 58% of the patients. The study results should be seen as positive efforts to improve the cancer patient's well-being and quality of life. Honey-coated and silver-coated bandages are therefore recommended for use in the treatment of patients with MWs.

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FEATURE

IV

Qualitative Bacteriology in Malignant Wounds— A Prospective, Randomized, Clinical Study to Compare the Effect of Honey and Silver Dressings

Betina Lund-Nielsen, MHS; Lis Adamsen, PhD; Finn Gottrup, MD; Mikael Rorth, MD; Anders Tolver, PhD; and Hans Jorn Kolmos, MD

Abstract

Between 5% and 10% of cancer patients develop malignant wounds. *In vitro* and some clinical studies suggest that silver- or honey-coated dressings may have an antibacterial effect in nonmalignant wounds, but their possible antibacterial effect in malignant wounds remains unknown. A prospective, randomized, single-blind controlled clinical study was conducted to evaluate the bacteriology of malignant wounds and compare the effect of a honey-coated (Group A) to a silver-coated (Group B) dressing on the qualitative bacteriology of malignant wounds. All wound interventions were performed by the same healthcare professional. Swab cultures were obtained at baseline and following a 4-week intervention and were evaluated without information about the patient treatment group. Of the 75 patients with advanced cancer and malignant wounds identified, 67 (34 in group A, 33 in group B; median age 64 years, range 47–92) consented to participate and completed the 4-week study. The majority were women (88%) with breast cancer (79%). No statistically significant differences were found between the type and number of different wound pathogens in the wounds during the course of the study or between Group A and Group B. Neither anti-neoplastic nor antibiotic treatment influenced the presence of wound pathogens. *Staphylococci* were found in 42%, enteric bacteria in 34%, anaerobic bacteria in 16%, *Pseudomonas* in 10%, and hemolytic streptococci in 6% of wounds at baseline; in total, 25 different bacterial species were identified. Sixty-one percent (61%) of wounds decreased in size following treatment, but no significant differences were observed between the type and variety of wound pathogens and whether wound size decreased. Although quantitative bacteriological changes may have occurred, the possible antibacterial effect of the honey or silver dressing could not be confirmed in these malignant wounds. Routine wound swabbing of malignant wounds is of little value and should be restricted to cases where signs of infection requiring antibiotic intervention are observed or where resistant organisms require special infection control measures.

Key Words: randomized controlled study, malignant wound, cultures, honey-coated dressing, silver-coated dressing

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Potential Conflicts of Interest: none disclosed

An estimated 5% to 10% of all cancer patients develop malignant wounds.¹ The wounds that often occur in advanced stage cancer result from tumors that infiltrate the skin and underlying tissues.² The base of the malignant wound is characterized by the presence of necrotic and tumor tissue, slough, and fibrin, stimulating the growth of anaerobic bacteria that can produce odor and infection in the wound.^{3,4} Complete healing, as a rule, is not a realistic outcome in this

type of patient due to the presence of cancer tissue in the wound base.⁵

One could speculate that if dressings with antibacterial properties could reduce the growth of bacteria and resultant odor in the malignant wound, optimal healing could be facilitated. Both honey^{6,7} and silver dressings⁸ have shown antibacterial effects in other chronic wounds such as leg ulcers, but there is no evidence from randomized clinical trials (RCTs)⁹

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HONEY VERSUS SILVER IN MALIGNANT WOUNDS

about their effect on malignant wounds, and no controlled studies exist that compare the effect of silver-coated versus honey-coated dressings in chronic wounds.

The aim of this study is to compare the effect of honey-coated and silver-coated dressings on the qualitative bacteriology in malignant wounds.

Materials and Methods

Design. The investigation was part of a larger study (Lund-Nielsen et al. In press) designed to compare two dressing regimens over a 4-week intervention period in cancer patients with advanced disease and malignant wounds ($n = 75$). The Group A regimen consisted of a honey-coated primary dressing (Algivon/Activon Tulle UMF 12+ [AdvaNordic Medical Group A/S]) covered with an absorbent dressing (Sorbion/Drymax [Mediq Danmark A/S]) and foam dressings (Allevyn Adhesive [Smith & Nephew A/S]). The Group B regimen consisted of a silver-coated primary dressing (Acticoat/Acticoat Absorbent [Smith&Nephew A/S]) and a secondary foam dressing (Allevyn Adhesive [Smith&Nephew A/S]). Both treatment groups also received psychosocial support and relaxation training. The project was designed as a prospective, randomized clinical intervention study as well as an exploratory, qualitative, interview study (registered under the identification number NCT00435474 at www.clinicaltrials.gov). Approval was received from the Danish National Data Inspectorate (2006110013A). The study adheres to guidelines set by the Ethical Research Committee for Copenhagen and Frederiksberg municipalities ([KF] 01 2006-5491).

The primary goal was to investigate the extent to which honey-coated dressings, compared with silver-coated dressings, could reduce wound size. A secondary goal was to investigate whether the two types of dressings influenced the presence of potential wound pathogens that may increase the risk of wound infection in the malignant wound.

Participants. Seventy-five (75) consecutive patients with advanced stage cancer and malignant wounds were identified and recruited from oncology units in 10 hospitals in Denmark. Whether a wound could be characterized as a malignant wound was established through clinical signs, not through biopsies. The clinical diagnosis was presented as a nonhealing wound that developed through the growth of a tumor through the skin or occurred in connection with metastases.

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Key Points

- The purpose of this randomized, controlled clinical study was to compare the effect of honey-coated and silver-coated dressings on the qualitative bacteriology in malignant wounds in 67 patients.
- Almost all wounds contained at least one type of pathogen, and the qualitative bacteriological results did not differ over time or between the two types of dressings used.
- The authors conclude that swab cultures of malignant wounds should not be routinely performed and that the potential antibacterial effect of the dressings used could not be confirmed in this patient population.

Danish-speaking cancer patients were included in the study if they met the following criteria: 18 years of age or older, had malignant wounds and advanced stage cancer (metastases to the lungs, bones, liver, or cancer outside of the localized region of the tumor), a survival prognosis of >3 months, and had not received radiation therapy to the wound area for the past 3 months. Patients undergoing anti-neoplastic treatment (eg, chemotherapy, anti-hormone treatment) and/or systemic antibiotic treatment were included.

Three of the 75 patients identified did not want to participate in the study or wish to use a dressing. Baseline and

Table 1. Demographic and medical characteristics of study participants

	Group A: Manuka honey (n=34)	Group B: Silver dressing (n=33)	Total	P value
Age (year)				0.470
Median	65	60	64	
Range	5–86	47–90	47–90	
Gender				1.000
Female	30	29	59 (88%)	
Male	4	4	8 (12%)	
Cancer diagnosis				0.618
Breast	27	26	53 (79%)	
Head/neck	5	3	8 (12%)	
Others	2	4	6 (9%)	
Anti-neoplasm treatment				0.765
Yes	28	26	54 (81%)	
No	6	7	13 (19%)	
Antibiotic treatment				0.341
Yes	4	7	11 (16%)	
No	30	26	56 (84%)	
Wound duration (months)				0.980
Median	7.5	6.5	7	
Range	1–86	1–48	1–86	

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Table 2. Number of wound pathogen isolates at baseline and after 4 weeks

Groups of wound pathogens	Bacteria species	Number of wounds containing isolate				
		Group A: Manuka honey dressing n=34		Group B: Silver dressing n=33		
		Baseline	4 weeks	Baseline	4 weeks	
Anaerobic bacteria	<i>Bacteroides fragilis</i>	1	1	0	0	
	<i>Bacteroides</i> species	1	1	3	1	
	<i>Porphyromonas</i> species	1	1	2	1	
	<i>Prevotella</i> species	1	0	1	2	
	<i>Peptococcus</i> species	1	0	0	1	
	<i>Peptostreptococcus</i> species	0	1	0	0	
Enteric bacteria	<i>Escherichia coli</i>	4	3	2	1	
	<i>Enterobacter cloacae</i>	5	3	2	2	
	<i>Klebsiella oxytoca</i>	0	1	2	2	
	<i>Klebsiella pneumoniae</i>	1	3	0	0	
	<i>Morganella morganii</i>	0	0	1	0	
	<i>Proteus mirabilis</i>	0	1	0	1	
	<i>Proteus vulgaris</i>	0	1	2	0	
	<i>Enterococcus faecalis</i>	2	6	4	3	
	<i>Enterococcus faecium</i>	1	0	0	0	
	Pseudomonads	<i>Pseudomonas aeruginosa</i>	3	3	4	2
		<i>Pseudomonas</i> species	1	0	2	2
<i>Pseudomonas stutzeri</i>		0	0	1	0	
<i>Stenotrophomonas maltophilia</i>		1	1	3	2	
Hemolytic Streptococci	Hemolytic Streptococci group B	1	5	1	4	
	Hemolytic Streptococci group C	0	0	1	1	
	Hemolytic Streptococci group G	1	1	0	1	
Staphylococci	<i>Staphylococcus aureus</i>	15	16	13	14	
	<i>Staphylococcus lugdunensis</i>	0	0	1	0	
Other pathogens	<i>Pasteurella canis</i>	0	0	0	1	

follow-up data from another five patients was not available, three patients died during the intervention period, and the wounds of two patients healed during the intervention, leaving a sample of 67 cancer patients (see Table 1).

When participants had given consent, they were randomized to Group A (honey-coated dressing) or Group B (silver-coated dressing). The Clinical Research Unit (KFE) at Department of Oncology, Copenhagen University Hospital — Rigshospitalet administered the computer-based randomization process. Stratification was used for gender, cancer diagnosis (+/- breast cancer), and treatment (+/- anti-neoplastic treatment).

Intervention. Wound care was administered in the patient's home every 2 to 3 days. Each visit lasted approximately 90 minutes. The first author, together with the patient and/or the wound care nurse, administered the wound care: cleansing with tap water and liquid medicinal soap (pH factor 4.5), and continued with the aid of tweezers and nonwoven pads. Modern wound healing principles were used, including cleansing routines and moist wound healing with application of either honey or silver dressings in combination with foam dressings.

Clinical and bacteriological procedures. Qualitative wound swabbing was performed at baseline and after completing the 4-week intervention. Digital photographs were taken that showed the precise measurements of the wound in mm² using the software Quantify Image Central® (K:L:O:N:K. Denmark).¹⁰

Wounds were swabbed using a charcoal swab stick. The lab investigation was solely qualitative—ie, it involved registering the presence of the different species of wound pathogens irrespective of their concentration. First, the wound was cleansed, after which a charcoal swab stick was rotated 360° over the surface of the wound and in a representative area measuring 1 cm x 2 cm. The swabbed area then was documented so swabbing following the intervention would involve the same wound area as before the intervention. Once swabbing was completed, the swab stick was placed in Stuart's transport medium and sent directly to the laboratory, where the specimens were cultured on aerobic 5% blood agar plates, blue plates (modified Conradi-Drigalski), and anaerobic plates (chocolate agar with vitamin K and cystein). The blood plates then were incubated in 5% CO₂, blue plates in atmospheric air at 35° C, and anaerobic plates in an anaerobic cabinet at 37° C.

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Table 3. Number of wounds containing isolates by major group and concomitant treatment

Groups of wound pathogens	Treatment		Antibiotic		Anti-neoplasm	
	Honey (n=34)	Silver (n=33)	Yes (n=11)	No (n=56)	Yes (n=54)	No (n=13)
Anaerobic bacteria						
Baseline	5	6	1	10	9	2
After 4 weeks	4	5	0	9	8	1
Enteric bacteria						
Baseline	11	12	6	17	19	4
After 4 weeks	15	9	6	18	19	5
Hemolytic <i>Streptococci</i>						
Baseline	2	2	0	4	1	3
After 4 weeks	6	6	1	11	7	5
<i>Pseudomonas</i>						
Baseline	3	4	1	6	5	2
After 4 weeks	3	2	1	4	4	1
<i>Staphylococci</i>						
Baseline	15	13	4	24	21	7
After 4 weeks	16	14	3	27	23	7

Table 4. Distribution of patients by number of wound pathogens and treatment at baseline and after 4 weeks

Number of wound pathogens	Baseline		Week 4	
	Honey (n=34)	Silver (n=33)	Honey (n=34)	Silver (n=33)
0	2	0	2	3
1	16	13	12	15
2	10	15	10	13
3	3	3	7	1
4	3	2	3	1

Readings for the bacteria were performed 2 days following lab procedures. The primary purpose of the lab findings was to ascertain the presence of hemolytic *Streptococci*, *Staphylococci*, *Pseudomonas*, enteric bacteria, and anaerobic bacteria, and whether any of them were multidrug resistant—eg, methicillin-resistant *Staphylococcus aureus* (MRSA) (see Table 2). Identification and susceptibility testing were performed by routine methods used by the laboratory. All laboratory analyses were performed without indication of patient treatment group.

Primary data analysis and statistics. A power calculation in a two-sided significance test showed that 70 patients should be included in order to prove a 20% difference between the two treatments for the primary study purpose concerning

wound size. Mann-Whitney U tests and Fisher's exact tests were used to compare the baseline characteristics of the treatment groups before the intervention. Binary outcomes measuring the prevalence of various bacterial groups were analyzed using a logistic regression model with treatment group and time (before/after completing of the intervention) as explanatory variables. A treatment effect during the intervention period corresponded to an interaction between treatment and time. Test for changes in the prevalence of a bacterial group corresponded with a main effect of time. A procedure for logistic regression was used, taking into account the within-subject correlation among samples from the same patient¹¹ as well as a Stuart-Maxwell test for marginal homogeneity to test for changes in the matched-pairs data recording the number of bacterial species present in each wound before and after intervention.¹² Finally, Fisher's exact test was used to explore if wound microbiology post-intervention depended on whether wound size decreased during the intervention

period. All *P* values were evaluated at a 5% significance level after a Bonferroni correction for multiple testing. The statistical analyses were made using *R: A Language and Environment for Statistical Computing*, version 2.10.1.¹³

Results

The median age of the 67 patients was 64 years (range: 47–90 years). The majority of participants (88%) were women, 79% had breast cancer, 81% were undergoing anti-neoplastic treatment with chemotherapy or anti-hormone treatment, and 16% were undergoing systemic antibiotic treatment. The median wound duration before intervention was 7 months (range 1–86). Baseline characteristics were similar in both groups.

No wound pathogens were found at the intervention baseline in two malignant wounds. The remainder showed colonization with one to four different wound pathogens (median = 2). At baseline, 25 different species in total were detected (see Table 2); *S. aureus* was the most prevalent species (found in 42% of wounds). None of the isolates was MRSA. Enteric bacteria were cultured in 34%, *Pseudomonas* in 10%, and hemolytic streptococci was detected in 16% at baseline. In 69% of wounds, the same species were found before and after the intervention.

The distribution of wound pathogens was the same in both wound dressing groups, both at baseline and after 4 weeks (see Table 3). Similarly, the distribution of pathogens did not differ between patients who did and did not receive antibiotic (eg, metronidazol, doxycycline) or anti-neoplastic treatment (eg, chemotherapy, anti-hormone-treatment).

FEATURE

Table 5. Distribution of wound pathogen presence by treatment and wound size reduction after 4 weeks

Wound pathogen present at week 4	Group A: Manuka honey Wound size reduction		Group B: Silver dressings Wound size reduction	
	Yes	No	Yes	No
	(n=23)	(n=11)	(n=18)	(n=15)
Anaerobic bacteria	4 (17%)	0 (0%)	2 (11%)	3 (20%)
Enteric bacteria	11 (48%)	4 (36%)	5 (28%)	4 (27%)
Hemolytic <i>Streptococci</i>	5 (22%)	1 (9%)	2 (11%)	4 (27%)
<i>Pseudomonas</i>	1 (4%)	3 (27%)	0 (0%)*	5 (33%)*
<i>Staphylococci</i>	12 (52%)	4 (36%)	6 (33%)	8 (53%)

* $P = 0.013$ for comparing the prevalence of *Pseudomonas* in Group B

Table 6. Distribution of patients by number of wound pathogens, treatment group, and wound size reduction after 4 weeks

Number of wound pathogens	Group A: Manuka honey Wound size reduction		Group B: Silver dressing Wound size reduction	
	Yes	No	Yes	No
	(n=23)	(n=11)	(n=18)	(n=15)
0	2	0	3	0
1	7	5	10	5
2	5	5	5	8
3	6	1	0	1
4	3	0	0	1

At baseline, no significant difference was found between the two treatment groups in number of species ($P = 0.54$) (see Table 4). Only two patients had no wound pathogens at baseline. The majority of patients (54) had one or two wound pathogens. Overall, a Stuart-Maxwell test for marginal homogeneity between the matched number of species before and after intervention for individual patients revealed no significant change for either of the treatment groups (honey: $P = 0.60$, silver: $P = 0.26$).

Median change of wound size was -15 cm^2 (range -221 to 160) for the honey group and -3 cm^2 (range -67 to 679) for the silver group. Wound size reduction was documented for 23 (67%) wounds in the honey and 18 (54%) wounds in the silver dressing group (see Table 5).

No significant differences between wounds that did or did not reduce in size and the prevalence of a particular group of wound pathogens after the 4-week intervention could be demonstrated. *Pseudomonas* had a tendency to be found less often in wounds that decreased in size ($P = 0.089$ and $P = 0.013$ for honey and silver dressings, respectively).

The presence or absence of decreased wound size after 4 weeks also did not significantly affect wounds with zero, one, two, three, or four different bacterial species (see Table 6) in

either the honey ($P = 0.318$) or silver ($P = 0.084$) dressing group.

Discussion

To the authors' knowledge, the current investigation is the first randomized study that compares the effect of honey-coated versus silver-coated dressings on bacteriology in malignant wounds in patients with advanced-stage cancer. No statistically significant difference was found in wound pathogen distributions over time or between the honey and silver dressing group. Neither anti-neoplastic nor antibiotic treatment influenced the occurrence of wound pathogens. No significant association between a reduction in wound size and prevalence of a particular group of wound pathogens after intervention could be demonstrated.

The wounds showed colonization with one to four different wound pathogens (median = 2). *Staphylococci* were found in 42%, enteric bacteria in 34%, and *Pseudomonas* in 10% of wounds. In total, 25 different species were identified.

A clinical study¹⁴ that included seven patients with venous ulcers found that silver-released dressings contributed to wound bed preparation, but did not attain a germ-free status. In their review, Fong and Wood¹⁵ indicated that nanocrystalline silver dressing is an effective antimicrobial for treating chronic wounds. In his review of 17 RCTs involving 1,965 patients treated with honey and 16 trials involving 533 wounds on experimental animals, Molan¹⁶ showed that honey's antibacterial activity clears infection and protects wounds from becoming infected. However, in the current study, researchers did not observe an effect of these dressings on wound microbiology in malignant wounds. Contrary to other chronic wounds, malignant wounds are under the continuous influence of the cancer's general progressive character and possible effects of the systemic treatment. This can lead to continuous tissue deterioration with a large volume of necrosis and slough. In the current study, culture results suggest that anti-neoplastic treatment with, for example, chemotherapy and anti-hormone treatment may not change these circumstances. As such, the wound pathogens have optimal growth conditions, and a continuous colonization of malignant wounds should be expected. This is also reflected in the results—97% of the wounds in the present study were colonized with between one and four species of wound pathogens (median = 2).

Mainly *in vitro* studies¹⁷⁻²⁰ have demonstrated that honey-coated and silver-coated dressings have an antibacterial effect against *Staphylococci*, enteric bacteria, and *Pseudomonas*. An RCT by Gethins²¹ ($n = 108$) that compared the effect of

HONEY VERSUS SILVER IN MALIGNANT WOUNDS

honey-coated dressings and hydrogel on bacteriology in chronic leg ulcers showed that Manuka honey was effective in eliminating MRSA from 70% of 16 leg ulcers infected with MRSA, and that *S. aureus* was the most common species present (38%). In a clinical study of 86 patients with traumatic and nonhealing wounds, Ziegler et al²² found that silver had antimicrobial activity against *Staphylococci*, MRSA, *Pseudomonas*, and *Klebsiella pneumoniae*.

The current study found no statistically significant difference in bacteriology between the two treatment groups, nor was a difference detected in the number and variety of species when comparing baseline to 4-week intervention culture results. *S. aureus* was the most prevalent species (found in 42% of wounds). No MRSA was detected, probably a reflection of its low presence in the authors' country.²³

Antibiotic treatment had no influence on the prevalence of the five groups of wound pathogens; in 69% of the wounds, the same species were found before and after the intervention period. Optimal effect of systematic antibiotic treatment requires vital and well-vascularized tissue. Most likely, the burden of tumor in the wound compromises vascularization, thereby reducing the effect of antibiotics.

Some of the authors' cancer patients receive antibiotics (eg, metronidazol, doxycycline) regularly in order to diminish the odor from the wound. Other of their patients receive antibiotics based on positive swab results, with no obvious signs of clinical infection (increase in temperature, redness and swelling of the tissue, pain, increased exudation). In the current study, 97% of the wounds were colonized with at least one type of wound pathogen. Extrapolating from that finding, swabbing from the malignant wound will in most cases show a series of wound pathogens that do not necessarily affect the wound or the patient's condition. Therefore, taking qualitative swabs from malignant wounds is not indicated unless clinical signs of infection are present or if MRSA is suspected. Further, current study results suggest that antibiotic treatment has little impact on the presence of bacteria in the malignant wounds and that assessing bacterial flora is not a suitable means of monitoring the clinical effect of treatment. Although the purpose of this study was not to evaluate healing outcomes, it is important to note that, with the possible exception of *Pseudomonas*, the proportion of wounds that did or did not exhibit a reduction in wound size did not appear to be effected by the number and type of bacteria present at the end of the intervention period.

FEATURE

Study strengths include randomization, single-blind (laboratory) analysis, and participation of a national cohort of patients from all oncology units in Denmark and representative of patients with malignant wounds. In addition, the same person performed the swabbing using established guidelines before and after completing the intervention throughout the entire data collection period, eliminating variegation in methods. The same type and brand wound care products were used throughout the entire study period, and procedures were performed in the same way by the first author and the trained wound care nurses she supervised.

Limitations

Limitations of the study include its small size and the fact that there was no untreated control group. The authors' pilot study² (n = 12) investigated the effect of silver-coated dressings versus no treatment in breast cancer wounds. Nine cancer wounds (75%) showed improvement using silver-coated dressings. Because post-intervention results were promising, including an untreated control arm in subsequent studies was considered unethical. Similarly, although regular routine swabbing techniques provide qualitative data only, a quantitative culture technique that would have provided more details was considered too invasive for this group of patients.

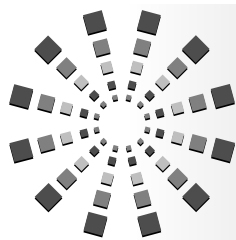
In a practice guideline, Dow²⁴ describes swab cultures as able to reliably detect bacteria in chronic wounds. Pellizzer et al,²⁵ comparing deep tissue biopsy to superficial swab culture monitoring techniques to assess diabetic foot infections, noted no statistical differences between the two procedures in detecting bacteria. In that study, the mean number of isolates per patient was 2.34 using swabbing and 2.07 by tissue biopsy. As such, swabs provided a reliable assessment of wound pathogens present, which can be interpreted as a relevant measure of the effect of the intervention. The method was advantageous in that it complies with the routine used in most microbiological laboratories, and as such the results directly correlate with clinical practice.

Conclusion

Malignant wounds are chronic wounds in which the progressive nature of cancer causes the production of tumor tissue, necrosis, and slough in the wound that triggers chronic colonization with wound pathogens. In this study, honey-coated or silver-coated dressings had no effect on the qualitative bacteriology of malignant wounds, and use of antibiotic or anti-neoplastic treatment did not affect culture results. Culture results also did not differ between wounds that did or did not reduce in wound size, suggesting that routine qualitative wound swabbing of malignant wounds is of little value. Swabbing malignant wounds may be restricted to cases with signs of infection requiring intervention with antibiotics or when the presence of MRSA or other antimicrobial-resistant organisms is suspected, and special infection control restrictions may be needed. ■

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An Avalanche of Ignoring—A Qualitative Study of Health Care Avoidance in Women With Malignant Breast Cancer Wounds

KEY WORDS

Breast cancer
Cancer wounds
Caregiver burden
Health care avoidance in oncology
Interview
Malignant wounds
Phenomenology
Qualitative

Background: A contributing factor to development of malignant wounds is patient-related delay caused by health care avoidance. **Objective:** The purpose of this study was to describe the experience of health care avoidance in women with advanced breast cancer who have developed malignant wounds. **Methods:** A qualitative study was conducted based on semistructured interviews. Seventeen women with advanced breast cancer (median age, 69 years; range, 47–90 years) who had avoided medical treatment despite development of malignant wounds participated. Systematic text-condensation analysis was used. **Results:** The women deliberately avoided health care for a median of 24 months (minimum, 3 months; maximum, 84 months). Despite being aware of the development of a malignant wound from a breast lump, the women avoided health care because of negative health care experiences and extremely burdening life situations. The women did not seek health care until their situations became unmanageable. The essence—“an avalanche of ignoring”—is pointing to the escalating, powerful development of destructive feelings behind health care avoidance. **Conclusions:** Health care avoidance may be a way of coping both for women who are primary and/or bereaved caregivers. Oncologists and nurses may contribute to the prevention

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hereof by means of information about the early signs of cancer, benefits of early diagnosis and treatment, and by paying special attention to these women, who may be at high risk for avoidant behaviors. **Implications for Practice:** In a preventive perspective, it seems advantageous to bring into focus the health of primary and bereaved caregivers, thereby potentially reducing patient delay and ultimately improving survival.

The incidence of malignant wounds in cancer is 5% to 10%;¹ of those cases, 62% are women with breast cancer.² Malignant wounds occur when an underlying localized tumor erodes the skin or infiltrates blood capillaries and lymph vessels, or they result from cutaneous metastatic growths from a primary tumor.³ Malignant wounds are often seen in advanced disease and can have physiological and psychosocial consequences,⁴ including seepage,⁵ malodor,^{6,7} bleeding,² pain,⁸ infection,⁹ altered body image,¹⁰ loss of femininity, and sexuality and social isolation, which pose substantial limits on the individual's everyday life and her social relations.³

A contributing factor to the development of malignant wounds is patient-related treatment delay, which is defined as the time from when the patient discovers the cancer symptoms to first contact with a doctor.^{11,12} A meta-analysis by Richards et al¹³ comprising 87 papers estimates that 20% to 30% of women wait a minimum of 3 months before contacting a doctor after they experience breast cancer symptoms and that approximately 25% delayed their initial visit to the doctor by 6 months. The 5-year survival rate declines 12% to 19% with 3 months' delay in treatment.¹³ Survival of cancer patients after development of cutaneous metastases is shown to be 11 months.¹⁴ Prolonged delay may result in the development of malignant wounds, advanced disease, and poor prognoses.¹⁵

Facione et al¹⁶ described the rationale behind patient-related delay (>3 months) as being complex and multifaceted and influenced by a broad range of personal, psychological, social, and cultural aspects. One major factor could be health care avoidance. The term *health care avoidance* is not an unambiguous or well-determined construct or concept relating to a single theory or discipline. In this paper, health care avoidance is used to describe a phenomenon whereby an individual deliberately postpones medical treatment indefinitely. The phenomenon is defined by Byrne^{17(pp291)} as a multidimensional coping mechanism utilized by individuals in response to perceived health care threat. The concept is linked to the more general term *avoidance behavior*, which in the psychiatric literature is defined by a conscious or unconscious defense mechanism by which a person tries to escape from unpleasant situations or feelings such as anxiety and pain.¹⁸ According to Bandura,¹⁹ stimuli that signal unfavorable consequences are fear inducing and lead to conditioning of emotional and instrumental avoidance behavior. In the psychiatric literature, avoidance behavior is relatively well described in relation to bereavement and depression.²⁰

An ongoing randomized clinical intervention study and an explorative qualitative interview study that is being conducted

estimate the effect of silver- versus honey-based wound treatment, in combination with psychosocial support based on cognitive therapy and relaxation training in cancer patients with malignant wounds (n = 75). During the study, it became evident that some women with breast cancer had kept their wounds covert and had omitted to seek medical treatment for several months and often years. However, no studies were identified that offered a comprehensive, in-depth exploration of health care avoidance that could contribute to an understanding of this complex phenomenon.²¹

The purpose of the present qualitative study was to describe the experience of health care avoidance in women with advanced breast cancer who have developed malignant wounds. The intention was to describe the phenomenon of health care avoidance as experienced by breast cancer patients themselves, in their natural context.²¹

■ Methodology

Design

The study was developed and conducted using a descriptive phenomenological approach including a semistructured in-depth interviewing technique.

Ethical Considerations

Approval was obtained from the National Data Inspectorate (2006110013A). The study adhered to guidelines set by the Ethical Research Committee for Copenhagen and Frederiksberg municipalities ([KF] 01 2006-5491).

Sampling

Participants were selected by means of purposeful sampling involving identification of information-rich cases for in-depth study.²² In accordance with the study's purpose; participants who had substantial experience with advanced breast cancer and neglect of malignant breast cancer wounds were selected. For this purpose, a combination of critical case and criterion sampling was used, involving the strategic selection of information-rich cases that intensely rather than extremely or unusually manifest the phenomenon.²³ The following criteria were applied: the participant must have (1) a malignant breast cancer wound and (2) deferred seeking medical treatment.

Recruitment

Participants were recruited for interviewing at the same time they were included in the primary above-mentioned randomized study. Health personnel referred them from all 10 oncology centers in Denmark. The author’s first contact with the woman was by telephone, to determine whether she met the inclusion criteria. If she did, information about the interview study was forwarded to the woman, who was given a week to decide about being in the study, and then she was contacted by telephone. If she agreed to participate, a time and setting for an in-depth interview were arranged.

In-depth Individual Interviews

The interviews explored the experience of health care avoidance in women with advanced breast cancer and malignant wounds who had omitted to seek medical treatment. Experience can be defined as immediate, prereflective of actual events and facts, and the anticipated regarding self and surroundings.²⁴ An interview guide covering different time periods and focus areas was used to structure the interview (Table 1).

The initial interview guide was based on findings from own previous research on the feminine and sexual perspectives on breast cancer wounds.³ The themes involved questions in regard to physiological factors, the development of the wound and experiences with wound care products, the wound’s influence on everyday living, and emotions and feelings while with other people. The initial interview guide was tested in 2 participants, on the basis of which we decided to include questions in regard to stressful live events and caregiver responsibilities. The aim of the interview was to obtain all the information required, while at the same time give respondents an opportunity to provide rich, detailed information about the phenomenon under study.²⁵ The interviews were tape-recorded, and the average duration was 70 minutes (minimum, 30 minutes; maximum, 180 minutes).

Analysis

All interviews were conducted by the first author and transcribed in full using the Microsoft Word application. During transcription, care was taken to transfer contextual annotations (ie, emphasized words, use of capital letters, symbols, etc). A data-driven analytical format, described by Crabtree and Miller²⁶ as editing analysis style, was applied. Furthermore, investigator triangulation was applied to minimize bias.²⁶ A data-driven, 4-step analysis, based on the phenomenological philosophy recommended by Giorgi²⁷ and modified by Malterud,²⁸ was applied. The first step in the analytical process aimed at obtaining a general and comprehensive sense of the information gathered. This was ensured by each of the investigators responsible for the analysis (the first and second authors) listening to the interviews and then reading through each interview transcript several times. Once we each had a sense of the whole, the next task was to discriminate what Giorgi²⁷ calls “meaning units,” which are understood as different units or blocks that express a self-contained meaning. This was ensured by carefully searching for the different key terms, aspects, attitudes, or values that highlighted the interviewees’ lived experiences. The next step involved relating each of these meaning units to the specific research question under study (ie, lived experiences of health care avoidance in women with breast cancer who have developed malignant wounds) and assembling them into especially revealing categories. At this point in the analysis, the investigators met several times to discuss the meaning of each of these categories and to rewrite, transform, and condense them further into a more psychological language. The final step involved summarizing the sense of each category into a single general analysis, which integrated and synthesized the transformed meaning units to describe the common and essential aspects of the studied phenomenon—referred to as the “essence.” In this last step of the analysis, the investigators began the process of free imaginative variation, “whereby aspects of the concrete

 **Table 1 • Interview Guide Shows Different Periods and Focus Areas**

Sequence and Focus Areas	Sample Questions
Initiation of health care avoidance: discovery and awareness of preliminary symptoms	What characterized your daily life during the period prior to becoming aware of breast changes? What was the most important thing in your life at that time? When and how did you first become aware of your breast changes? What went through your mind? What did you do?
Continuation of health care avoidance: development of malignant wound	How did the breast changes develop? How did you come to terms with the breast changes (the wound)? How did you feel about looking at the wound? Who in your family/social circle knew about your wound? Did you consider seeing a doctor about it?
Termination of health care avoidance: seeking medical assistance	When did you become aware that the wound might be associated with breast cancer? What or who changed your mind about seeking medical assistance? How would you describe the doctor’s reaction? How has your life changed since you started treatment? What is the most important thing in your life today?

phenomenon are varied until its essential or invariant characteristics show themselves.”^{29(pp206)} Giorgi:²⁷ suggested that essence could be defined as the most invariant and unchangeable characteristics of the particular phenomenon under study. Discussion and adjustment of the essence were carried out in continuous collaboration between the investigators and continued until unanimity could be attained.

Findings

Participants

Seventeen participants with malignant breast cancer wounds who had omitted to seek medical treatment were interviewed at home. Demographic and medical characteristics of the women are displayed in Table 2. The women’s median age was 69 years (range, 47–90 years). Most of the women (n = 15) were alone and not any longer in work (n = 14). They had all advanced disease and were inoperable. Time since development of the malignant wound was at a median of 24 months (range, 3–84 months). We classified the wounds in 4 categories according to localization, exudation, malodor, bleeding, and wound pain. Photographs 1 to 4, taken at the time of the patient interviews, provide graphic wound characteristics (Table 2).

Phenomenological Analysis

The analysis process, as shown in Table 3, resulted in several meaning units related to the different periods and focus areas in the interview guide (Table 1). These meaning units were recaptured and condensed further into 3 major categories: disbelief, shame, and relief, which collectively reflected the sequential course of the participants’ experiences. The 3 categories were further condensed into the expression “an avalanche of ignoring,” which is presented as the universal, invariant essence of the phenomenon health care avoidance.

INITIATION OF HEALTH CARE AVOIDANCE: DISBELIEF

The women in the study could all describe specifically (according to a date or an event) when and how they first noticed changed in their breast (ie, a lump, nipple discharge, a wound). They informed that initially they deliberately decided to put the experience to the side and ignore the changes. This was triggered by parallel experiences of extreme emotional and social strain imposed on them by highly demanding external factors. Fourteen of participants reported that, during the period, when they experienced breast changes, they were the primary caregivers for family members (partners, parents, siblings) with terminal disease (among them 7 cases of cancer) and approaching death. A 69-year-old woman with a 24-month wound duration and a wound type 4 explains: “If I had lied down to sleep at night and not woken up again, it would have been a relief because my [sick] siblings were such a burden for me. I had no time to look after myself. I was alone. I was forced to take responsibility because there was no one else.”

Table 2 • Demographic, Medical, and Wound Characteristics of the Participants



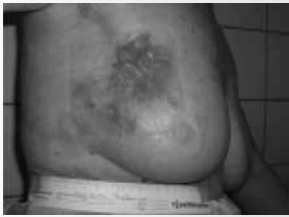

Patients (n = 17)	Median Value
Age	69 y (range, 47–90 y)
Time since development of the malignant wound (symptom awareness)	24 mo (range, 3–84 mo)
Frequency (n)	
Duration of health care avoidance, ^a mo	
3–12	7
13–24	6
25–48	2
49–84	2
Stage of the disease	
Advanced breast cancer (stage IV) with metastases to	
Bones	3
Lung	3
Lung + bone	3
Lung + liver + bone	1
Skin metastases outside local area	6
Skin and + lymph metastases on the neck	1
Inoperable	17
Marital status	
Married	2
Widowed	11
Single	3
Divorced	1
Education	
None (no education after grade school)	8
Short (<3 y, ie, completion of high school)	7
Middle-range training (3–5 y, ie, completion of college degree)	2
Long (>6 y, ie, completion of university degree)	0
Current work status	
Sick leave	3
Early retirement pension	2
Retired	12
Wound characteristics	5
	
Type 1: The affected breast is eroded. Superficial wound with moderate tendency for exudation, malodor, and wound pain	3
	
Type 2: The wound affects the sternum. Moderate tendency to produce scab and malodor and to bleed	

Table 2 • Demographic, Medical, and Wound Characteristics of the Participants, continued

Patients (n = 17)	Median Value
	4
<p>Type 3: The wound is located in the breast. The skin around the wound appears red or peau d'orange. Superficial wound with low tendency for exudation and malodor</p>	
	5
<p>Type 4: Malignant fungating wound with high tendency for exudation, pain, infection, and an overwhelming malodor</p>	

^aSelf-reported time from development of the wound on the skin's surface to when medical assistance was sought.

A minor fraction of the participants (n = 3) informed of experiencing a conjunction of at least 3 of the following major stressful life events: divorce, being a single parent, moving residence, home renovation, fighting economical problems, running own business, and/or a new demanding job. A 50-year-old woman with a 9-month wound duration and a wound type 4 explains: "I got a new job that was more important for me than the illness, since we were reliant on the money. I chose not to go to the doctor right away and knew that it would get worse. But I thought that I could handle it."

A common factor was the experience of being alone with overwhelming responsibility and lack of resources. The women felt powerless and simultaneously obliged to continue to try to master their respective life situations. The women shared the feeling that seeking medical assistance presupposes surplus energy, which they neither had nor were willing to mobilize at that time. Although they suspected that they might be having cancer, they did not feel ill and as such justified to themselves that initially they reluctantly but deliberately chose to avoid health care. This conscious neglect of their symptoms was furthermore founded on their fear and anxiety of receiving a cancer diagnosis and having to undergo treatment. The women informed that they did not believe that the cancer treatment could help them. A 68-year-old woman, with a 42-month wound duration and a wound type 3 explains: "I saw my sisters go to the doctor for the same thing, and they

all had operations, but it spread anyway later on. I thought that if I could avoid having the operation, I would be better off. So, I guess that I made a bit of a conscious decision not to go to the doctor because I couldn't let go of those other stories. I was the one who actually looked after them [sisters] while they were dying."

As a consequence of the grief and confusion of having lost a close relative following a long-term hospitalization, these women were convinced that "when you go to the doctor, you become sick and die," which prevented them from seeking medical assistance until their faith was restored.

CONTINUATION OF HEALTH CARE AVOIDANCE: SHAME

The cancer disease deteriorates, and the breast lump develops into malignant wounds. The women informed that they originally intended to seek medical assistance for their cancer wound but that this could not happen before their commitments and responsibilities as primary caregivers and/or lone supporter or self-employed allowed it. While their cancer wound advanced and the disease became more pronounced, the women had a sense of shame and blame that reinforced their avoidance behavior. A 55-year-old woman with a 12-month wound duration and a wound type 1 explains: "I must admit that I was ashamed. And that probably influenced why I let it drag out. It kept getting worse and uglier to look at, and I did try to tell myself that if I went to the doctor now, it would look better than if I waited another 2 months—so do it! The shame came from the fact that if one was an intelligent, logical person, one would seek medical attention."

Developing a breast cancer wound contributed in itself to the women's belief that they might have surpassed any possibility that medical assistance could help. As such, they felt trapped in the secret that they could not share. The participants informed that the wound under all circumstances should be concealed. A 47-year-old woman with a 12-month wound duration and a wound type 1 explains: "No one knew about it. Of course, it was difficult to be alone with the problem, but as soon as you reveal it... I drove 580 km/h and was so pleased with my job and my new house. I'm a nurse, so I knew how to look after it [the wound]. I used a little cotton wool, handkerchiefs, etc, that I stuffed into my bra—and it felt hidden and out of my mind, and this allowed me to keep going."

The women tried to disassociate themselves from their bodies. They reported that during that period they experienced discomfort when looking in the mirror and worried about odor and wound bleeding that threatened to reveal their secret. The cancer-related pain, weight loss, and vomiting were ignored and played down despite the women's increasing weakness. As a consequence of their persistent secrecy, the women lived with extreme loneliness and dismissal that heightened their lack of resources and led them into depression, with no hope or comfort. A 60-year-old woman with 60-month wound duration explains: "I had to keep away from all of those whom I cared about. I had to build a wall around myself so that they didn't suspect anything. But they knew I was sick. I kept saying that I was not sick, and despite that, I

 **Table 3 • Analysis Process^a**

Sequence and Focus Area	Meaning Units (Selected)	Categories	Essence
Initiation of health care avoidance: discovery and awareness of preliminary symptoms	Overwhelming responsibility Total lack of resources Obligated to laying own needs to the side When you go to the doctor, you get sick, and die Others are more important than I Didn't have the time It wouldn't matter Used to take care of myself and handle my own problems Forced to ignore it Couldn't handle going through treatment In deep mourning	Disbelief	An avalanche of ignoring
Continuation of health care avoidance: development of malignant wound	Thought I could handle it Feeling ashamed Beyond point of no return Complete loneliness Hiding the wound Keeping the wound out of my mind Necessary to keep it a secret No one was to know Own responsibility Own decision Isolation No choice left	Shame	
Termination of health care avoidance: seeking medical assistance	Not my choice People finally noticed Didn't dare to look at it Feeling pain Breathlessness Bleeding Completely open about it Appreciation New focus Hope to get better The doctor was very helpful	Relief	

^aDivided in 4 steps: (1) focus area, (2) the abstracted meaning units, (3) the content of the categories, and (4) the essence of the phenomenon.

went to the garage and vomit because I didn't want them to see. I felt like a hunted animal. It was really hard.”

TERMINATION OF HEALTH CARE AVOIDANCE: RELIEF

As a consequence of metastasis from the advanced cancer, for example, breathing problems, spontaneous bone fractures, and/or disabling mobility, the women could no longer hide their cancer wound. This changed their avoidance behavior and forced them to seek medical assistance. A 60-year-old woman with a 60-month wound duration and a wound type 3 explains: “The wound was first noticed when I had water in my lungs and couldn't breathe. When I couldn't take it any more, I let my son drive me to the hospital. I had lost 20 kg, and I vomited constantly. My children said that there was a strange smell around me. But I didn't bathe either because I dared not look at myself. I just put some cotton wool over it

and kept changing this—it was a mess.” The participants reported that up to that point they neither understood nor believed that they required medical care. Another woman, 76 years old, with 84-month wound duration and a wound type 1 explains: “I first sought medical assistance for the wound when I couldn't stop the bleeding. It forced me to go to the hospital. I just couldn't breathe.”

After the women sought medical attention, they experienced a full sharing of responsibility and total relief. They were grateful to finally reveal their secret and be relieved of the need to hide their illness. The women expressed a sense of renewed hope and faith that they could be helped and were prepared to collaborate with the treatment process. A 47-year-old woman with a 12-month wound duration and a wound type 1 explains: “My thoughts about the future are to concentrate on happiness, life, and coming out into the fresh air and to do things that I have neglected until now—planning trips perhaps. I'll start moving

on this as soon as I get better.” The women optimistically embraced the care they received and appreciated the opportunity to share control and responsibility over their bodies and lives. The women reported that at that point they desired full openness about their situation and needed to talk about the cancer disease and to show their wound to others. A 60-year-old woman with a 60-month wound duration and a wound type 3 explains: “Now we speak about it a lot with family and friends. Earlier on, it was very important to keep it a secret, but since it was discovered, it is important to speak openly about it. I don’t hide the fact that I didn’t bathe and that I had a few glasses too many of wine and gin—that came along with it all. It was great to come out of that deep secret place into the open—it was like being born again. It’s a total relief. There was nothing more to hide—and since then I really enjoy every day”. However, the women maintained that the initial secrecy was necessary and justified.

Essence: An Avalanche of Ignoring

The essence of the descriptions of the study participants’ lived experiences of health care avoidance may be summarized with reference to the overriding concept, an avalanche of ignoring. This constitutes and symbolizes the fundamental and common characteristics of understanding why and how women with advanced breast cancer, who have developed malignant wounds, have avoided health care. In the search for the essence of the phenomenon, we were especially interested in capturing the dynamics of what constituted the women’s descriptions of their feelings. Essential to the women’s experiences is that the avoidance of health care was something that developed and gained strength over time and which—as it gained strength—became more and more unstoppable and destructive. Moreover, and central to the women’s experiences, was that they felt forced to ignore the changes until it was suddenly too late and the damages were too many and too insurmountable. What started out as a minor alteration turned out—because of continued ignoring—a disaster that crashed and ended only when ignoring was no longer an option. Thus, health care avoidance may be understood as an escalating, uncontrollable, and capturing and powerful destructive process of ignoring. The process is initiated by disbelief related to negative experiences with the health care system and concurrent experiences of extreme burden in daily life.

Discussion

Insight was gained into this complex phenomenon, which may be interpreted as an escalating destructive process initiated by feelings of disbelief, which over time led to feelings of shame, thus reinforcing inability to take action. The term *avoidance*, as used in this study, is understood as a deliberate and conscious action anchored in the experience of powerlessness, lacking resources, fear of cancer diagnosis, and lack of belief that cancer treatment is beneficial. It is a complex and multifaceted phenomenon and cannot be explained by a single theory or in a cause-effect context.

The term *delay* is often used in combination with avoidance, the latter may be described as the act of keeping away from something that is thought to cause mental or physical distress.^{17,30} In this sense, it may be argued that the women saw health care as a threat. To better understand this concept, it is important to note that the women in this study admitted that at the time when they became aware of their breast change they experienced distress due to an extremely burdening life situation characterized by high responsibility and/or feelings of loss and despair. It is possible that most of the women may have been experiencing caregiver burden, which can be manifested as feelings of loneliness, isolation, exhaustion, and fear and which, in conjunction with strain can be potent contributors to depression and anxiety.^{31–33} Thus, a caregiving burden may not only have a damaging effect on health,^{34,35} but may also lead to burnout and render the individual incapable of adopting healthy behavior. In this sense, avoiding medical treatment may be seen as a coping strategy, whereby the individual abstains from medical treatment to master or tolerate the concurrent stressful events.³⁰

One possible explanation of the women’s behavior is to regard it as a way to exceed control in a lasting condition of overwhelming anxiety. Being diagnosed with breast cancer and undergoing treatment signal unfavorable consequences and may therefore be fear inducing and lead to conditioning of emotional and instrumental avoidance behavior. The moment the women decide against health care, the anxiety rapidly dissipates and leaves her with an experience of relief. However, the relief illustrates the principle of negative reinforcement, which describes behaviors that increase in frequency—in this case, seeking health care—because they terminate an aversive stimulus.²⁰

The avoidance of health care denies the women the opportunity of discovering that health care and treatment may have positive outcomes. This is, according to Leventhal,²⁰ an important loss of positive reinforcement and may cause depression, which lead the women to develop negative ideas (cognitions) about themselves and the health care system that contribute to continuing avoidance, isolation, and depression.

The literature on cancer wounds describes that the consequences of living with a malodorous and seeping wound are feelings of guilt, fear, and embarrassment¹⁰ as well as a sense of stigmatization,³⁶ withdrawal, and social isolation.³⁷ In this study, feelings of shame, caused by advancing damage to the breast, are seen to reinforce the women’s avoidance behavior. Once a wound develops, feelings of shame block the women from coming to terms with the need to start treatment. This indicates that the avoidance behavior develops into denial as a defense mechanism that allows a conscious or subconscious escape from painful events or emotions.^{38–40} Denial is a clinically relevant concept in cancer patients and is manifested as failure to accept, or appearing oblivious to, the diagnosis, and they therefore minimize the consequences of their illness.³⁸ However, in accordance with Salander and Windahl,³⁸ who propose reconceptualizing the original psychoanalytic term *denial*, they see it as a subconscious repudiation of reality. More likely, the women experienced “disavowal.” Disavowal is an

emotion-focused coping strategy: “a process whereby the perceptual image is registered and acknowledged, while its affective meaning or significance for the individual is disregarded.”^{38(pp269)} Disavowal is also described as a conscious action, which is in line with the women’s reactions. The participants know they have cancer but that knowledge “seems to have lost its personal reference.”^{36(pp2706)} In a case of self-neglect and caregiver status, Ortiz et al⁴¹ report how the woman continued to neglect her symptoms of advanced endometrial cancer and could not find the time or have surplus energy to react to her own signs of illness, primarily because of her role as primary caregiver for her demented mother. This reaction confirms the findings in this study that the women who assumed caregiver roles for seriously ill or dying relatives prioritized their role over their own health.

Methodological Considerations

No published studies have used a qualitative methodology to describe underlying experiences related to sustained treatment avoidance that consequently may lead to developing malignant wounds and to premature death. The study adds to previous knowledge by revealing important psychological and psychosocial mechanisms that may constitute a decisive factor in avoidance of health care. However, given the qualitative nature of the study, the findings should not be regarded as facts that are applicable to the population at large.²⁸

The aim of this qualitative study was to increase the understanding of a complex phenomenon and not criteria-based validation, in which agreement among different sources confirms validity.²⁸ The trustworthiness of the study was supported by the use of researcher triangulation. The analysis was carried out by 2 investigators (the first and second authors), who were representing 2 different disciplines (nursing and psychology). The aim was not to obtain agreement among the researchers to confirm validity, but rather to ensure transparency and share of preconceptions.²⁸ To further improve communicative and pragmatic validity, every step of the research process was discussed with clinicians. Because of the physical and mental fragility of the participants in this study, we decided, for ethical reasons, to perform respondent validation during the interview rather than conduct a second interview. Thus, the interviewer carefully and continuously, during the interview, summed up the participant’s descriptions and asked whether she believed that she had understood them correctly.

The interview method proved useful to examine attitudes, processes, and experiences, especially as these related to interactions and activity.⁴² The interviewer (first author) has worked in the field of malignant wounds for several years, and this has contributed to making the informants feel more comfortable. Participant descriptions referred to thoughts and feelings that for some date as far back as 7 years and thus could have been subject to recall bias. Even though the order is retrospective, the health care avoidance should be viewed as a process that evolves over time and ends at the time of first medical contact (ie, a few weeks prior to the interview). How-

ever, professionals need to be aware that the women may continue to experience feelings of shame and guilt because of their concealment.

Conclusion

In conclusion, our findings suggest that consideration of psychosocial life events is needed to understand and manage health care avoidance, and an open, nonjudgmental attitude should be maintained when in direct communication with patients.

The results indicate that women who experience persistent emotional and social strain and who discover breast changes may try to cope with their life situation by ignoring their symptoms to avoid health care. Potentially, this results in the development of breast cancer wounds and poor prognosis.

The conceptualization of health care avoidance as identified in this study supports the theory of avoidance as a way of coping with negative and stressful events and must be taken into consideration in future studies seeking to prevent patient-related delay.

Clinical Implications and Further Research

With reference to the women’s feelings of shame and embarrassment, it seems crucial that the women are given the opportunity to share their story and that they receive unprejudiced care. Because avoidance behavior typically is controlled by negative reinforcement,¹⁹ one important strategy may be, through psychological intervention, to assist the individual in correcting negative cognitions including the idea that health care may be harmful or dangerous and thereby install/restore approach behavior necessary for resolution of the problem and resumption of normal functioning.¹⁹ In this connection, it is important to support the primary caregiver or bereaved individual to gradually find new sources of positive reinforcement that is part of accommodating to the loss.

Health care avoidance, delay, and subsequent development of malignant wounds in women who are primary, and often bereaved, caregivers may be prevented if doctors and nurses in the oncology settings, general practitioners and district nurses, are aware of the need for special attention to this group of women. By means of information about the early signs of cancer, these women may become conscious of the need to react to possible own symptoms.

On the assumption that health care avoidance is not limited to cancer, the results of this study may be transferable to patients within other medical specialties. Thus, it is likely that primary and bereaved caregivers could also ignore symptoms indicating heart and/or cardiovascular disease, which in theory may never be revealed especially because the symptoms, in comparison to the symptoms of breast cancer, may be easier to hide. Thus, the results are transferable on the conceptual and theoretical levels⁴³ to clinical settings where patients

deliberately neglect bodily changes and physical symptoms to avoid health care, which may result in poor prognosis.

In a preventive perspective, it seems advantageous to bring into focus the health of primary and bereaved caregivers, thereby potentially reducing patient delay and ultimately improving survival. This could imply development of information material concerning awareness of stress-related symptoms and bodily alterations in caregivers, which may be distributed through the primary sector and the hospital sector as well as patient organizations and the media.

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Appendix A

Questionnaires:

- EORTC-QLQ-C30
- HADS
- Mini-MAC



EORTC QLQ-C30 (version 3.0)

Vi er interesserede i at vide noget om Dem og Deres helbred. Vær venlig at besvare alle spørgsmålene selv ved at sætte en ring omkring det svar (tal), som passer bedst på Dem. Der er ingen "rigtige" eller "forkerte" svar. De oplysninger, som De giver os, vil forblive strengt fortrolige.

Skriv venligst Deres for bogstaver her:

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Deres fødselsdato (dag, måned, år):

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Dato for udfyldelse af dette skema (dag, måned, år):

31

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	Slet ikke	Lidt	En del	Meget
1. Har De nogen vanskeligheder ved at udføre anstrengende aktiviteter, som f.eks. at bære en tung indkøbstaske eller en kuffert?	1	2	3	4
2. Har De nogen vanskeligheder ved at gå en <u>lang</u> tur?	1	2	3	4
3. Har De nogen vanskeligheder ved at gå en <u>kort</u> tur udendørs?	1	2	3	4
4. Er De nødt til at ligge i sengen eller at sidde i en stol om dagen?	1	2	3	4
5. Har De brug for hjælp til at spise, tage tøj på, vaske Dem eller gå på toiletet?	1	2	3	4

I den forløbne uge:

	Slet ikke	Lidt	En del	Meget
6. Var De begrænset i udførelsen af enten Deres arbejde eller andre daglige aktiviteter?	1	2	3	4
7. Var De begrænset i at dyrke Deres hobbyer eller andre fritidsaktiviteter?	1	2	3	4
8. Havde De åndenød?	1	2	3	4
9. Har De haft smerter?	1	2	3	4
10. Havde De brug for at hvile Dem?	1	2	3	4
11. Har De haft besvær med at sove?	1	2	3	4
12. Har De følt Dem svag?	1	2	3	4
13. Har De savnet appetit?	1	2	3	4
14. Har De haft kvalme?	1	2	3	4
15. Har De kastet op?	1	2	3	4

Vær venlig at fortsætte på næste side

I den forløbne uge:

	Slet ikke	Lidt	En del	Meget
16. Har De haft forstoppelse?	1	2	3	4
17. Har De haft diarré (tynd mave)?	1	2	3	4
18. Var De træt?	1	2	3	4
19. Vanskeliggjorde smerter Deres daglige gøremål?	1	2	3	4
20. Har De haft svært ved at koncentrere Dem om ting som f.eks. at læse avis eller se fjernsyn?	1	2	3	4
21. Følte De Dem anspændt?	1	2	3	4
22. Var De bekymret?	1	2	3	4
23. Følte De Dem irritabel?	1	2	3	4
24. Følte De Dem deprimeret?	1	2	3	4
25. Har De haft svært ved at huske?	1	2	3	4
26. Har Deres fysiske tilstand eller medicinske behandling vanskeliggjort Deres <u>familieliv</u> ?	1	2	3	4
27. Har Deres fysiske tilstand eller medicinske behandling vanskeliggjort Deres <u>omgang med andre mennesker</u> ?	1	2	3	4
28. Har Deres fysiske tilstand eller medicinske behandling medført økonomiske vanskeligheder for Dem?	1	2	3	4

Ved de næste 2 spørgsmål bedes De sætte en ring omkring det tal mellem 1 og 7, som passer bedst på Dem

29. Hvordan vil De vurdere Deres samlede helbred i den forløbne uge?

1 2 3 4 5 6 7

Meget dårligt

Særdeles godt

30. Hvordan vil De vurdere Deres samlede livskvalitet i den forløbne uge?

1 2 3 4 5 6 7

Meget dårlig

Særdeles god

The Hospital Anxiety and Depression Scale (HADS)

Dato:

Dette spørgeskema er udformet med henblik på at hjælpe læger med at finde ud af, hvordan du har det.

Læs hvert spørgsmål og sæt kryds ved det svar, der kommer tættest på, hvordan du har haft det i den sidste uge.

<p>1. Jeg føler mig anspændt:</p> <p><input type="checkbox"/>₁ Næsten hele tiden</p> <p><input type="checkbox"/>₂ Meget af tiden</p> <p><input type="checkbox"/>₃ Engang imellem</p> <p><input type="checkbox"/>₄ Slet ikke</p> <p>2. Jeg nyder stadig de ting, som jeg tidligere har nydt:</p> <p><input type="checkbox"/>₁ Helt, som jeg plejer</p> <p><input type="checkbox"/>₂ Ikke helt så meget</p> <p><input type="checkbox"/>₃ Kun lidt</p> <p><input type="checkbox"/>₄ Næsten ikke</p> <p>3. Jeg er bange for, at der skal ske noget frygteligt:</p> <p><input type="checkbox"/>₁ Helt bestemt og meget voldsomt</p> <p><input type="checkbox"/>₂ Ja, men det er ikke så slemt</p> <p><input type="checkbox"/>₃ Lidt, men det bekymrer mig ikke</p> <p><input type="checkbox"/>₄ Slet ikke</p>	<p>4. Jeg kan le og se det morsomme i en situation:</p> <p><input type="checkbox"/>₁ Lige så meget, som jeg plejer</p> <p><input type="checkbox"/>₂ Ikke helt så meget nu</p> <p><input type="checkbox"/>₃ Helt klart ikke så meget nu</p> <p><input type="checkbox"/>₄ Slet ikke</p> <p>5. Jeg gør mig bekymringer:</p> <p><input type="checkbox"/>₁ En stor del af tiden</p> <p><input type="checkbox"/>₂ Meget af tiden</p> <p><input type="checkbox"/>₃ Engang imellem, men ikke så tit</p> <p><input type="checkbox"/>₄ Kun lejlighedsvis</p> <p>6. Jeg føler mig glad</p> <p><input type="checkbox"/>₁ Slet ikke</p> <p><input type="checkbox"/>₂ Ikke så tit</p> <p><input type="checkbox"/>₃ Nogle gange</p> <p><input type="checkbox"/>₄ Det meste af tiden</p>
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Fortsæt venligst på næste side →

<p>7. Jeg kan sidde roligt og føle mig afslappet</p> <p><input type="checkbox"/>₁ Helt bestemt</p> <p><input type="checkbox"/>₂ Som regel</p> <p><input type="checkbox"/>₃ Ikke så tit</p> <p><input type="checkbox"/>₄ Slet ikke</p> <p>8. Jeg føler det som om jeg fungerer langsommere:</p> <p><input type="checkbox"/>₁ Næsten hele tiden</p> <p><input type="checkbox"/>₂ Meget ofte</p> <p><input type="checkbox"/>₃ Nogle gange</p> <p><input type="checkbox"/>₄ Slet ikke</p> <p>9. Jeg føler mig bange, som om jeg har ”sommerfugle i maven”:</p> <p><input type="checkbox"/>₁ Slet ikke</p> <p><input type="checkbox"/>₂ Lejlighedsvis</p> <p><input type="checkbox"/>₃ Temmelig tit</p> <p><input type="checkbox"/>₄ Meget ofte</p> <p>10. Jeg har mistet interessen for mit udseende:</p> <p><input type="checkbox"/>₁ Fuldstændig</p> <p><input type="checkbox"/>₂ Jeg er ikke så omhyggelig, som jeg burde være</p> <p><input type="checkbox"/>₃ Måske er jeg knap så omhyggelig som før</p> <p><input type="checkbox"/>₄ Jeg er lige så omhyggelig, som jeg altid har været</p>	<p>11. Jeg føler mig rastløs, som om jeg hele tiden skal være i bevægelse:</p> <p><input type="checkbox"/>₁ Virkelig meget</p> <p><input type="checkbox"/>₂ Temmelig meget</p> <p><input type="checkbox"/>₃ Ikke særlig meget</p> <p><input type="checkbox"/>₄ Slet ikke</p> <p>12. Jeg glæder mig til ting, som skal ske:</p> <p><input type="checkbox"/>₁ Lige så meget som før</p> <p><input type="checkbox"/>₂ Noget mindre, end jeg plejer</p> <p><input type="checkbox"/>₃ Helt klart mindre end tidligere</p> <p><input type="checkbox"/>₄ Næsten ikke</p> <p>13. Jeg får en pludselig fornemmelse af panik:</p> <p><input type="checkbox"/>₁ Særdeles tit</p> <p><input type="checkbox"/>₂ Temmelig ofte</p> <p><input type="checkbox"/>₃ Ikke særlig ofte</p> <p><input type="checkbox"/>₄ Slet ikke</p> <p>14. Jeg kan nyde en god bog eller et radio/TV-program:</p> <p><input type="checkbox"/>₁ Ofte</p> <p><input type="checkbox"/>₂ Nogle gange</p> <p><input type="checkbox"/>₃ Ikke særlig tit</p> <p><input type="checkbox"/>₄ Meget sjældent</p>
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MINI-MAC SKALA

Dato for udfyldelse: _____

Nedenfor er angivet en række udsagn, som beskriver folks reaktion på at have eller have haft en kræftsygdom. Sæt venligst kryds i kasserne til højre for at angive, i hvilken udstrækning spørgsmålene passer på dig på nuværende tidspunkt.

	Passer bestemt ikke på mig	Passer ikke på mig	Passer på mig	Passer bestemt på mig
1. For øjeblikket tager jeg én dag ad gangen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Jeg ser på sygdommen som en udfordring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Jeg har overgivet mig til Gud	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Jeg har lyst til at give op	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Jeg er meget vred over det, der er sket	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Jeg er fuldstændig i vildrede over, hvad jeg skal gøre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Det er en ødelæggende oplevelse for mig	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Jeg glæder mig over de små ting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Jeg er bange for, at sygdommen vender tilbage eller bliver værre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Passer bestemt ikke på mig	Passer ikke på mig	Passer på mig	Passer bestemt på mig
10. Jeg forsøger at bekæmpe sygdommen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Jeg afleder mig selv, når tanken på sygdommen dukker op	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Jeg kan ikke håndtere det	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Jeg er ængstelig	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Jeg er ikke særligt forhåbningsfuld om fremtiden	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Jeg synes ikke, der er noget, jeg kan gøre for at hjælpe mig selv	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Jeg føler, at dette er slutningen på alt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Det hjælper mig ikke at tænke på det	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Jeg er meget optimistisk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Jeg har haft et godt liv resten er ren bonus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Jeg synes, livet er håbløst	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Jeg holder det ikke ud	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		Passer bestemt ikke på mig	Passer ikke på mig	Passer på mig	Passer bestemt på mig
22.	Jeg er rystet over at have en kræftsygdom	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23.	Jeg har besluttet mig til at bekæmpe sygdommen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24.	Efter at have fået denne sygdom er jeg blevet klar over, hvor værdifuldt livet er, og jeg vil få det mest mulige ud af det	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25.	Jeg har svært ved at tro, at dette er sket for mig	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26.	Jeg gør et godt forsøg på ikke at tænke på min sygdom	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27.	Jeg skyder bevidst alle tanker om sygdommen ud af mit hoved	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28.	Jeg er meget angst omkring sygdommen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29.	Jeg er en smule bange	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

TAK FOR DIN MEDVIRKEN!

Appendix B

**Model 1. for
Ignoring and Health Care Avoidance
in relation to malignant wounds in breast
cancer patients.**

Annex: Model 1. – Ignoring of Malignant Wound in Women with Advanced Stage Cancer – Health Care Avoidance

