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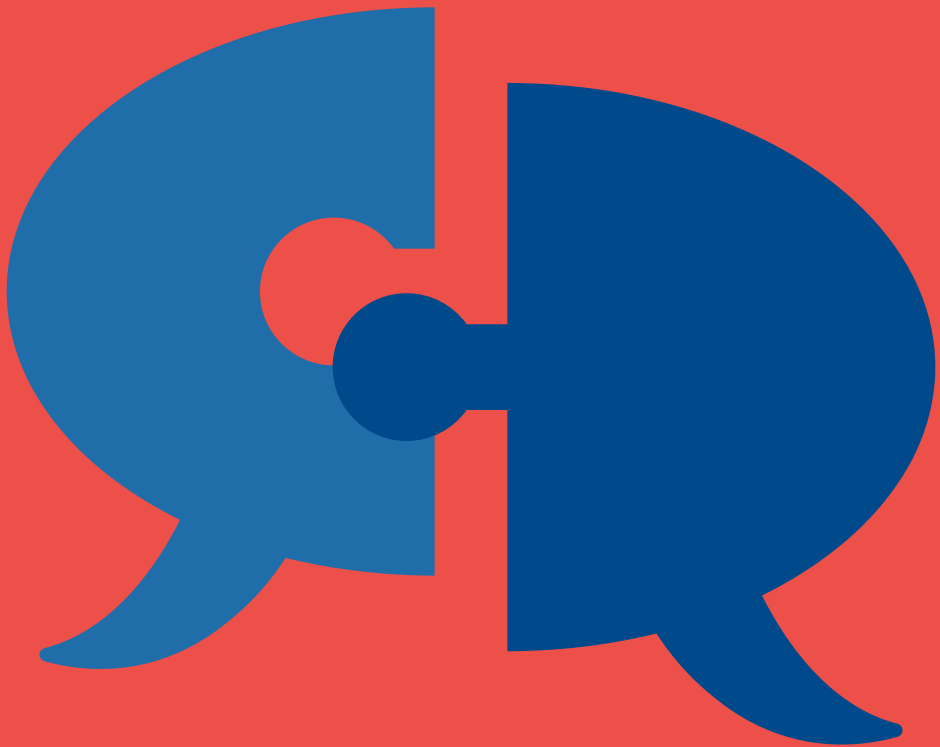
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Tailored decision making with patients suffering from open wounds

The impact of negative
pressure wound therapy on
the quality of life of patients
with wounds



Alexandra Helena Jacoba Janssen

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ISBN: 978-94-6361-811-3

Layout and printing by Optima Grafische Communicatie (www.ogc.nl)

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MA Healthcare ltd. (Chapter 2 and 3)

Elsevier Ltd. (Chapter 4 and 5)

Wounds International (Chapter 7)

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Tailored decision making with patients suffering from open wounds

The impact of negative pressure wound therapy on the quality of life of patients with wounds

Proefschrift ter verkrijging van de graad van doctor
aan de Radboud Universiteit Nijmegen
op gezag van de rector magnificus prof. Dr. J.H.J.M. van Krieken,
volgens besluit van het College van Decanen,
in het openbaar te verdedigen op

donderdag 30 maart 2023
om 14.30 uur precies

door

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CONTENT

Chapter 1 Introduction	9
Chapter 2 Impact of Negative Pressure Wound Therapy and Standard Wound Care on Quality of Life. A systematic review	19
Chapter 3 Negative pressure wound therapy for patients with hard-to-heal wounds: a systematic review	33
Chapter 4 Which determinants are considered to be important for adherence to Negative Pressure Wound Therapy: A multimethods study	49
Chapter 5 The association of potential prognostic determinants to nonadherence to negative pressure wound therapy: An exploratory prospective prognostic study	67
Chapter 6 Preferences of patients treated with negative pressure wound therapy in relation to shared decision making and participation in wound care, a qualitative study using thematic analysis	93
Chapter 7 Promising results in wound care with a new Rapid Capillary Action Dressing; A case series study	115
Chapter 8 General discussion	131
Summary	147
Samenvatting	155
Research data management	163
Portfolio	167
List of publications	173
Dankwoord	179
Curriculum Vitae	185

1

Introduction

INTRODUCTION

Evidence based medicine (EBM) involves the integration of clinical expertise, patients' values, and the best available evidence in making patient care decisions.^[1] The concept, of doing the right things, was initially developed within medicine. In time, as many health care professionals (HCPs) have embraced an evidence-based way of practice, the original term "evidence-based medicine" is expanded to "evidence-based practice" in order to reflect a common approach across all health professions.^[2, 3] As a side effect this expansion facilitated interprofessional communication and collaboration on giving the right care informed by evidence. Evidence-Based Practice requires that "decisions about health care are based on the best available, current, valid and relevant evidence".^[4] These decisions or choices should be made by patients, informed by knowledge of HCPs, within the context of available resources.^[4]

In 2012 the international campaign "Choosing Wisely" started. This campaign refers to evidence based recommendations for treatments, however, the main aim is to engage HCPs and patients in conversations about unnecessary tests, treatments and procedures.^[5, 6] Several national and international programs have been initiated to stimulate the ideas of this worldwide campaign. The concept of "Choosing Wisely" proposes that the communication between HCPs and consumers about the treatment plan should be (1) evidence-based, (2) not duplicative of other tests or procedures already received, (3) free from harm, and (4) indeed necessary.^[6] The international Choosing Wisely Campaign specifically pays attention to abandon 'low-value care' out of health care practices. The concept of low-value care is defined by Verkerk et al. (2018) as care that is unlikely to benefit the patient given the harms, costs available alternatives, or preferences of the patients.^[7] HCPs need to be aware which treatments are evidence based, and which could be labelled as 'low-value care', to be able to inform patients about the highest-value, most effective health care procedures and practices.^[8] Discussing these evidence based treatments in relation to the patients preferences to their desired outcomes will facilitate the conversation with the patients in an shared decision way.

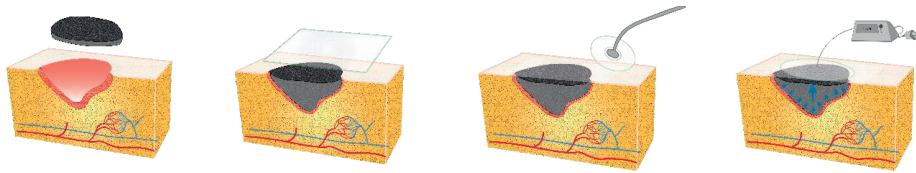
In the light of the international 'Choosing Wisely' campaign, in the Netherlands the 'Outcome-Oriented Care' program is started. In this program, the Federation of Medical Specialists, the Ministry of Health, Welfare and Sport and the umbrella organizations of patient organizations, nurses, hospitals and health care insurance companies work together to provide insight into the outcomes of care. Insight into evidence based outcomes and patient reported experiences is necessary in order to be able to properly inform other patients about the most appropriate treatment for them, in the light of treatment outcome and patients' experiences of treatment, and for HCPs to improve their care.^[9]

Wise choices are intended as an incentive for HCPs and patients to start a conversation about the right care at the right time. These shared decision making (SDM) conversations about the usefulness and necessity of certain medical treatments can make an important contribution to improving the quality, affordability, and accessibility of care.^[9] Evidence Based Practice is closely intertwined with the process of Shared decision Making (SDM). In this process of SDM, a health care professional and patient jointly participate in a health decision about the right care after discussing the options according to the last state of evidence, the benefits and harms, and considering the patient's values, preferences, and circumstances.^[10] As Hoffmann et al. (2014) mentioned in their editorial: "Medicine cannot, and should not, be practiced without up-to date evidence. Nor can medicine be practiced without knowing and respecting the informed preferences of patients. Clinicians, researchers, teachers, and patients need to be aware of and actively facilitate the interdependent relationship of these approaches. Evidence-based medicine needs SDM, and SDM needs EBM."^[11] Shared decision making should be the norm in most practices of HCPs, not only for respecting autonomy (enabling individuals to make reasoned choices), but it is also necessary for benevolence (balancing treatment benefits against the risks and costs) and non-harmfulness (avoidance of damage).^[12]

In the field of wound care, EBP and SDM are still challenging because robust evidence on different wound treatment options is still lacking.^[13] Because of the lack of randomized clinical trials, and systematic reviews reporting sparse data, uncertainties remain regarding the clinical and cost effectiveness of treatments for wounds healing by secondary intention.^[13-16] Beside the lack of evidence on treatment options, there is a huge paucity of research on patients' preferences regarding different wound care treatments.^[17] This lack of evidence and insights in preferences results in a widely and random use of treatments by HCPs,^[13] and hampers EBP and thus SDM in wound care.

Meanwhile, there is an increased use of technology in wound care.^[18] Smart glasses, electrodynamic fields and transdermal oxygen devices have found their way to wound care and are still studied for their added value.^[19-21] One of the relatively new and very well implemented wound care treatments is negative pressure wound therapy (NPWT). Negative Pressure Wound Therapy was developed independently in both Germany and the USA by Fleischmann (Germany)^[22] and Argenta and Morykwas (USA)^[23] in the early 1990s.^[24] Negative Pressure Wound Therapy consist of an electric device that creates a vacuum in the wound using a wound filler of polyurethane foam, polyvinyl alcohol foam dressing or gauze. The foam or gauze needs to fit exactly to the wound size (or a little bit smaller to contract the wound edges). After the wound filler has been placed in situ, a transparent adhesive drape is placed to cover the entire wound. A hole is made in the drape, through which a tube is attached to the wound. The tube is connected to the medical device, and to a canister to collect exudate. 80-125 mmHg sub atmospheric pressure is applied, the actual pressure depending on the device used. See figure 1.

Figure 1 : Dressing technique. Pictures made by D.L.C. de Jong.



Early fundamental studies concluded that NPWT increases blood flow to a wound, accelerates the rate of granulation tissue formation, decreases bacterial counts, and improves flap survival.^[25, 26] Since its introduction in the 1990s, it has expanded to currently several thousand applications each day worldwide,^[27] and there is no doubt that NPWT has revolutionized wound management.^[28] The latter seems to be controversial to the current lack of rigorous evidence on effectiveness of NPWT when applied on leg ulcers, pressure ulcers and surgical wounds healing by secondary intention.^[14, 29, 30]

Patients experience physical, psychological, social, and financial consequences of having a wound. Furthermore, the applied wound treatments can significantly affect the quality of their daily lives.^[31, 32] When robust evidence on treatment is lacking, it becomes even more important to explore patients' experiences and preferences regarding their treatment choice. Besides treatment choice, patient involvement in wound care has been shown to have a great impact on patients' satisfaction.^[33] To be able to address the preferences of the patients, we need to know how they experience different treatment options and which treatment they prefer. In this way HCPs can facilitate SDM in wound treatment in the future.

As mentioned at the beginning of this introduction, one of the three pillars of EBP, is the patients' value and preference. However, literature on EBP reveals that this part has received less attention compared to the other two pillars, i.e., clinical expertise, and available research evidence.^[34] The expansion of EBM to EBP offered opportunities to nurses to fill in this gap, being pre-eminently suitable to explore and address patients' values and preferences. In 2013 a group of nurse leaders, health policy, health care researchers and clinicians acknowledged that health systems continue to face challenges in meeting the basic needs of many of our patients due to a range of complex factors.^[35] They draw up a framework to integrate the Fundamentals of Care (FOC) (e.g., active listening, being empathetic, helping patients to cope, working with patients to set, achieve, and evaluate progression of goals) into patient-centered care. The Framework emphasises the importance of nurses and other HCPs developing trusting therapeutic relationships with patients and their families. The relational actions of nurses (e.g., active listening, being empathic) mediate the need to integrate people's different fundamental needs; namely their physical (e.g., nutrition, mobility) and psychosocial needs (e.g., communication, privacy, dignity).^[35] Patients may be tended to share their thoughts and values more easy

with nurses than to doctors, because nurses help patients and families understand their options in the context of individual patients' lives.^[36] It is the daily practice of nurses to consider and address the patients' needs and preferences, maybe even more than implementing science in their treatment decisions.

In the field of wound care, EBP might even be more challenging. There is a lack of high-level evidence on effectiveness of different treatments.^[37] Thereby, or probably also because of this paucity of research evidence, HCPs use a wide range of wound products and treatments, based on their own experiences and personal preferences.^[38] As a result of the lack of robust evidence and the availability of many wound treatment option, the preferences of the patients regarding treatment choice become even more important. One patient may experience a treatment completely different from another patient. Exploring the patients' needs and preferences, and assess which wound treatment suits this patient best, is particularly important in wound care.

Concluding, the patient should be at the center of EBP, just like in the FOC, and in all decision-makings, surrounded by a team of HCPs.^[39] These HCPs, comprising different disciplines such as doctors, nurses, rehabilitation specialists and physiotherapists, should work together interprofessional to provide better patient care.^[40] This thesis is established by an multidisciplinary research team of specialists, nurses and researchers. The diversity of HCPs in our team provided the opportunity to study and illuminate different aspects of the patient and his treatment with NPWT.

OBJECTIVES AND OUTLINE OF THIS THESIS

The main aim of this thesis is to provide insight in the experiences and preferences of patients with wounds, treated with negative pressure therapy. Knowing these experiences and preferences will facilitate HCPs to inform patients more thoroughly about treatment options and facilitate the conversation in an EBP and SDM way. In this way, HCPs together with patients, will be able to choose a wound therapy which suits each individual patient best.

To find answers to different subareas of this topic, studies with different research designs are conducted. In **Chapter 2**, the aim was to study the impact of NPWT on the quality of life of patients with wounds. A *systematic review of quantitative studies* was conducted to provide knowledge on the impact of NPWT on the QoL and whether this impact differs from the impact of standard wound care on the QoL. In the next chapter (**Chapter 3**), more in-depth insight in what this impact of NPWT on the QoL of patients with wounds entails, will be provided. Content analysis of included studies in *systematic review of qualitative studies* identified themes regarding the impact of NPWT on patients' lives.

Subsequently, in **Chapter 4**, the purpose was to explore the number of patients with wounds premature ceasing NPWT on their own request. A *retrospective chart study* in a Dutch general hospital was conducted to explore the amount of patients with postoperatively infected abdominal wounds who asked to cease NPWT because of the restrictions in their daily lives, caused by this therapy. Thereafter, to gain more insight in what determines this nonadherence (i.e., premature cessation of NPWT on request of the patient), a *narrative review* was conducted to identify general determinants of nonadherence to health care related therapies. With the results of this narrative review, an *e-survey* among wound care nurses in The Netherlands was held. Per determinant retrieved from the narrative review and the retrospective study, the wound care nurses were asked to indicate on a 10-point scale how decisive they thought this determinant is with respect to adherence to NPWT. In **Chapter 5**, the optional prognostic determinants retrieved from the survey, were assessed on their predictive value on nonadherence to NPWT in an *exploratory prospective prognostic multicenter cohort study*). Knowing which (patient-, treatment and health care related) factors are associated with a premature cessation of therapy, will facilitate SDM and making a patient-centered choice of therapy.

Subsequently, in **Chapter 6** the experiences and preferences of patients treated with NPWT regarding treatment choice and participation in wound care are presented. In *semi-structured interviews* patients were invited to share their experiences and preferences regarding this topic. After content analysis, themes emerges from the patients' stories which will help us understand and address the patients' needs regarding SDM and patient participation in wound care treatment.

Having found that a significant amount of people did not benefit from NPWT, an alternative wound therapy was looked for. In **Chapter 7**, the results of a *case series* on a potential alternative to NPWT are shown. Finally, in **the last chapter, Chapter 8**, our findings on the impact of NPWT on the QoL of patients are discussed.

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2

Impact of Negative Pressure Wound Therapy and Standard Wound Care on Quality of Life. A systematic review

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Journal of Wound Care 2016; 25(3), 154–159.

ABSTRACT

Objective

Negative Pressure Wound Therapy (NPWT) is a widely accepted treatment modality for open or infected wounds. Premature ending of NPWT occasionally occurs due to negative effects on the Quality of Life (QoL). The impact of NPWT on QoL however, is unknown. The aim of this review is to analyse the effect of NPWT and Standard Wound Care (SWC) on QoL when used for the treatment of open or infected wounds.

Method

A systematic literature search in the following databases (PubMed, CINAHL, Medline, Web of Science, Science Direct Freedom Collection, SwetsWise, PSYCArticles and Infrotrac Custom Journals) using the following search terms; 'Standard wound care', 'wound dressing', 'dressing', 'treatment', OR 'Negative pressure wound therapy [MESH]', OR 'vacuum assisted closure' AND 'quality of life [MESH]', 'patient-satisfaction', OR 'experiences' was performed. Methodological Quality was assessed using the Methodological index for non-randomized studies (MINORS) checklist.

Results

There were 42 studies identified, five matched the inclusion criteria: two randomized clinical trials (RCT's), one clinical comparative study, one exploratory prospective cohort study and one quasi experimental pilot study. Median MINORS-Score was 75% (58-96%). There were seven different questionnaires used to measure QoL or a subsidiary outcome. QoL in the NPWT group was lower in the first week, though no difference in QoL was observed thereafter.

Conclusion

This systematic review observed that QoL improved at the end of therapy, independent which therapy was used. NPWT leads to a lower QoL during the first week of treatment, possible due to anxiety, after which a similar or better QoL was reported when compared to SWC. It could be suggested that NPWT might be associated with increased anxiety.

INTRODUCTION

Negative Pressure Wound Therapy (NPWT) is a widely accepted modality for the accelerated treatment of open and infected wounds, and in most clinics the first choice for these patients.¹⁻³ The clinical - and cost effectiveness of NPWT has been extensively studied in several RCT's and meta-analysis.⁴⁻⁶ However, as most of the original trials concerning NPWT received financial support from NPWT equipment manufacturers, the evidence to define NPWT as the treatment of choice for accelerated open wound management is, at least, biased.^{4,7}

As the success rate of NPWT depends heavily on patient adherence⁸, it was disturbing to note that an increasing number of patients prematurely transferred from NPWT to SWC in our hospital. This phenomenon was also recently described by Keskin.⁹ The need to carry an electric device, anxiety due to noisy alarms, unpleasant wound odor, or hospitalization for sponge changes were reasons mentioned by patients to prematurely discontinuation. These factors had a substantial impact on their mental health and quality of life (QoL).^{10,11} Standard wound care (SWC) also has an equally important impact on QoL due to dressing changes, leakages, unpleasant odor and pain. However, it is still unclear what ultimately leads to the best QoL in these open wound patients: SWC or NPWT.

This study was designed to analyse the effect of NPWT versus SWC on the QoL in patients with open or infected wounds.

MATERIALS AND METHODS

This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.¹²

Types of studies included

All randomized controlled trials (RCT's), clinical trials, cohort studies and quasi experiments describing the impact of NPWT and/or SWC on patients with open and/or infected wounds, published between 1940 and 2014 were included. Due to the low expected number of studies, no limitations were applied to randomisation or location of the wound(s).

Types of outcome measures included

The primary outcome of this review was the impact of NPWT and SWC on QoL or mental health. No limits were applied to the questionnaires used for assessing QoL. Studies

concerning depression, anxiety, social implications or any other subset of QoL were also considered for inclusion.

Search method

A literature search of the following electronic databases was performed: PubMed, CINAHL, Medline, Web of Science, Science Direct Freedom Collection, SwetsWise, PSYCARticles and Inprotrac Custom Journals using the following search terms;

‘Standard wound care’, ‘wound dressing’, ‘dressing’, ‘treatment’, OR ‘Negative pressure wound therapy [MESH]’, or ‘vacuum assisted closure’ AND ‘quality of life [MESH]’, ‘patient-satisfaction’, or ‘experiences’. The reference lists of all eligible studies were searched to identify additional studies eligible for inclusion. Language was restricted to Dutch, English and German. All studies were screened for eligibility by three authors (SJ, EM, JW).

Selection of studies

All articles were screened for eligibility by means of title and abstract. Irrelevant studies and duplicates were removed (Figure 1). The remaining articles were screened by means of full-text analysis by two independent reviewers (SJ, EM) to extract all relevant data and findings. Disagreements were solved by means of discussion. If disagreements could not be solved, a third author (JW) was consulted for arbitration.

Methodological quality and risk of bias

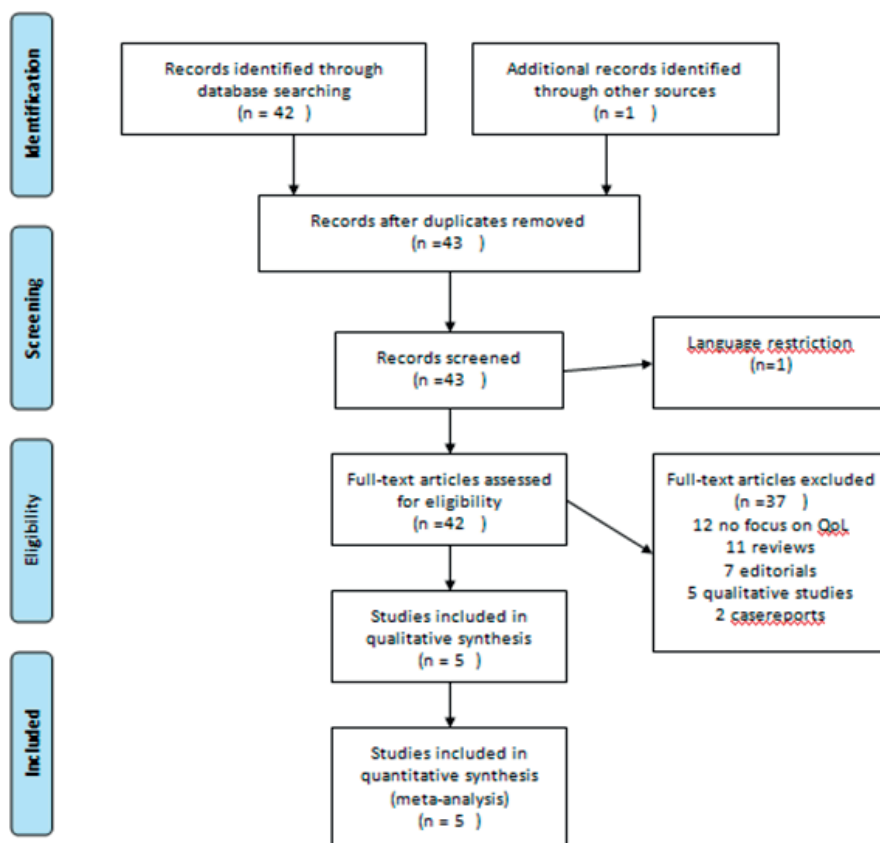
Methodological quality and risk of bias were determined for all studies eligible for inclusion. Two reviewers (SJ, EM) independently scored methodological quality according to the MINORS checklist.¹³ This validated checklist consists of 12 items and is frequently used for scoring surgical clinical trials. The outcome of this checklist is measured on a 24 point scale for comparative studies or a 16 point scale for non-comparative studies. A study with a MINORS score less than 60% is considered to have a poor methodological quality, likewise, a score between 60 and 75% is moderate, and a study with a score over 75% is good quality.

RESULTS

Literature search

The database search identified 43 potentially eligible studies (figure 1). There were twelve excluded based on the abstract alone. Of the remaining 31 articles 26 were excluded based on methodological format (figure 1). This left five studies (214 patients) which were included in this systematic review. Of these, 2 were randomised controlled

Figure 1 Flow of studies through the review



n=number of studies; QoL=Quality of life; other sources=searching of reference lists of eligible studies.
This Flowchart is in accordance with the PRISMA statement 2009

studies, 1 clinical comparative study, 1 cohort study and 1 quasi-experimental study. Table 1 describes the characteristics of the included studies and the methodological quality.

Research funding

All the included studies were screened for (financial) relationships that could lead to bias. Vuerstaek et al (2012) received financial support of Kinetic Concepts Inc.¹⁴ Ousey et al (2012) received a grant from Smith and Nephew.¹⁵ Karatepe et al (2011)¹⁶, Keskin et al (2008)⁹ and Mendonca et al (2007)¹⁷ received no funding and disclosed no conflict of interest with NPWT manufacturers or other pharmaceutical organisations.

Table 1. Summary of included studies

Author, year of publication	Study design	n (SWC / NPWT)	Type and location of wounds	Wound infection present	QoL Measurement tool	Frequency of QoL measurement	Primary Outcome	MINORS score
Mendonca et al. 2007 ¹⁷	cohort study	0/26	50% acute wounds, 50% chronic, 58% lower limb.	NPWT 65%	CWIS	Day -1 and +28 or at wound healing	No significant change in QoL of patients whose wounds had healed. QoL worsened in patients that needed surgical intervention.	12/16 (75%)
Keskin et al. 2008 ⁹	CCS	20/20	Traumatic wounds, lower extremity	unknown	SAI and HAM-A	Day -1 and +10	Significant increase in anxiety in both groups. More anxiety in NPWT group than SWC group	16/24 (67%)
Karatepe et al. 2011 ¹⁶	RCT	37/30	Diabetic foot ulcers	SWC 81%; NPWT 80%	SF-36	Day -1 and in the month following wound healing	Significant better QoL in the NPWT group than the SWC group	19/24 (79%)
Ousey et al. 2012 ¹⁵	pilot study	11/10	Leg and diabetic foot ulcers.	unknown	CWIS	Week 1,2,3,4, 8 and 12	No difference in QoL	14/24 (58%)
Vuerstaek et al. 2012 ¹⁴	RCT	30/30	Chronic leg ulcers	SWC 20%; NPWT 27%	EQ-DSI, SF-MPQ and PPI	EQ-DSI 1/wk in hospital. SF-MPQ and PPI during dressing changes.	Reduced QoL in NPWT group versus SWC group in the first week, no difference in QoL hereafter. Significant increase in QoL in both groups at end of therapy.	23/24 (96%)

CCS = Clinical Comparative Study; CWIS = Cardiff Wound Impact Schedule; EQ-DSI = EuroQoL Derived Single Index; HAM-A = Hamilton Rating Scale for Anxiety; NPWT = Negative Pressure Wound Therapy; RCT=Randomized Controlled Trial; SAI = State Anxiety Inventory test; SF-36 = Short Form (36) Health Survey; SF-MPQ = Short Form-McGill Pain Questionnaire; SWC = Standard Wound Care; PPI = Present Pain Intensity; QoL = Quality of Life; VAC = Vacuum assisted wound Closure

Outcome measures

Overall, 7 different questionnaires were used to measure QoL or a subsidiary outcome. The Cardiff Wound Impact Schedule (CWIS) is a condition-specific questionnaire, consisting of 5 key sections: demographic data, physical symptoms and daily living, social life, well-being and overall health-related QoL. Each question is scored on a scale from 1 to 5.¹⁸

Keskin et al.⁹ used the Hamilton Rating Scale for Anxiety (HAM-A) complemented with the State Anxiety Inventory test (SAI). The HAM-A is one of the most widely used semi-structured assessment scales to evaluate treatment outcome in anxiety disorders.¹⁹ The HAM-A consists of 14 items, each with a score ranging from 0 (absence) to 4 (very severe). The State Anxiety Inventory (SAI) is a self-reporting instrument that measures the anxiety state at a specific point in time and provides a 4-point Likert-type scale for all 20 items.^{9,20}

The SF-36 questionnaire, a multi-purpose, generic, short-form health survey with 36 questions reports an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index.²¹ The EuroQol Derived Single Index (EQ-DSI), a generic questionnaire consisting of five dimensions: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression.²² The Short Form-McGill Pain Questionnaire (SF-MPQ) and the Present Pain Intensity (PPI) score can be used as adjectival pain scales.²³ The SF-MPQ is designed to provide quantitative measures of clinical pain. It consists of 15 descriptors of 11 sensory and four affective items. The PPI score measures pain intensity on a 5 point scale, a higher number coincides with a higher degree of pain.¹⁴

Description of the included studies

Mendonca et al.¹⁷ performed an exploratory prospective cohort study including 26 patients with both acute and chronic wounds. Measurements were taken pre-therapy and four weeks post-therapy or at wound healing, whichever came first. No change in QoL was observed for patients with healing wounds, 12 patients (46%) experienced an improvement in physical-functioning and 11 patients (42%) a deterioration. Subgroup analysis demonstrated that the global QoL scores worsened for patients in need of surgical intervention. Furthermore an increase in the physical function domain score was observed in obese patients ($p < 0.05$). In ambulatory patients a reduction of the physical function domain score was observed ($p < 0.05$), because the device limited their ability to undertake physical activities. Overall 46% ($n=12$) of the participants experienced an improvement of their social-functioning.¹⁷ The quality of this study was determined to be moderate (MINORS score 75%).

Keskin et al.⁹ performed a clinical comparative study in 40 patients. The primary outcome measure was anxiety following NPWT or SWC. Psychiatric evaluation was performed before and 10 days after initiation of the therapy.⁹ Both groups showed a significant increase in anxiety compared to the baseline characteristic ($p < 0.0001$). Overall anxiety, measured by the HAM-A and the SAI test was increased significantly higher in the NPWT group compared to the SWC group ($p < 0.0001$). The authors suggested that the pain caused by the NPWT dressing changes and restriction of activities, due to the lack of a mobile device, were most likely the cause for the increase in anxiety.⁹ Overall methodological quality was moderate and limited due to a per protocol analysis of the included patients and subsequent exclusion of patients that had not received the secondary measurement. Furthermore, data analysis was not blinded.

Karatepe et al. performed an RCT in 67 patients with diabetic foot ulcers.¹⁶ The authors found a substantial mood change in both groups. In the NPWT group 28/30 (93%) patients reported a depressive mood before treatment and 2 (7%) patients after treatment. In the SWC group 32/37 (86%) patients reported a depressive mood before treatment and 4/37 (11%) after treatment. Also, a statistically significant increase in QoL (mental health $p = 0.0287$; physical health $p = 0.004$) was found during the period of wound healing in the NPWT group compared with the SWC group. The benefits of NPWT over SWC were performance of once-daily wound dressing, decrease in the frequency of patient disturbance for the management of debridement, feeling less anxiety because of exudation and comfortable movements of the patient.¹⁶ Overall methodological quality was good.

Ousey et al.¹⁵ conducted a quasi-experimental pilot study exploring QoL in patients undergoing NPWT and SWC. The study included 21 patients with leg ulcers, category 3 or 4 pressure ulcers, diabetic foot ulcers and other wound types healing by secondary intention. Of the ten patients that started NPWT six transferred to the SWC group for reasons that were not described. The four remaining patients in the NPWT group were lost to follow-up before the final measurement could be obtained.¹⁵ The methodological quality was poor due to the fact that no randomisation was performed, data-analysis was not blinded, no baseline measurement of QoL was reported and the NPWT group was lost to follow up. No valid data could be extracted and therefore no conclusions could be drawn from this study.

Vuerstaek et al.¹⁴ performed a RCT with 60 leg ulcer patients. QoL was measured using the EQ-DSI questionnaire at baseline and once a week during hospitalization. During the first week the QoL score was significantly lower in the NPWT group ($p = 0.031$). In the second week, this difference had disappeared ($p > 0.05$) and during follow-up QoL remained similar in both groups.¹⁴ Both groups showed a significant decrease in pain at the end of follow-up ($p < 0.05$). Pain scores were similar until week 5, after that the PPI scores were lower in the NPWT group ($p < 0.05$). As a possible explanation for the more

rapidly improved QoL in the NPWT group, the authors mentioned an accelerated wound preparation phase with NPWT. The initial decrease during NPWT treatment may be due to the necessity of strict bed rest as a negative influencing factor of QoL. Initial pain scores were similar in both groups, though after five weeks of treatment, the PPI scores were significantly lower in the NPWT group ($p < 0.05$). The authors did not elaborate on the difference in PPI-scores.¹⁴ Overall methodological quality was good (MINORS score 96%).

DISCUSSION

This is the first review comparing the effect of NPWT and SWC on the QoL in open-wounds patients, using a systematic evaluation of the methodological quality of the included studies. Our results found two studies demonstrated no difference in QoL between NPWT and SWC after one week of therapy, one study favoured NPWT while another study favoured SWC due to increased anxiety with NPWT. QoL in the last study was directly related to absence or presence of wound healing. Thus, although NPWT is supposed to have many advantages in wound healing compared to SWC, this review did not demonstrate an overall superiority of NPWT in QoL.

In the moderate quality Keskin study⁹, the NPWT group experienced a higher level of anxiety than the SWC group. Keskin explained the premature termination of NPWT by some patients due to nervousness caused by the therapy itself.⁹ The use of non-portable NPWT devices, which hospitalised the patients and reduced their range of motion, might also be an explanation for this. The immobility of patients may also explain the lower QoL in the first week of NPWT patients in Vuurstaek's study.¹⁴

In 2013 Upton reviewed both quantitative and qualitative literature concerning patient experiences with NPWT.¹⁰ No formal systematic evaluation of methodological quality was performed. That study observed that pain and the unfamiliarity with the NPWT device from both patient and health professional could have a marked impact on the QoL. It could result in a negative self-image and low self-esteem due to the impact of NPWT on daily routine and social life.¹⁰ Despite the evidence that NPWT can lead to accelerated wound healing, Upton et al. concluded that concerns regarding the impact on QoL do exist.¹⁰

From this review it seems that the benefits of NPWT treatment over SWC can be summarized as an overall decrease in the frequency of patient disturbance for wound management and improved comfort when moving.¹⁶ The reported free range of movement during NPWT was a surprising major positive characteristic if a portable device was used.¹⁶ When non-transportable NPWT devices are used, motion restriction and hospitalization may lead to higher levels of anxiety.⁹ Furthermore, while wound closure

may be enhanced, problems with odor and occasional pain during therapy could arise during NPWT. If adverse effects occur, patients' QoL could be negatively affected, and issues with patient compliance may be anticipated.¹⁷

Limitations

There are several limitations to this review. The level of evidence of our conclusions is undermined by the fact that there is only a very limited body of literature on this subject and that two out of five eligible studies were granted by industry. Most studies have a small sample size and an enormous heterogeneity in assessment tools and time points at which QoL was measured exists. Furthermore, the studies differed in the use of portable or non-portable NPWT systems. The reported outcome measures were also heterogeneous, reducing the comparability of the individual studies and rendering pooled analysis inappropriate. Finally, the included studies only describe patients with wounds at the lower extremities. There are no studies describing QoL in patients with abdominal wounds. These wounds may have a potential higher impact on QoL, compared to wounds of the extremities, due to wound size, close proximity to the core and reduction in core mobility. Thus, the conclusions of this review may not apply to patients with NPWT for open abdominal wounds.

Conclusion

This systematic review observed that QoL improved at the end of therapy, independent which therapy was used. NPWT patients did demonstrate a temporarily lower QoL during the first week of treatment and an increased anxiety, compared with SWC; immobility of the patient due to non-portable devices was probably the cause of this. Why some patients decide to discontinue the NPWT treatment and transfer to SWC remains unclear and is subject for further research.

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3

Negative pressure wound therapy for patients with hard-to-heal wounds: a systematic review

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Journal of Wound Care 2020; 29(4), 206–212

ABSTRACT

Objective

Despite the lack of evidence, negative pressure wound therapy (NPWT) is commonly used in patients with hard-to-heal wounds. In our medical centre, one third of patients with abdominal wounds infected postoperatively end this therapy prematurely due to negative experiences and prefer standard wound care. This study was designed to explore the effects of NPWT on quality of life (QoL).

Method

A search from 2000 to 2019 in eight databases was performed to identify qualitative studies of patients treated with NPWT. Studies were selected by two independent reviewers, who appraised the methodological quality, extracted and structured the data and performed content analysis.

Results

A total of five qualitative studies with good methodological quality, incorporating 51 individual patients, were included. After content analysis, four major themes emerged: reduced freedom of movement caused by an electric device; decreased self-esteem; increased social and professional dependency; and gaining self-control.

Conclusion

NPWT has major effects on the physical, psychological and social domains of QoL. Knowledge of these effects may lead to improved treatment decisions for patients with hard-to-heal wounds regarding use of NPWT or standard wound care.

INTRODUCTION

Negative Pressure Wound Therapy (NPWT) is a widely used treatment modality.^[1] It is mainly used in the treatment of wounds with complicated healing, like pressure ulcers and diabetic foot ulcers, but also in wounds with other aetiologies, such as postoperatively infected abdominal wounds.^[2-4] NPWT is created by a foam dressing that is placed in the wound, fixed under a film, and connected to an electric pump which provides a vacuum.^[5] It increases the local blood flow by traction through the vacuum in the contracted wound edges under the film. This hyperaemia leads to cell proliferation and granulation tissue formation. Also, the constant removal of debris by suction decreases bacterial overgrowth and oedema, thereby promoting the healing process.^[6-14] The popularity of NPWT over standard wound care, as claimed by the manufacturer, is due to a faster recovery, better patients' comfort, and reduced workload for caregivers.^[15,16]

However, NPWT has only demonstrated faster wound healing rates compared with standard wound care in lower extremity, hard-to-heal wounds.^[17,18] Faster healing rates have never been extensively studied or demonstrated in other types of hard-to-heal wounds. Additionally, the application of NPWT does not lead to a better quality of life (QoL) compared with treatment with standard wound care.^[19] Furthermore, based on a retrospective chart study in a general hospital in the Netherlands, it was found that 20% of patients with postoperatively infected abdominal wounds ceased NPWT prematurely because they felt limited in their daily activities by the NPWT.^[20] These patients switched to standard wound care due to negative experiences such as anxiety and fear from using the medical device. It appears that NPWT has strong effects on their QoL and was not the best choice in the treatment for these patients.^[20] Therefore, this study aimed to explore the personal experiences of patients with NPWT in relation to QoL, to elucidate possible reasons for early cessation of NPWT.

MATERIALS AND METHODS

A systematic review of qualitative studies was conducted, and the Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) was used to report our synthesis and results.^[21]

Inclusion and exclusion criteria

Qualitative studies were eligible if they addressed patients' experiences with NPWT in relation to QoL. No distinction was made regarding wound types and wound location. This was because patient experiences with NPWT do not necessarily depend on the location of the wound, but are mainly determined by NPWT itself. Non-English or non-

Dutch articles were excluded to avoid misinterpreting the data. Furthermore, the search period was limited to studies published after the year 2000, when the first studies on mobile NPWT systems were published. Only full-text articles were included.

Information sources and electronic search strategy

A broad search of the scientific literature was performed in various biomedical bibliographic databases, namely PubMed, Cinahl, Medline, Web of Science, Science Direct Freedom Collection, SwetsWise, PSYCArticles, and Inprotrac Custom Journals between 1 January 2000 and 1 March 2019. Reference lists of the included studies were searched to identify other relevant studies. The search terms used are shown in Table 1.

Table 1. Search strategy PubMed

User query:
(: “negative pressure dressing”[Title/Abstract] OR “negative pressure therapy”[Title/Abstract] OR “negative pressure therapy system”[Title/Abstract] OR “negative pressure wound therapy”[Title/Abstract] OR “subatmospheric pressure dressing therapy”[Title/Abstract] OR “subatmospheric pressure dressing”[Title/Abstract] OR “subatmospheric pressure dressings”[Title/Abstract] OR “suction dressing”[Title/Abstract] OR “topical negative pressure”[Title/Abstract] OR “topical negative pressure therapy”[Title/Abstract] OR “topical negative pressure treatment”OR “topical negative pressure wound therapy”[Title/Abstract] OR “vac”[Title/Abstract] OR “vacuum assisted closure”[Title/Abstract] OR “vacuum assisted closure negative pressure wound therapy”[Title/Abstract] OR “vacuum assisted closure device”OR “vacuum assisted closure dressing”[Title/Abstract] AND “quality of life”[Title/Abstract] OR “quality of life/impact”[Title/Abstract] OR “quality of life/patient”[Title/Abstract] OR “quality of life/satisfaction”[Title/Abstract] OR “patient experiences”[Title/Abstract] OR “patients experiences”.[Title/Abstract]) AND ((“2000/01/01”[PDat] : “2019/03/01”[PDat]))

Study screening method

Eligibility of the studies was independently screened by two authors (AJ and JW) based on titles and abstracts. After this first selection, full-text versions of articles were obtained if they matched the eligibility criteria or if further scrutiny was needed regarding eligibility.

Data collection and analysis process

The first author (SJ) summarised the study characteristics, including the number of respondents, the NPWT devices used, and the types of wounds.

Appraisal process

The included studies were evaluated for their methodological quality using the Critical Appraisal Skills Program (CASP) for Qualitative Research.^[22] CASP is a validated tool and consists of 10 items (Table 2). Each item was independently assessed by three authors (AJ, JW, and TdVR) as ‘sufficient’ or ‘insufficient’. A consensus was obtained in case of different judgements. A study was considered good if at least 90% of the CASP items were graded as sufficient. All text under the headings ‘Results/Conclusion’ of the studies was extracted manually.

Table 2. Critical Appraisal Skills Programme (CASP) items to assess methodological quality in qualitative research

Items	
1	Was there a clear statement of the aims of the research?
2	Is a qualitative methodology appropriate?
3	Was the research design appropriate to address the aims of the research?
4	Was the recruitment strategy appropriate to the aims of the research?
5	Was the data collected in a way that addressed the research issue?
6	Has the relationship between researcher and participants been adequately considered?
7	Have ethical issues been taken into consideration?
8	Was the data analysis sufficiently rigorous?
9	Is there a clear statement of findings?
10	How valuable is the research?

Data collection and analysis process

The first author (SJ) summarised the study characteristics, including the design of the study, the number of respondents, NPWT devices used, types of wounds, and funding resources.

Content analysis was used to extract and define central themes in patients' personal experiences. This is a well-known and validated research technique to extract the content of a qualitative study objectively and systematically.^[23,24]

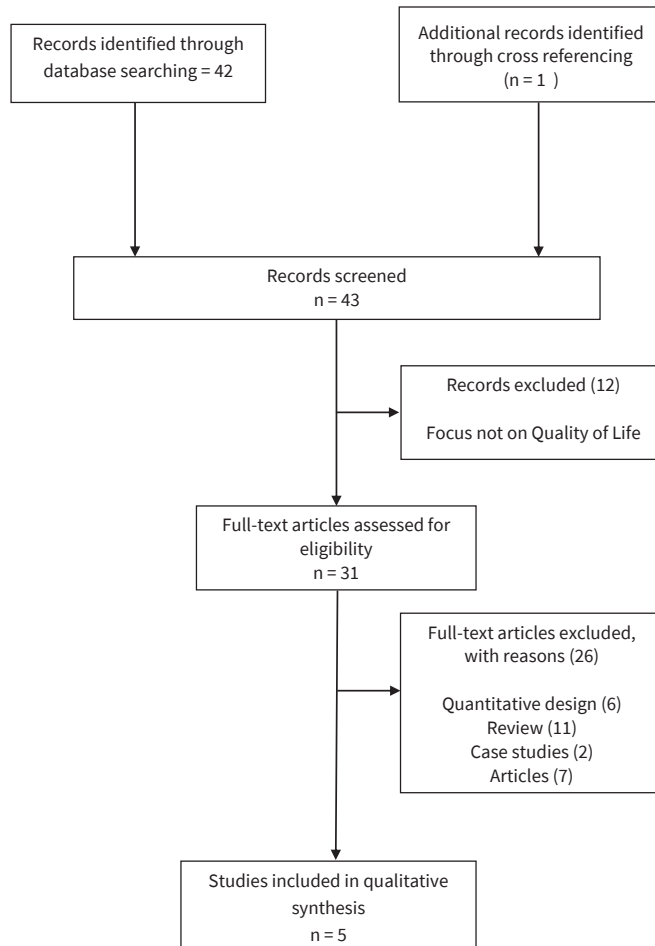
The results of each study were coded line by line to search for concepts. Subsequently, studies were coded into pre-existing concepts, and new concepts were created when deemed necessary.^[25] The selection of central themes that affect the QoL in patients treated with NPWT were agreed by two authors (AJ and JW). In an inductive thematic synthesis approach, salient themes are identified via coding of the data without the use of a preexisting coding frame or any preconceptions held by the analysts; therefore, the study is not purely inductive.^[26]

RESULTS

Literature search

The flow of information through the different phases of this systematic review is shown in Fig. 1. After screening 43 articles, five met the eligibility criteria in which a total of 51 individual patients shared their personal experiences with NPWT.^[27-31] The main reason we excluded studies was that the studies did not focus on QoL or had a non-qualitative research design.

Figure 1. Flow diagram



Characteristics of the included studies

Most of the studies ($n = 4$) included patients with a variety of hard-to-heal wounds and at different body locations.^[27, 28, 30, 31] Only one study solely investigated patients with wounds on the lower extremities.^[29] Of the five studies, two collected data while patients were still in treatment with NPWT,^[29,31] two studies collected data retrospectively,^[28,30] and one study did both.²⁷ Only one of the included patients received NPWT as an inpatient, all other patients received NPWT both in hospital (starting as an inpatient, then continuing as an outpatients) and at home.^[27-31]

The NPWT devices used were not described in two studies.^[28,31] In the other three studies, portable devices were used when the patient received NPWT at home.^[27,29,30] The number of participants ranged from six to 15. All studies were conducted between 2010 and 2013, in Europe.

Appraisal results

The methodological quality of each study using the relevant CASP items is shown in Table 3. CASP items not given in this table (1, 2, 7, 9, and 10), were equal and were graded as sufficient in the included studies. Ethical considerations for each study were clearly stated. The eligibility of the study by Moffat et al. was discussed because neither the number of patients refusing to participate nor the relationship between the researchers and the participants were mentioned.^[30] The study also received funding from an NPWT manufacturer. A consensus was reached that these findings had little impact on the methodological quality of the study and therefore the study by Moffat et al. was considered eligible for this review. Overall, all five included studies were considered to have good methodological quality.

Synthesis output

After content analysis, four central themes were identified, namely (1) Reduced freedom of movement caused by an electric device, (2) Decreased self-esteem, (3) Increased social and professional dependency, and (4) Gaining self-control. Table 4 highlights the most important findings per study. Below we describe the central themes in more detail.

1. *Reduced freedom of movement caused by an electric device*

Being ‘attached to a device’ results in physical limitations.^[27-29, 31] Patients feel that they are stuck to a device, resulting in reduced freedom of movement.^[27-29, 31] Patients indicate that they are faced with an unknown and impressive electrical device: an electric pump with a tube attached to their body.^[27, 31] The physical restrictions caused by the tube itself were mentioned several times. For some, it raised uneasiness and safety challenges as they had to make extra efforts not to trip over it, and not to forget their device when going to the bathroom.^[27-31]

Carrying an electric therapeutic device also has psychological consequences.^[28] The device could sound its alarm, at inappropriate times during the day or night, leading to anxiety.^[28-30] Patients experience these alarms as a threat, both for their safety and for the effectiveness of the therapy.^[28-30]

By being so obviously ‘in treatment’, they felt ashamed.^[27, 28, 31] Patients reported that they tried to cover the device and the tube with their clothes so that the family and visitors could not see the fluid running through the tube.^[27, 28, 31] Visits and trips were carefully planned around the status of the pump’s battery.^[28] Some patients preferred to stay at home, and radically reduced their social interactions.^[27, 28, 30] Patients indicated that they needed to be thoroughly informed about the device’s user manual and any constraints caused by using the NPWT device before being discharged.^[27, 28, 30, 31]

Table 3. Outcome of Critical Appraisal Skills Programme (CASP) - evaluation (including funding)

	Abbotts (2010)	Bolas (2012)	Fagerdahl (2013)	Moffatt (2011)	Ottosen (2013)
Design	subtle realism	a phenomenological approach based on Heideggerian philosophy	diaries	semi-structured interviews	phenomenological-hermeneutic framework interviews
Country	UK	UK	Sweden	UK	Denmark
n	12	6	15	8	10
Recruitment strategy	participating in focus group	participants were selected from the authors' clinical caseload. Nothing mentioned about if there were patients who refused to take part in the study	all patients who completed their diaries during the first year of recruitment were included	purposive, stratified sampling approach. Nothing mentioned about refusers	13 potential participants; of these, three refused
Data collection	focus group interview	semi-structured interviews	diaries	interviews	semi-structured interviews
Relationship between researcher and participants	yes	yes	yes	unknown	yes
Data-analysis	from the line-by-line transcript, data were coded according to the specific issues mentioned. A thematic analysis was manually undertaken	interpretative phenomenological analysis	according to Graneheim and Lundman	according to the 'Framework' method developed by the National Centre for Social Research.	based on a Ricoeur-inspired method
Funding	NHS Quality Improvement Scotland	unknown	none	manufacturer	none

Table 4. Main results per study

Title	Patients' view on topical negative pressure: 'effective but smelly'	Negative pressure wound therapy: a study on patient perspectives	Patients' experience of advanced wound treatment	Experience of patients with complex wounds and the use of NPT in a home-care setting	Patients' experiences of NPT in an outpatient setting in Denmark
Author (year published)	Abbotts (2010)	Bolas (2012)	Fagerdahl (2013)	Moffatt (2011)	Ottosen (2013)
Main themes	<ul style="list-style-type: none"> -healing, -smell, -embarrassment, -pain, -nurse training, -self-care, -information provision, -getting out of hospital, -getting back to normal. <p><i>'The nurses came on the Friday. It was fine Saturday. But by the time they were coming back on the Monday to change it was really reeking then and that's when the family smelt it.'</i></p>	<ul style="list-style-type: none"> -Altered sense of self (altered self-image / dependence on others) -New culture of technology (relationship with technology / patient education / staff education) -Leading a restricted life (physical restriction / social restriction) <p><i>'It made me feel very, very uncomfortable and very shy with it. Maybe not shy, but embarrassed ... it was so awkward and ugly.'</i></p>	<ul style="list-style-type: none"> Threat to normality (impact on daily life / manageability / powerlessness) <p><i>"Feels like being connected to an umbilical cord."</i></p> <p><i>'Looking back now, I would have said let's get everything in place before I get home. But my wife didn't know what the device was going to be like. I was really ill and my wife was under pressure and she was trying to deal with it, and to try and sort things out by yourself is asking a bit too much.'</i></p>	<ul style="list-style-type: none"> -Developing a wound through crisis (a failing body / missed diagnosis / failed professional intervention) -Decreased control (poor communication / failed wound healing / poor discharge planning / failure to recover) -Increased control (understanding what is happening / symptom control / positive professional relationships / returning to health) -Using NPWT (information / understanding of NPWT / expectations and experience of NPWT) -Participant recommendations about the device (device-related issues / improving professional practice) 	<ul style="list-style-type: none"> -'It works' -Dependency on and attachment to the technology -Embarrassment and odour -Anxiety, uneasiness and care -Need for care and support from relatives <p><i>'I can't manage without my husband's help, but the other person [the relative] should want to help, and I don't think that's always the case. Maybe it's distasteful for another person to look at?'</i></p>

NPWT-negative pressure wound therapy

2. *Decreased self-esteem*

Patients reported a clear psychological effect of having a wound.^[28, 30, 31] Patients who developed a wound infection after surgery, experienced this infection as a failure of their body,^[28, 30] and that their body's healing ability let them down.^[28, 30] Treatment with NPWT means living attached to a device which constantly reminds them of their wound.^[28] The shame of the wound and the inconveniences that accompanied this, such as pain, smell, inability to shower, the perceived ugly appearance of the wound, and dependence on others, gave them an unpleasant feeling.^[27, 28, 30, 31] Patients felt unattractive and had an altered sense of themselves.^[28, 29]

3. *Increased social and professional dependency*

The need for professional help and support from family and friends was often indicated by patients.^[28-31] This support, both psychological and practical, was considered very important.^[28-31] Motivational and practical support by family and friends for general daily activities, such as dressing up and , was mentioned.^[28, 31] The dependency that resulted in being constrained from fulfilling a normal role in the family led to social impairment.^[28]

Professional assistance was considered a requisite from caregivers (nurses) who are familiar with the working principles of NPWT, the progress of the wound healing, and the implications of this therapy for the patient.^[27-31] Before being discharged from the hospital, patients wanted to be instructed on who to turn to in the event of problems, who was going to change the bandages and where.^[27-31] Some patients preferred to have the vacuum sponge changed at home, others in the outpatient clinic.^[31]

4. *Gaining self-control*

With time, patients seemed to tolerate NPWT better. They understood 'what the therapy is doing, and that it works'.^[27, 29-31] Patients gained control over their situation and learn to respond to the alarm.^[27, 29, 30] Patients felt responsible for their healing process and became empowered.^[27, 29, 30] Learning how to handle the pump and the inconveniences associated with it helped in accepting this therapy.^[27, 29] At this point, patients may have experienced NPWT as a new, positive, and active therapy.^[27, 29] A positive professional relationship with the care provider, combined with family support, helped patients to accept NPWT.^[29-31]

DISCUSSION

This systematic review of qualitative studies gives valuable insights into the effects on the QoL of patients treated with NPWT. Based on the identified themes, NPWT results

in reduced freedom of movement caused by the electric device, decreased self-esteem, increased social and professional dependency, and a gain of self-control as the therapy progresses. Therefore, it can be concluded that NPWT leads to serious restrictions in the physical, psychological, and social domain of QoL. These insights may facilitate dialogue with patients and enable personalised, shared decision making with patients on their choice of treatment.

The findings in this study are in concordance with the results of a recently published quantitative systematic review that studied the differences in QoL between patients treated with NPWT and standard wound care.^[19] The authors concluded that NPWT patients had a lower QoL compared to standard wound care, possibly due to anxiety, during the first week of treatment. The anxiety can be explained by the size of the electric device with its alarms, tubes and the need for professional support. That review also revealed that QoL improved at the end of therapy, independent of which therapy was used. Huber et al.'s definition of 'positive health' as the ability of people to adapt to and control a new situation, in light of the physical, emotional, and social challenges of life, suggests that when the patient gets more control over their lives, independent of which treatment is chosen, this positively influences their image of health.^[32]

Limitations

The main limitation of this review is that wound location was heterogeneous among the included studies. Thereby, it could be suggested that any patient with a hard-to-heal wound may experience some degree of decreased self-esteem and increased need for support, independent of whether the patient is treated by NPWT or standard wound care. However, this study explicitly clarified that NPWT as a treatment modality by itself has a major impact on QoL. Thus, the choice for NPWT should be tailored to the patient. This also fits with the current paradigms of shared decision-making and person-centered care in health care.^[33]

The clinical observation of premature cessation of NPWT in our patients could be explained by the fact that the observed central themes in this study were not adequately discussed with the patients before commencing NPWT. NPWT was applied as the standard clinical routine to treat wounds with complicated healing.

Conclusion

The results of this study emphasise that a health professional should be aware of the strong effects of NPWT on patient QoL, and assess the ability of a patient to cope with such a device. The decision to use NPWT should be tailored to the patient. Performing this assessment, in a shared shared-decision-making setting, will lead to better identification of patients with a hard-to-heal wound who would benefit from NPWT or standard wound care.^[34]

This study may also provide input to the development of a decision-making algorithm, just like the review of outcomes of dysvascular partial foot amputation compared with transtibial amputation is suggested for use in developing shared decision-making resources.^[35]

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4

Which determinants are considered to be important for adherence to Negative Pressure Wound Therapy: A multimethods study

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Journal of Tissue Viability 2021; 30(2), 250–255.

ABSTRACT

Aim

To explore the extent of patients that choose to cease Negative Pressure Wound Therapy (NPWT) prematurely in a clinical setting, and to explore the determinants of nonadherence.

Method

This study exists out of: (1) a retrospective study to assess the number of patients who ceased NPWT prematurely; (2) a narrative review (NR) to identify determinants of nonadherence; and (3) a survey among wound care specialists to explore specific determinants of nonadherence to NPWT.

Results

- (1) Based on the retrospective study, 20% ceased NPWT prematurely because of experienced limitations in daily activities.
- (2) Based on 22 studies, 23 determinants that might influence nonadherence were identified and added as questions in the survey.
- (3) Twenty-two percent (n=136) wound care specialists completed the survey. Confidence with the healthcare team, consistency in therapy advices, coping with pain, former negative experiences with NPWT, a normal activity pattern, social support from family or friends, and support from the healthcare team were identified as highly relevant determinants of nonadherence to NPWT. Only religion scored distinctively lower.

Conclusion

This study is a first step in exploring the determinants of nonadherence to NPWT. In 20% NPWT was prematurely ceased at the request of the patient, this means that this therapy may have not been the best choice of therapy for this particular patient. The identification of potential determinants of nonadherence may help healthcare professionals in their dialogue with patients. The next step should be a prognostic study to assess which determinants best predict adherence to NPWT.

INTRODUCTION

Negative Pressure Wound Therapy (NPWT) has been used to aid healing since the late 1990s. NPWT consists of continuously or intermittently negative pressure to the wound surface, frequently varying between -125 and -75 mmHg depending on the material used and patient acceptability.^[1] It intends to accelerate wound healing by increasing the local blood flow, removal of bacteria, debris, and oedema, and contracting the wound edges together.^[1-9] NPWT can be used until granulation tissue has been formed up to the level of the skin.^[10]

In many clinics, NPWT is the first choice of treatment for (slightly) deeper wounds.^[11-13] Since the introduction of NPWT, it has expanded to currently several thousand applications each day worldwide. This includes acute wounds (e.g., postoperatively infected wounds), but also chronic wounds (e.g. pressure ulcers, diabetic foot ulcers and leg ulcers).^[14]

Although NPWT is widely used, available Cochrane systematic reviews emphasize the lack of rigorous evidence on effectiveness of NPWT when applied on leg ulcers, pressure ulcers and surgical wounds healing by secondary intention.^[15-17] Thereby, the success of NPWT is not only determined by its efficacy, but also by its impact on the patients' quality of life (QoL). When a patient experiences a deterioration of QoL due to NPWT, e.g., a restriction in performing daily activities, this may lead to a premature cessation of therapy and a switch to standard wound care (SWC). Even though wound healing may not be delayed by this therapy switch, the patient may have suffered from the initially prescribed therapy which in fact implicates that NPWT was not the best choice of therapy for this particular patient. Up to now, it is unclear how many patients with open wounds cease NPWT prematurely and which factors contribute to this decision. Several studies have been conducted on determinants of adherence to other therapies, such as wearing compression stockings to prevent and treat leg ulcers. Wrong perceptions of the cause and healing of leg ulceration, the need for health education, the socioeconomic and the sociocultural status of patients are pointed out to be determinants of adherence to these therapies.^[18-20]

Being conscious of the specific determinants of adherence to NPWT, stated as no premature cessation of therapy on request of the patient, is important to balance the pros and cons of NPWT for individual situations. This will subsequently enable personalized shared decision making with patients on the treatment choice. Therefore, the aim of this study was (1) to explore the extent of patients prematurely ceased NPWT, (2) to identify general determinants of nonadherence, and (3) to explore specific determinants of nonadherence to NPWT in the Netherlands.

METHODS

A multimethods sequential design was used, including three studies : (1) a retrospective chart study to assess the number of patients who ceased NPWT prematurely; (2) a narrative review to identify general determinants of nonadherence; and (3) a survey among wound care specialists to explore the specific determinants of nonadherence to NPWT. Findings from each study wer used to plan and conduct the next study. This study is reported according to applicable criteria of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement and the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).^[21, 22]

The Medical Research Involving Human Subjects ACT (WMO) does not apply to our research project. Because the WMO only applies to research where there is an infringement of the physical and/or psychological integrity of the subject, official approval of this project by a Medical Ethics Review Committee was not required.^[23]

Study 1: Retrospective chart study.

The charts of patients who were treated for abdominal wound dehiscences (due to infection or other causes) at a general hospital in the Netherlands were reviewed. This general hospital with 450 beds, has two surgical units, and a wound expertise center. Retrospective data were collected over a 5-year period from June 2012 to December 2017. The number of patients treated with NPWT, the number of patients who prematurely ceased the therapy and the reason for this decision (if reported) were noted. In addition, we collected patient characteristics (e.g., age, Body Mass Index and medication), surgical indication, comorbidities (e.g., Diabetes Mellitus and Chronic Obstructive Pulmonary Disease) and treatment related issues (i.e., duration of NPWT and time to achieve complete wound healing).

Study 2: Narrative review

The literature search focused on the identification of general determinants for the adherence to healthcare related therapies. A search was carried out in the leading bibliographic database MEDLINE/PubMed to find eligible studies, covering the period up to April 2018. The keywords used were: “adherence” OR “compliance” OR “engagement” OR “concordance” AND “determinants” AND “therapy”. No restriction was used on publication year for the included studies. Furthermore, the reference lists of eligible articles were searched to identify additional studies (snowballing technique).

We included scientific reports, reviews and clinical trials, with a focus on determinants of adherence to healthcare related therapies. Furthermore, the studies should be published in peer-reviewed journals in English and full text must be available. Studies

with a focus on medication adherence were excluded, because of the different impact on the QoL.

After selecting the studies, a narrative synthesis was conducted. Findings of the included studies were categorized using the framework of Köberlein et al.^[24] This framework comprises of five dimensions of determinants of patient adherence; (1) social/economics determinants, (2) treatment related determinants, (3) patient related determinants, (4) condition related determinants, and (5) health system determinants.^[24]

Study 3: National survey among wound care specialists

To specify the general determinants of adherence to healthcare related therapies, explored from the literature review, into more specific determinants of adherence to NPWT, a survey was developed. Subsequently a national e-survey (sent by e-mail) was held among 620 Dutch wound care nurses, all members of a Dutch professional association of wound care nurses (Verpleegkundigen & Verzorgenden Nederland, Department of Wound expertise). Per determinant retrieved from the literature and our own retrospective study, the wound care nurses were asked to indicate on a 10-point scale how decisive they thought this determinant was with respect to the adherence to NPWT. Zero points indicated not decisive at all, and 10 points indicated a highly determinative factor. Two weeks after the first email, a reminder was sent.

Data were analyzed using IBM SPSS Statistics 64 for Windows (SPSS Inc., Chicago IL, USA). As our data appeared not to be normally distributed, we reported the median and interquartile range (IQR) per determinant.

RESULTS

Study 1: Retrospective chart study

In our general hospital, 131 patients were treated for abdominal wound dehiscences. Of these patients, 84 patients (64%) were treated with NPWT. In all cases, NPWT was started while the patient was hospitalized, and continued in the home care setting. The ACTIV.A.C.™ Therapy System of KCI-Medical was used, and the foam was changed twice a week.

An overview of the baseline characteristics is shown in Table 1. Thirty-two of the 84 patients (38%) ceased NPWT prematurely, 17 of these 32 patients (53%) because they felt (too) limited by the therapy in their daily activities. See table 2 for the reasons for premature cessation of NPWT. All cessations took place in the outpatient clinic. Overall, 17 patients out of the 84 (20%) patients chose to cease NPWT prematurely due to experienced restrictions in daily life caused by NPWT. Mean age of these 17 patients was 61 years (SD=16.0), ranging from 30 to 81 years. They felt uncomfortable with an electric

device, due to the alarms and flickering lights. It made them feel anxious and uncertain. Furthermore, the location of the wound and therefore, the location of the tube at the body resulted in inconveniences in performing their daily life activities and their ability to perform their jobs.

Table 1 Study 1: Retrospective chart study - Baseline characteristics.

	NPWT (N=84)	SWC (N=47)
Mean age in years (SD)	64 (13)	63 (15)
Number of smokers: n (%)	10 (12)	4 (9)
BMI: n (%)		
> 25	6 (7)	19 (40)
20-25	77 (92)	26 (55)
< 20	1 (1)	2 (4)
Diabetes Mellitus: n (%)	12 (14)	10 (21)
Corticosteroids and / or rheumatism medication: n (%)	12 (14)	6 (13)
Emergency surgery (<24 hour): n (%)	21 (25)	17 (36)
Surgery*: n (%)		
Ventral hernia repair	24 (29)	3 (6)
Bowel surgery	56 (67)	41 (87)
Cholecystectomy	2 (2)	3 (6)
Splenectomy	2 (2)	1 (2)
Vascular surgery	2 (2)	0
Mean time to complete wound healing in days (SD)	210 (310)	168 (64)

NPWT Negative Pressure Wound Therapy; SWC Standard Wound care; SD Standard Deviation; BMI Body Mass Index

*Some patients underwent both bowel and ventral hernia repair surgery in one procedure

Table 2 Study 1: Retrospective chart study - Reasons for premature cessation of NPWT

Reason for premature cessation of therapy	N (%)
Feeling (too) limited in daily activities	17 (54)
Infection	5 (16)
Re-surgery	3 (9)
Other	2 (6)
Necrosis of the wound bed	1 (3)
Start of chemo radiation and narrow sinus	1 (3)
Fragile fascia	1 (3)
Fistula	1 (3)
Wound deterioration	1 (3)

Study 2: narrative review

The literature search yielded 124 articles. These were reduced to 22 by further selection on title, from which full text evaluation yielded sixteen relevant articles that were included in this review. An overview of the characteristics of the included studies is

presented in Table 3. Mainly, reviews (n = 7) and studies with a qualitative design (n = 5) were included. All studies but one described the determinants of (non)adherence to prescribed therapies. (See table 3) They are described in more detail below. From the literature, we compiled a list of 23 determinants that might influence adherence to NPWT.

1. Social/economics determinants

Several articles described an association between age and nonadherence. If patients are older, the chance of nonadherence increases.^[25, 26] In contrast to this, the cohort study of Tinker et al. showed that a being younger increases the probability of nonadherence to dietary advices.^[27] Also higher and lower levels of education are found to be determinants of nonadherence.^[25, 27-31] This inconsistency is also found according to culture and religion as determinants of adherence. One study found that being an immigrant was associated with higher attrition^[29]; however, another found that overall, no significant effect of ethnicity was observed.^[28] Manduz et al. found that one of the three most frequent reasons for irregular use and discontinuation of wearing compression stockings was that the stockings prevented them from performing ablutions.^[19]

The results of studies on social support from family and friends are more consistent, showing that motivation from family and friends stimulates adherence.^[20, 25, 32-35] Also unemployment is mentioned as a determinant of nonadherence.^[25]

2. Treatment related determinants

Previous negative experiences as well as hearing about negative experiences with the therapy from others are found to be a determinants of nonadherence.^[19, 25, 34] The included studies also showed that having a sensitive skin, and not being able to shower resulted in nonadherence to therapy.^[18-20] Autonomy, as the patients' sense of self-regulation in formulating their goals, and self-efficacy is found to be a strong modifiable predictor of adherence.^[20, 25, 27, 33, 34, 36]

Understanding the therapy is indicated as a determinant of adherence in several included studies.^[25, 33, 34, 36, 37] Patients were less adherent when the doctor omitted to explain the purpose of the therapy.^[32] Besides this, the expectations of therapy, being convinced of the appropriateness, usefulness, and effectiveness of the treatment stimulates adherence to the therapy.^[27, 38]

3. Patient related determinants

Three studies found that pain attributed to nonadherence.^[18, 20, 33] Also, anxiety, and the patients' mood affects adherence to lifestyle interventions.^[25] Furthermore, it was shown that the feeling of being attached to a device resulted in physical limitations.^[39]

Chapter 4 | Which determinants are considered to be important for adherence to NPWT:
A multimethods study

Table 3 - Study 2: Narrative Review- Characteristics of the included studies

First author,	Year of publication	Country	Subject	Study design	N
Becker ^[32]	1975	USA	Sociobehavioral determinants of adherence with health and medical care recommendations	Literature review, hypothetical model development	Unclear
Bolas ^[39]	2012	Ireland	Patient perspectives on Negative Pressure Therapy	Phenomenological study	6
Burgess ^[25]	2017	Australia	Determinants of adherence to lifestyle intervention in adults with obesity	Systematic review	24 studies
Courneya ^[26]	2010	Canada	Predictors of Adherence to Supervised Exercise in Lymphoma Patients	Randomized Trial	60 participants
Edwards ^[18]	2003	London	Compliance to compression bandaging	Hermeneutic approach (interviews)	14 participants
Glanz ^[37]	1990	USA	Health behavior and health education	Book chapter	
Golin ^[34]	1996	USA	Model of the determinants of adherence to diabetes self-care	Literature review	Unclear
Heijnen ^[33]	2007	The Netherlands	Sedentary patients with venous or mixed leg ulcers: determinants of physical activity	Qualitative research: interviews that combined both semi-structured and open-ended questions.	25 participants
Manduz ^[19]	2018	Turkey	The level of awareness and the attitude of patients recommended for use of compression stockings in Turkish society, and investigation of the factors affecting their use	Face-to-face questionnaire	1,004 participants
McAuley ^[35]	2000	USA	Self-efficacy determinants and consequences of physical activity	Review	
Renzi ^[38]	2002	Italy	Association of dissatisfaction with care and psychiatric morbidity with poor treatment adherence	Longitudinal study (self-completed questionnaires and telephone interviews)	396 participants
Riachy ^[41]	2016	Lebanon	Factors predicting CPAP adherence in obstructive sleep apnea syndrome	Cross-sectional study	138 participants
Roumen ^[36]	2009	The Netherlands	Lifestyle intervention for prevention of diabetes: determinants of success for future implementation	Review	16 studies
Thorneloe ^[40]	2013	United Kingdom	Adherence to medication in patients with psoriasis	Systematic literature review	29 studies

Table 3 - Study 2: Narrative Review- Characteristics of the included studies (continued)

First author,	Year of publication	Country	Subject	Study design	N
Tinker ^[27]	2007	USA	Predictors of dietary change and maintenance in the Women's Health Initiative Dietary Modification Trial	Longitudinal study	19,541 participants
Van Hecke ^[20]	2011	Belgium	Adherence to leg ulcer lifestyle advice	Systematic review	31 studies

4. Condition related determinants

Multi-morbidity was identified as a main determinant of nonadherence in two of the studies.^[20, 33] In contrast to this, one study found a reversed association of a higher adherence being associated with an improved disease severity.^[32]

5. Health system determinants

Nurses mentioned that non-adherent behavior might be affected by organizational determinants, such as inadequate staff or resources, and the type of care setting.^[20] Possibly, the relationship between the healthcare professional and the patient and the confidence the patient has in the healthcare professional could be even more determinative.^[18, 20, 32, 34, 40] Active support from the healthcare professional in terms of frequent contact resulted in a better adherence.^[27, 33, 36, 41]

Two studies revealed the inconsistency in advice by healthcare professionals as one of the primary reasons for nonadherence.^[19, 20] A shared decision/discussing alternative treatment options is likely to improve the adherence to self-care.^[34] Tailored information and advice may increase the intention to adopt a certain lifestyle aspect.^[36]

Study 3: National Survey

In total, 136 of 620 (22%) members of a Dutch professional association of wound care nurses responded.

Potential determinants of nonadherence to NPWT

An overview of the scores of potential determinants of nonadherence to NPWT are shown in Table 4. Seven potential determinants of nonadherence to NPWT had a median score of eight; confidence with healthcare team, consistency in therapy advices, coping with pain, former negative experiences with NPWT, a normal activity pattern, social support from family or friends, and support from the healthcare team. In contrast, religion had a median score of four. Other low scored items (median score six) were ability to take a shower, autonomy, culture, education, and work satisfaction.

Table 4 - Study 3: National survey- Overview of potential determinants of nonadherence to NPWT

Potential determinant	Median (IQR)
Confidence in healthcare team	8 (2)
Consistency in therapy advices	8 (1)
Coping with pain	8 (2)
Former negative experiences with NPWT	8 (1)
Normal activity pattern	8 (2)
Social support from family, friends	8 (1)
Support from care team	8 (2)
Sensitive skin	7,5 (3)
Age	7 (4)
Coping with anxiety	7 (1)
Decision for NPWT made in a Shared Decision way	7 (2)
Expectations of NPWT	7 (3)
Handiness technique	7 (2)
Heard from negative experiences with NPWT from others	7 (3)
Illness experience	7 (3)
Knowledge and understanding of NPWT	7 (3)
Relation between healthcare professional and patient	7 (3)
Setting were NPWT is given	7 (3)
Work status	7 (2)
Wound location	7 (3)
Ability to take a shower	6 (3)
Autonomy	6 (3)
Culture	6 (3)
Education	6 (3)
Work satisfaction	6 (3)
Religion	4 (3)

NPWT Negative Pressure Wound Therapy; IQR Interquartile range

DISCUSSION

One fifth of the patients choose to cease NPWT prematurely, due to restrictions in their daily activities. For a patient-centred approach in wound care, it is important to be familiar with potential determinants that may influence this nonadherence. Based on a retrospective study and a narrative review we were able to identify 26 general determinants of nonadherence to treatment regimes. Most of these determinants were not investigated in wound care. However, based on the clinical expertise of wound care nurses, most of the determinants were also considered to be relevant regarding adherence to NPWT. Only religion scored distinctively lower and is therefore considered as less relevant.

The specific determinants of adherence to NPWT, described in this study, are in line with the findings of Szabo et al.^[42] In their systematic review on patient adherence to burn care, they explored that discomfort and physical limitations are determinants being associated with nonadherence. Also, being convinced of the efficacy of treatment, social support, and personal factors (e.g., the use of coping strategies) as well as knowledge and understanding of the treatment increased the adherence to the treatment.^[42, 43] However, none of the included studies in the review of Szabo et al. examined which determinants had the strongest association to treatment adherence.

Furthermore, another study explored nonadherence to chronic wound treatments.^[44] They reported that both patients and professionals agreed that patients' lifestyle preferences and motivation were often critical to patients' decision-making about adherence to treatment. However, professionals and the industry rarely considered these preferences when making treatment decisions.^[44] The main provider of NPWT devices did recognize the problems with nonadherence to this therapy and developed a remote therapy monitoring (RTM) system to be used in the home care setting.^[45] In conjunction with RTM, a network of trained professionals call patients when their NPWT usage is low and provide education to assist with therapy adherence, and to motivate the patient to maintain the therapy. Based on the evaluation research of the RTM system, it was found that influencing patient adherence through active engagement has the potential to improve outcomes and reduce the costs of wounds.^[46]

This example shows that adherence is a multidimensional phenomenon determined by the influence and interaction of different factors. Therefore, patients are not solely responsible for adherence to the therapy, as their behavior can be affected by a range of factors.^[24] Insight into these factors helps to stimulate shared-decision making (SDM) in treatment choices. SDM is more than just informing patients about the pros and cons, but is an extensive process in which professionals and patients work together to select tests, treatments, management or support packages, based on best available evidence and the person's informed preferences.^[47] This process can be challenging in wound care choices, especially concerning NPWT. There is still an ongoing discussion about the efficacy of NPWT applied to wounds of different aetiologies. Therefore, it might be even more important to explore the patient's preferences before starting wound therapy.^[15-17] If we are familiar with which properties and circumstances determines whether a patient accomplishes NPWT till the endpoint (as determined at the start of the therapy), we can discuss these factors with the patients before the choice of therapy is made. These steps support SDM and tailor therapy to the patient. This is assumed to lead to a better QoL for the patient, and to improve the quality and efficiency of healthcare.

Limitations

Some limitations of this study should be mentioned. In the retrospective study, we focused only on the number of patients who prematurely ceased the therapy and the reason for this decision. We were not able to conduct subgroup analyses as our sample size was not large enough. Therefore we were not able to investigate if there is an association between patient and treatment characteristics for nonadherence (e.g. duration of treatment, location of treatment, and age). We used a narrative review to get insight in the existing evidence; however, this method is open for debate, as we did not follow a rigorously systematic approach. Furthermore, all studies were given equal consideration rather than evaluating the quality of the evidence related to adherence. This may have led to the bias of the author's interpretation and conclusions.^[48] However, predictors of adherence were extracted and judged by independent wound care specialists.

Another limitation is the inclusion of only those studies whose main topic of research was adherence. This may have caused exclusion of articles with another main focus but nonetheless discussed adherence to healthcare related therapies. We have tried to offset this limitation by adding a final question in the survey to ask if the participant missed a potential determinant.

The response rate of the survey was 22%, but this rather low response is conform survey response rates in other fields of research.^[49] Empirical assessments over the past decade have led to an increasing recognition that the degree to which sampled respondents differ from the survey population as a whole (i.e., nonresponse bias) is central to evaluating the representativeness of a survey, rather than response rates per se.^[50, 51]

In this study, only specialized wound care nurses were contacted. On the other hand, in the Netherlands, NPWT is mostly coordinated and applied by specialized wound care nurses. Therefore, we think that the results of our study are quite robust. Another limitation of our study is that we did not asked patients in the assessment of the potential determinants but used the experience of wound care nurses. We realize that caregivers' view is not always consistent with the experiences of patients.^[20] However, based on a 5-year analysis on nonadherence in our hospital, it is known that nonadherence is a serious problem in the treatment of NPWT. Notably, one fifth of the patients with dehiscent abdominal wounds, ceased NPWT prematurely.

Conclusion

This study is the first step in exploring the determinants of adherence to NPWT. Nonadherence to treatment is a worldwide problem and can result in poor health outcomes and increased healthcare costs.^[24] If NPWT is prematurely ceased at the request of the patient, this means that this therapy may have not been the best choice of therapy for this particular patient. This study yielded a combination of patient characteristics and non-medical characteristics as potential predictive determinants. The next step should

be a prospective prognostic study, measuring all explored determinants and to assess which determinants best predict adherence to NPWT. Knowledge of these determinants may facilitate the dialogue with patients and thus, help to tailor and personalize the decision of therapy to the patients characteristics and preferences.

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Chapter 4 | Which determinants are considered to be important for adherence to NPWT:
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5

**The association of potential prognostic
determinants to nonadherence
to negative pressure wound therapy: An
exploratory prospective
prognostic study**

**Helmond study
HELderheid in (on)MOgelijkheden van
Negatieve Druktherapie
(Clarity in (im)possibilities of Negative
Pressure Wound Therapy)**

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Surgery 2022; 172(1), 349–357

ABSTRACT

Background

Up to now it is unclear which determinants influence nonadherence to negative pressure wound therapy. This study aimed to assess the predictive value of prognostic determinants to nonadherence to negative pressure wound therapy (NPWT).

Methods

A multicenter prospective cohort study on patients with wounds treated with NPWT. Data of 25 potential prognostic determinants of nonadherence were collected using a web-based case record form. Primary outcome was nonadherence to NPWT, defined as premature termination on request of the patient. Logistic regression analyses were used to explore the association between the potential determinants and nonadherence.

Results

Nonadherence to negative pressure wound therapy was found in 32 out of 264 patients (12.1%). Univariable analyses identified six candidate prognostic determinants: having a sensitive skin (OR 2.32, 95% CI 1.10-5.10, $p = .03$), decision for NPWT made as a shared decision (OR 2.43, 95% CI 1.06-6.30, $p = .05$), handiness technique (OR 1.80, 95% CI 0.86-3.89, $p = .13$), alternatives discussed (OR 1.78, 95% CI 0.83-3.75, $p = .13$), knowledge and understanding NPWT (OR 0.50, 95% CI 0.18-1.20, $p = .15$) and previous experience with NPWT (OR 0.42, 95% CI 0.10-1.24, $p = .17$). In the multivariable analysis, only having a sensitive skin appeared to be significant (OR 2.20, 95% CI 1.02-4.85, $p = 0.05$).

Conclusion

Patients who have a sensitive skin may have an increased risk of premature termination of NPWT. Further research is warranted to determine which strategies are successful to overcome skin irritation problems to avoid nonadherence to NPWT.

INTRODUCTION

It is estimated that 1.5 – 2 million people in Europe suffer from acute or chronic wounds.^[1] In light of the socio-economic impact of wounds and the international trend to promote value-based healthcare, it is essential that wound care leads to fast healing and minimizes discomfort and pain for patients against the lowest possible burden on quality of life (QoL) and the healthcare system.^[2, 3] Most wounds are historically treated by standard wound care, compromising daily cleansing of wounds and application of wound materials that provide a moist wound environment, facilitate granulation, and stimulate wound healing.^[4, 5]

An alternative treatment option is Negative Pressure Wound Therapy (NPWT) which has, since its introduction in 1995, expanded to several thousand applications each day worldwide.^[6] NPWT consists of foam or gauze, film, vacuum, drainage, and cannister and intends to accelerate wound healing by increasing local blood flow, removal of bacteria, debris and edema and contracting the wound edges together.^[7-12] Nevertheless, available Cochrane systematic reviews on NPWT emphasize lack of rigorous randomized controlled trial (RCT) evidence of the effectiveness of NPWT.^[13-15] The fact that NPWT was not developed to achieve complete wound closure, which is considered the most clinically meaningful outcome in wound treatment efficacy studies, may be one of the causes.^[16] In addition, a quantitative systematic review compared SWC with NPWT and demonstrated that NPWT negatively influences QoL during the first treatment week; after this period, QoL scores were similar.^[17] A qualitative review on the impact of NPWT on QoL demonstrated four major themes: (1) reduced freedom of movement caused by an electric device; (2) decreased self-esteem; (3) increased social and professional dependency and (4) increased self-control (with time).^[18] The first three experiences can lead to premature termination of NPWT by patients, even before eventually reaching the point of better tolerance and becoming more accustomed to the therapy (theme 4). This premature termination, defined as termination of the therapy before the aim (granulation tissue up to skin level) is reached, is confirmed in a cross-sectional study that was carried out in the Netherlands.^[19] It was found that over one third of the patients with postoperatively infected abdominal wounds who were primarily treated with NPWT terminated this therapy prematurely. The most important reasons given for this were negative experiences in daily life (anxiety) and inconvenience caused by the electronic device.^[19]

Based on a preliminary narrative study considering general determinants of nonadherence and a survey among wound care specialists to indicate the importance of these determinants with respect to the adherence to NPWT, a list of 25 potential prognostic determinants predicting nonadherence to NPWT was drawn up.^[19] (table 1)

To date, it is unclear which of these 25 potential prognostic determinants indicated by wound care specialists best predicts patient nonadherence to NPWT, defined as the patient's choice to prematurely terminate NPWT. Exploration of the association of each determinant to nonadherence to NPWT will support the process of preselection of predictors for the development of a prediction model that can assist patients and healthcare providers in therapeutic decision-making. Awareness of the most associative determinants helps patients and their specialists to select a treatment that is best suited to each individual patient.

Table 1. Overview of 25 potential determinants of nonadherence to Negative Pressure Wound Therapy

Potential determinant
Ability to take a shower
Age
Autonomy
Confidence in healthcare team
Consistency in therapy advices
Coping with anxiety
Coping with pain
Culture
Decision for NPWT made in a Shared Decision way
Education
Expectations of NPWT
Former negative experiences with NPWT
Handiness technique
Heard from negative experiences with NPWT from others
Illness experience
Knowledge and understanding of NPWT
Normal activity pattern
Relation between healthcare professional and patient
Sensitive skin
Setting were NPWT is given
Social support from family, friends
Support from care team
Work satisfaction
Work status
Wound location

MATERIALS AND METHODS

Study design

This multicenter prospective observational cohort study on patients receiving NPWT was designed to explore the association of potential determinants to nonadherence to NPWT. The study was conducted according to the principles of the Declaration of Helsinki (version 7, October 2013). The need for ethical approval was waived by the Central Committee on Research Involving Human Subjects (CCMO) Radboud University Medical Centre Nijmegen in the Netherlands because the Medical Research Involving Human

Subjects Act (WMO) does not apply to our study protocol (reference number 2019-5108). The checklist according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement was followed to describe the design of the study. ^[20] According to the General Data Protection Regulation (GDPR), data were collected anonymously and untraceably.

Participants

Sixteen hospitals (1 academic hospital, 3 teaching hospitals, 10 general hospitals and 2 private centers) in the Netherlands participated in this study. All adult patients (≥ 18 years) with any type of wound treated with NPWT were eligible for inclusion the study, after verbal and written informed consent. Prescription of NPWT was undertaken by a hospital-based (wound care) specialist. No strict policies regarding the application of NPWT were prescribed, with the exception that the subatmospheric pressure should be set between 80 and 125 mmHg, continuously. Local wound care guidelines should be used at the application of NPWT and wound edges should be protected by the use of a hydrocolloid.

Data collection

A web-based case record form was designed for collecting data of baseline determinants and 25 potential prognostic determinants of nonadherence. These determinants were indicated in another study by wound care specialists as potential predictors of patient nonadherence to NPWT.^[19] Each local wound-care specialist received a personal login code for the online electronic database (Castor EDC, 2020.2 The Netherlands), to collect their patients' data. Only the central coordinator (AHJJ) had access to the anonymized data of all centers. When NPWT was started, data were retrieved from patient charts and additional information was requested from the patient, mainly in the form of multiple choice questions such as sex, etiology, and NPWT device, and ordinal scoring scale items such as coping with pain, illness and experience, ranging from 1 to 5. The length, width, and depth of the wound were measured using a ruler. The volume (length x width x depth) of the wound was calculated by entering the wound dimensions into the database. Data of health system determinants such as confidence in the healthcare team, decision for NPWT made as a shared decision, and outcomes data were collected after the conclusion of NPWT. The wound care specialist registered whether the goal of NPWT, such as granulation up to the skin level or the wound is ready for skin grafting, was achieved. When the goal was not achieved, the reason for premature termination of NPWT was noted in the database and categorized into termination on advice of the wound care specialist for reasons such as infection or deterioration of the wound, and nonadherence defined as premature termination of NPWT at the patient's request for reasons such as excessive irritation of the skin and limitations in daily life.

Sample size

Based on the inclusion of 84 patients with postoperative abdominal wounds treated with NPWT at a general hospital within 5.5 years in a retrospective chart study to assess the number of patients who prematurely ceased NPWT,^[19] we expected to include at least 244 patients within 1 year in 16 hospitals. We conducted univariable regression analyses and included variables with the lowest p-values into the multivariable linear regression analyses using forward selection. The principle of event per variable rate (EPV) was used.^[21]

Handling of missing data

In the case of missing data ($\leq 10\%$ per variable) in the dataset, pairwise deletion was used minimizing loss of data in logistic regression analysis, assuming missing data were completely at random (MCAR). Associations between determinants and nonadherence found in pairwise analysis were compared to complete case analysis to evaluate the MCAR assumption.

Statistical analysis

Statistical analyses were performed using statistical software package R (version 4.0.4), R Foundation for Statistical Computing, Vienna, Austria.^[22] Descriptive statistics were used to describe patients' baseline characteristics. Continuous determinants were expressed as mean and standard deviation or as median and interquartile range (IQR) in case of a skewed distribution. In case of non-linearity, continuous determinants were dichotomized, the cut-off point was chosen closest to the median value of both determinants.^[23] Categorical determinants and ordinal scoring scale items were presented as counts and percentages (%). Linearity and outliers in ordinal data were evaluated in scatterplots. To simplify development of the model, nominal and ordinal data were dichotomized, preventing infrequent occurrence in groups, if possible. Scores of 1, 2 and 3 on the Likert scales were categorized as low and scores of 4 and 5 as high.^[23, 24]

In univariable logistic regression analyses, the association between determinants and nonadherence to NPWT was explored. Candidate prognostic determinants for nonadherence to NPWT were defined for determinants with a p-value ≤ 0.20 .^[25] In a post hoc analysis, univariable logistic regression analysis of having sensitive skin and nonadherence to NPWT due to skin irritation was performed to explore any association. Determinants with the lowest p-values in the univariable analyses were entered into a forward multivariable logistic regression analysis. Odds ratios, p-values and 95% confidence intervals were calculated and a p-value $\leq 0,05$ was considered significant.^[26, 27] The EPV rule 1:10 was applied for the maximum number of potential prognostic determinants included in the multivariable logistic analysis preventing erroneous inclusion of determinants into the model, and based only on chance.^[28]

RESULTS

Between January 25, 2019 and May 13, 2020, a total of 264 patients treated with NPWT from 16 hospitals in the Netherlands agreed to participate in this study. Four patients refused participation and five had missing data in 4 health system determinants (1.5 - 1.9% missing data per determinant), which were collected after concluding NPWT. Due to the coronavirus disease -2019 (COVID-19) pandemic that started in the Netherlands in March 2020, we were forced to prematurely terminate the study prior to reaching the desired sample size.

Baseline characteristics of the cohort

The cohort comprises 157 males (59.5%) and 107 females (40.5 %) with a median age of 68 years (IQR 57-75). Patients with different types of wounds were included, including surgical (n=137; 51.9 %), traumatic (n=45, 17 %) and hard-to-heal wounds (n=82, 31.1%) such as pressure ulcers, venous and arterial leg ulcers, and diabetic foot ulcers. The median wound size at the onset of NPWT was 36 cm³ (IQR 8-106). The majority of wounds were located on the feet and legs (n=166, 62.9 %). The median length of NPWT treatment was 31 days (IQR 19-48) and did not significantly differ (p=0.68, Kruskal-Wallis test) among the different wound etiologies (surgical wounds median 29.0 days (IQR 21-47); trauma wounds median 30,0 days (IQR 18-37), hard-to-heal wounds median 31.0 days (IQR 19-53). In terms of NPWT devices, 232 patients (87.9%) were treated with portable devices and 33 (12.1%) with nonportable devices. Baseline characteristics of the cohort can be found in Table 2 (section baseline determinants). Additionally, the distribution of the number of patients for each determinant is described in Table 2 (section potential prognostic determinants and section prognostic health system determinants).

Premature termination of NPWT

The goal of NPWT was reached in 173 patients (65.5%); 91 (34.5%) prematurely terminated NPWT. More than one-third of these patients (n=32 out of 91, 35.2 %) terminated NPWT at the patient's request due to irritation of skin (n=14, 5.3%), limitation in daily life (n=9, 3.4%), excessive pain (n=7, 2.7%), or nuisance from the noise of the pump (n=2, 0.8 %). Overall, in 32 out of 264 (12.1%) patients, termination of NPWT at the patient's request was defined as nonadherence. Most patients who terminated NPWT decided to stop on the advice of the wound care specialist (n=59 out of 91, 64.8%), due to noneffective wound healing (n=32, 12.1%) or infection (n=22, 8.3%). Other reasons for premature termination were starting a surgical intervention (n=4, 1.5%) or sudden death (n=1, 0.4%). Reasons for termination of NPWT are listed in Table 3.

Chapter 5 | The association of potential prognostic determinants to nonadherence to NPWT:
An exploratory prospective prognostic study

Table 2. Description of the cohort (n=264)

Baseline determinants	n	%	Median (IQR)
Etiology			
Surgical wounds	137	51.9	
Traumatic wounds	45	17.0	
Hard to heal wounds:	82	31.1	
Pressure ulcer	9	3.4	
Arterial ulcer	11	4.2	
Diabetic foot wound	51	19.3	
Oncological wound	6	2.3	
Other	5	1.9	
Age (years)			
≤ 65	115	43.6	68 (57-75)*
> 65	149	56.4	
Device			
Portable			
ActiVAC	232	87.9	
Vac Via	204	77.3	
Snap	1	0.4	
Renasys Go	10	3.8	
PICO	14	5.3	
PICO	3	1.1	
Nonportable			
InfoVAC	32	12.1	
Vac Ultra	7	2.7	
Vac Ultra	25	9.5	
Length of NPWT treatment (days)			31 (19-48)*
Location Wound			
Arm	9	3.4	
Leg	83	31.4	
Foot	83	31.4	
Chest	14	5.3	
Abdominal	47	17.8	
Perineal	1	0.4	
Spine	4	1.5	
Tuber ischii	2	0.8	
Buttocks	6	2.3	
Hip	3	1.1	
Groin	8	3.0	
Os coccygis	4	1.5	
Sex			
Male	157	59.5	
Female	107	40.5	
Wound-dimensions at start NPWT (cm³)			36 (8 – 106)*
≤ 35	127	48.1	
> 35	137	51.9	
Potential prognostic determinants			
Activity pattern			
1 Not active	10	3.8	
2	28	10.6	
3	54	20.5	
4	74	28.0	
5 Very active	98	37.1	

Table 2. Description of the cohort (n=264) (continued)

Autonomy		
1 Very unimportant	91	34.5
2	41	15.5
3	43	16.3
4	41	15.5
5 Very Important	48	18.2
Coping with anxiety		
1 Very hard coping with anxiety	129	48.9
2	49	18.6
3	36	13.6
4	35	13.3
5 Very easy coping with anxiety	15	5.7
Coping with pain		
1 Very hard coping with pain	8	3.0
2	8	3.0
3	43	16.3
4	106	40.2
5 Very easy coping with pain	99	37.5
Cultural Background		
Dutch	247	93.6
Other	17	6.4
Expectations of NPWT		
1 Very useless	5	1.9
2	7	2.7
3	43	16.3
4	82	31.1
5 Very useful	127	48.1
Previous Experience with NPWT		
Yes	49	18.6
Yes, positive	32	12.1
Yes, neutral	10	3.8
Yes, negative	7	2.7
No	215	81.4
Handiness technique		
1 Not very handy	37	14.0
2	45	17.0
3	41	15.5
4	67	25.4
5 Very handy	74	28.0
Having a sensitive skin		
Yes	117	44.3
No	147	55.7
Heard of negative experience with NPWT from others		
Yes	7	2.7
No	257	97.3
Highest Level of Education		
Primary and Secondary Education	125	47.3
Vocational and Higher Education	139	52.7

Chapter 5 | The association of potential prognostic determinants to nonadherence to NPWT:
An exploratory prospective prognostic study

Table 2. Description of the cohort (n=264) (continued)

Illness experience		
1 Not so ill	150	56.8
2	50	18.9
3	36	13.6
4	19	7.2
5 Very ill	9	3.4
Knowledge and understanding NPWT		
1 I understand nothing about it	17	6.4
2	17	6.4
3	45	17.0
4	80	30.3
5 I understand everything about it	105	39.8
Limitation of taking a shower		
1 Not annoying at all	44	16.7
2	46	17.4
3	53	20.1
4	47	17.8
5 Very annoying	74	28.0
Setting where NPWT is given		
Home	170	64.4
Not at home	94	35.6
Social Support		
Yes	248	93.9
No	16	6.1
Work status		
At work	74	28.0
Not at work	190	72.0
Prognostic health system determinants		
NA (n)	n	%
Alternatives discussed		
Yes	92	34.8
No	172	65.2
Confidence in healthcare team		
1 No confidence	2	0.8
2	2	0.8
3	13	4.9
4	80	30.3
5 Very much confidence	167	63.3
Consistency in therapy advice		
1 Very inconsistent	5	1.9
2	7	2.7
3	6	2.3
4	28	10.6
5 Very consistent	68	25.8
	150	56.8

Table 2. Description of the cohort (n=264) (continued)

Prognostic health system determinants		n	%
NA (n)			
Decision for NPWT made as a shared decision			
Yes			
Yes, that was nice		163	61.7
Yes, it was not nice		158	59.8
No			
No, I don't like that		101	38.3
No, I like that		84	31.8
		17	6.4
Relation between NPWT health care specialist and patient			
1 Very dissatisfied	4	5	1.5
2		1	0.4
3		14	5.3
4		67	25.4
5 Very satisfied		173	65.5
Relation between NPWT subscriber and patient			
1 Very dissatisfied	4	4	1.5
2		0	0
3		9	3.4
4		64	24.2
5 Very satisfied		183	69.3
Support from care team			
1 Very dissatisfied	4		1.5
2		3	1.1
3		2	0.8
4		11	4.2
5 Very satisfied		83	31.4
		161	61.0

NA, Not Applicable; n, number of patients; IQR, Inter Quartile Range; NPWT, Negative Pressure Wound Therapy
*skewed distribution

Table 3. Reasons for premature termination NPWT (N=264)

Reason for termination NPWT	n	%
Premature termination NPWT	91	34.5
on request of the patient (nonadherence)	32	12.1
skin irritation	14	5.3
limitation in daily life	9	3.4
excessive pain	7	2.7
nuisance from noise of the pump	2	0.8
advised by NPWT wound care specialist	59	22.3
wound healing was not effective	32	12.1
infection	22	8.3
other reasons	5	1.9
surgical intervention	4	1.5
death	1	0.4

n, number of patients; NPWT, Negative Pressure Wound Therapy

Univariable analysis

Univariable analysis showed no significant difference in nonadherence between the surgical wounds and wounds due to other etiologies (see Table 4). An overview of the univariable association of determinants to termination on request of the patient are shown in Table 5. A significant association was noted for two determinants, having sensitive skin (OR 2.32, 95% CI 1.10-5.10, $p = 0.03$) and the decision for NPWT made as a shared decision (OR 2.43, 95% CI 1.06-6.30, $p = 0.05$). An additional four determinants appeared as a candidate prognostic determinant with a p -value ≤ 0.20 , handiness technique (OR 1.80, 95% CI 0.86-3.89, $p = 0.13$), alternatives discussed (OR 1.78, 95% CI 0.83-3.75, $p = 0.13$), knowledge and understanding of NPWT (OR 0.50, 95% CI 0.18-1.20, $p = 0.15$) and previous experience with NPWT (OR 0.42, 95% CI 0.10-1.24, $p = 0.17$). A univariable regression analysis between having sensitive skin and nonadherence to NPWT due to irritation of the skin resulted in a significant association (OR 8.29, 95% CI 2.20-53.97, $p < 0.01$) (Table 6).

Table 4. Univariable analysis of etiology and wound location, and nonadherence to NPWT (n=264)

Etiology / Location wound	Nonadherence	Adherence	OR	95 % CI	p*
Surgical wounds	16	121			
Traumatic wounds	3	42	1.85	0.58-8.24	0.35
Hard-to-heal wounds	13	69	0.70	0.32-1.57	0.38
Foot and leg	17	149			
Other	15	83	0.63	0.30-1.34	0.23

OR, Odds Ratio; 95%CI, Confidence Interval; p, p-value; NPWT, Negative Pressure Wound Therapy

* Summary Waldtest

Table 5. Univariable analysis of determinants and nonadherence to NPWT (n=264)

Baseline determinants					
Determinant	Non-adh* Adherence**		OR	95 % CI	p***
Etiology					
Surgical wounds	16	121			
Traumatic wounds	3	42	1.85	0.58 – 8.24	0.35
Hard to heal wounds	13	69	0.70	0.32 – 1.57	0.38
Age (years)			1.00	0.98 – 1.03	0.74
Age (decade)			1.05	0.80 – 1.35	0.74
Age					
≤ 65	15	100			
> 65	17	132	1.16	0.55 – 2.45	0.69
Device					
Portable	30	202			
Non- portable	2	30	2.23	0.63 – 14.21	0.29
Location Wound					
Foot and Leg	17	149			
Other	15	83	0.63	0.30 – 1.34	0.23
Sex					
Male	16	141			
Female	16	91	0.64	0.31 – 1.36	0.25
Wound- dimensions (cm³)					
Wound-dimensions (100 cm ³)					0
Wound-dimensions					
≤ 35	17	110	1.00	1.00 – 1.00	.94
> 35	15	122	1.26	0.60 – 2.66	0.55
Potential prognostic determinants					
Determinant	Nonadherence* Adherence**		OR	95 %CI	p***
Activity pattern					
Low (1-3)	12	80			
High (4-5)	20	152	1.14	0.52 – 2.42	0.74
Autonomy					
Low (1-3)	18	157			
High (4-5)	14	75	0.61	0.29 – 1.32	0.20
Coping with anxiety					
Low (1-3)	26	188			
High (4-5)	6	44	1.01	0.42 – 2.85	0.98
Coping with pain					
Low (1-3)	7	52			
High (4-5)	25	180	0.97	0.37 – 2.26	0.95
Cultural Background					
Dutch	30	217			
Other	2	15	1.04	0.27 – 6.78	0.96
Expectations of NPWT					
Low (1-3)	7	48			
High (4-5)	25	184	1.07	0.41 – 2.51	0.88

Chapter 5 | The association of potential prognostic determinants to nonadherence to NPWT:
An exploratory prospective prognostic study

Table 5. Univariable analysis of determinants and nonadherence to NPWT (n=264) (continued)

Potential prognostic determinants					
Previous experience with NPWT					
Yes (Positive, Negative and Neutral)	3	46			
No	29	186	0.42	0.10 – 1.24	0.17
Previous positive experience with NPWT					
Yes	2	30			
No (Not, Negative and Neutral)	30	202	0.45	0.07 – 1.60	0.29
Handiness technique					
Low (1-3)	19	104			
High (4-5)	13	128	1.80	0.86 – 3.89	0.13
Having a sensitive skin					
Yes	20	97			
No	12	135	2.32	1.10 – 5.10	0.03
Heard of negative experience with NPWT from others					
Yes	1	6			
No	31	226	1.22	0.06 – 7.44	0.86
Highest level of education					
Primary and secondary education	13	112			
Vocational and higher education	19	120	0.73	0.34 – 1.54	0.42
Illness experience					
Low (1-3)	28	208			
High (4-5)	4	24	0.81	0.29 – 2.90	0.71
Knowledge and understanding NPWT					
Low (1-3)	6	73			
High (4-5)	26	159	0.50	0.18 – 1.20	0.15
Limitation of taking a shower					
Low (1-3)	17	126			
High (4-5)	15	106	0.95	0.45 – 2.02	0.90
Setting where NPWT is given					
At home	20	150			
Not at home	12	82	0.91	0.43 – 2.01	0.81
Social support					
Yes	29	219			
No	3	13	0.57	0.17 – 2.61	0.41
Work status					
At work	8	66			
Not at work	24	166	0.84	0.34 – 1.89	0.68

Table 5. Univariable analysis of determinants and nonadherence to NPWT (n=264) (continued)

Prognostic health system determinants					
Determinant	Nonadherence* Adherence**		OR	95% CI	p***
Alternatives discussed					
Yes	15	77			
No	17	155	1.78	0.83 – 3.75	0.13
Confidence in healthcare team					
Low (1-3)	1	16			
High (4-5)	31	216	0.44	0.02 – 2.25	0.43
Consistency in therapy advice (N=259)					
Low (1-3)	5	36			
High (4-5)	26	192	1.02	0.33 – 2.65	0.96
Decision for NPWT made as a shared decision					
Yes					
No	25	138			
	7	94	2.43	1.06 – 6.30	0.05
Relation between NPWT wound care specialist and patient (N=259)					
Low (1-3)	2	18			
High (4-5)	29	210	0.80	0.12 – 2.99	0.78
Relation between NPWT subscriber and patient (N=259)					
Low (1-3)	1	12			
High (4-5)	30	216	0.60	0.03 – 3.21	0.63
Support from care team (N=259)					
Low (1-3)	3	13			
High (4-5)	28	215	1.77	0.39 – 5.92	0.39

Non-adh, Nonadherence; OR, Odds Ratio; 95 % CI, Confidence Interval; p, p-value; NPWT, Negative Pressure Wound Therapy

*Nonadherence – termination of NPWT on request of the patient (table 2)

**Adherence – goal achieved, or termination advised by NPWT wound care specialist or other reasons (table 2)

*** Summary Waldtest

Chapter 5 | The association of potential prognostic determinants to nonadherence to NPWT:
An exploratory prospective prognostic study

Table 6. Univariable analysis of having a sensitive skin and nonadherence to NPWT due to skin irritation (n=264)

Determinant	Nonadherence due to skin irritation	Adherence or termination for any other reason	OR	95 % CI	p*
Having a sensitive skin					
Yes	12	105			
No	2	145	8.29	2.20 – 53.97	< 0.01

OR, Odds Ratio; 95%CI, Confidence Interval; p, p-value; **NPWT**, Negative Pressure Wound Therapy

* Summary Waldtest

Multivariable analysis

A maximum of three determinants were selected in the forward multivariable logistic analysis due to the EPV (1:10) in a sample of 264 patients. After stepwise addition of the determinant decision for NPWT made as a shared decision to the determinant having sensitive skin in the multivariable analysis, only having sensitive skin appeared as a significant determinant (OR 2.20, 95% CI 1.02-4.85, p = 0.04) (Table 7).

Table 7. Multivariable regression analysis of prognostic determinants and nonadherence to NPWT (forward analysis, N=264)

Potential prognostic determinants	OR	95% CI	p*
Having a sensitive skin	2.20	1.02 – 4.85	0.04
Decision for NPWT made as a shared decision	2.29	0.99 – 5.96	0.07

OR, Odds Ratio; 95%CI, Confidence Interval; p, p-value; **NPWT**, Negative Pressure Wound Therapy

* Summary Waldtest

Impact of missing data

Univariable analysis undertaken in a complete case analysis (listwise deletion) resulted in similar significant association and selection of candidate prognostic determinants as pairwise univariable analysis (see Supplementary Table S1).

DISCUSSION

In this study, more than one third of the participants terminated NPWT before the goal was achieved. Thirty-five percent of these patients requested for termination of NPWT due to patient related determinants. Six candidate prognostic determinants were identified, indicating an ability to predict nonadherence to NPWT, from which having sensitive skin and the decision for NPWT made as a shared decision were significantly associated with nonadherence to NPWT. Sensitive skin increasing nonadherence to NPWT confirms the expectation of this association by Dutch wound care specialists in a national survey.^[19] Worldwide, ~60–70% of women and 50–60% of men report having some degree of sensitive skin.^[29] In our study, 44.3% of patients labeled their skin as ‘sensitive’. The

majority of patients who prematurely terminated NPWT due to skin irritation had mentioned having sensitive skin before the onset of treatment, indicating that this potential prognostic determinant could be important in predicting nonadherence. A significant association found in a univariable analysis of having sensitive skin and nonadherence to NPWT due to skin irritation reinforced this assumption. Peri-wound skin is often delicate and can easily be affected by the use of medical adhesives associated with wound care products.^[30] The majority of participants used a polyurethane occlusive foil and an electrically powered device (Table 2). The number of participants with a mechanically powered device was too small (n=10) for sub analysis to determine whether they experienced more or less skin irritations caused by the therapy. The main manufacturer of NPWT devices and disposables has already acknowledged a skin irritation problem associated with their devices and products, and in the near future plans to launch a novel silicone-acrylic drape that seems to be more skin-friendly.^[30]

The second determinant significantly associated with nonadherence to NPWT, the decision for NPWT made as a shared decision, was also mentioned as a potential determinant for nonadherence to NPWT in a national survey among wound care specialists in the Netherlands.^[19] Remarkably, when the decision for NPWT was made as a shared decision, a significant increase of odds to nonadherence (although with a wide confidence interval) to NPWT was seen, indicating that shared decision making (SDM) resulted in increased nonadherence. SDM has been defined as ‘an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences’.^[31] Awareness of alternative options could be an explanation for the increase in nonadherence. This assumption is reinforced by the fact that the determinant ‘discussing alternative wound therapies’ was identified as a candidate prognostic predictor of increased NPWT nonadherence.

The SDM process, patient characteristics, clinical context, patient outcomes, and design of decision tools are challenges that actually impact SDM performance in clinical practice.^[32] In our study, we do not know exactly how the SDM process was conducted in each institution, and whether all challenges mentioned above were addressed. Since this is unclear, careful interpretation the significant association between SDM and nonadherence to NPWT found in our study must be taken.

More knowledge and understanding of NPWT lead to an increase of odds to nonadherence, contradicting the assumption of wound care specialists in the Netherlands that this determinant improves adherence to therapy.^[19] In a qualitative study on patients’ experiences regarding their wound treatment with NPWT in a home-care setting, it was found that patients seemed to better tolerate NPWT as the therapy progresses.^[33] In our study, patients were asked to describe their personal knowledge and understanding NPWT at start of the therapy. We do not know how the education and training process

was conducted prior to the start of NPWT, or whether patients were educated by the wound care professional during their twice weekly wound dressing changes.

A better understanding of the technique leads to a decreased likelihood of nonadherence to NPWT; this may be related to an increased feeling of control during NPWT. In a systematic review of NPWT for patients with hard-to-heal wounds, two qualitative studies also demonstrated that an increased knowledge on how to handle the pump helped patients to accept the therapy.^[18, 34, 35]

In addition, prior experience with NPWT was identified as a candidate prognostic determinant of decreased nonadherence to NPWT. Most of the patients' prior experience in our study were indicated as positive, motivating patients to continue their therapy. This association, as well as the reverse that prior negative experiences is a determinant for nonadherence, was also found in several other studies on nonadherence to different health care therapies.^[36-38] Having a former positive experience seems to result in an intrinsic motivation to continue the therapy until the ultimate goal is achieved.

No significant differences between the different wound types and nonadherence were found. It seems that the nature of the therapy, more than the wound etiology and location, is determinative for nonadherence. Due to the low number of some wound locations, such as the hip (n=3) and perineal wounds (n=1), this association needs to be further explored in future studies.

Strengths and limitations

This study has some strengths. Due to the COVID-19 pandemic, we were forced to prematurely terminate the study, before reaching the desired events (premature termination of NPWT on request of the patient). However, the inclusion of 264 patients provided a strong basis to explore the association between potential prognostic determinants to nonadherence to NPWT, which should be further tested in prediction and causation studies.^[39, 40] Prognostic modelling in small datasets when plausible prior predictive associations are unknown is hard, for the number of determinants to be tested in a prediction study should be reduced when the EPV (1:10) is violated. However, the rule of thumb of ≥ 10 EPV in logistic models is not a well-defined clear distinction and systematic discounting of results from any model with less EPV does not appear to be justified.^[41] Although preselection of the best predictors is preferred, instability of this selection, limited power, and overestimated regression coefficients should be considered in case of small datasets combined with a large set of determinants.^[42] Identification of the predictive value of candidate prognostic determinants is a first step for preselection of determinants based on predictive association to nonadherence.

Another strength of this study is the limited amount of missing data. In order to address missing data, pair wise deletion was used to handle the missing data leading to less loss of power. Comparing the univariable analysis done in a complete case

analysis (listwise deletion) and pairwise univariable analysis, similar results were found; therefore the assumption of MCAR was accepted. Furthermore, only 4 patients refused participation in the study.

There are also some limitations that need to be addressed. First, the decision of premature termination of patient inclusion was made three months after the start of the lockdown due to the COVID-19 pandemic. In addition, travel restrictions made it difficult for patients to come to the hospital for their normally weekly or twice weekly dressing changes. Furthermore, it was strongly advised to limit face-to-face contact, and a shift from providing regular health care toward urgent services only seen.^[43] For this reason, 49 patients who participated in the study between March to August 2020 could be influenced by these restrictions in their decision of early termination of NPWT. However, based on the finding that only 3 out of 49 patients terminated NPWT at the patient's request during this period, we expect a limited effect on the results.

Second, exploration of 30 determinants in a univariable regression analysis using a data set with 32 events of nonadherence to NPWT resulted in a low EPV value. Therefore, due to a lack of power, true predictors could have been excluded in the selection of candidate prognostic determinants.^[42] Conversely, covariables may be included because of multiple testing.^[42] However, because of the explorative phase of this study, no correction for multiple testing on the probability value was made.^[44] The associations found between nonadherence to NPWT and the candidate prognostic determinants have to be considered as indicative and is not a definitive estimate of the strength. In future research, larger datasets resulting in higher EPVs are needed to determine stronger evidence for association.

We did not use a clear definition of 'sensitive skin, but instead used the patients' own judgement in defining having sensitive skin at the start of NPWT. Since sensitive skin can appear normal, it is common to use the patients' self-declared judgement of having sensitive skin.^[45, 46] For this reason, we do not know exactly what kind of skin irritation occurred in those patients who prematurely ceased NPWT. It might be that the sensitive skin did not tolerate the foil, the skin became macerated by the foil, or the exudate or the foam overlapped the wound edges. The precise cause and appearance of the skin irritation should be explored in future studies.

Lastly, data were collected in a web-based survey, the majority as multiple choice items and ordinal scoring scale items. The specific language used in the survey questions can have significant impact on the subjects' responses. For example, a yes/no question with regard to sensitive skin or rating the degree of sensitivity (e.g. "very", "moderate", "slightly", "not") resulted in a different prevalence of having sensitive skin, also depending on the choice of the cut-off point.^[29] In this study, ordinal scoring scale items were dichotomized into a low score (1-3) and a high score (4,5) to simplify modelling, inducing bias caused by choosing cut-off points based on avoiding infrequent occurrence in cat-

egories. In future prediction studies, decisions for dichotomization need to be validated in order to determine appropriate cut-off points.

Conclusion

This study is, to the best of our knowledge, the first prospective observational cohort study to explore the association between potential prognostic determinants and nonadherence to NPWT. Based on our findings, the determinant of having sensitive skin seems to be important as predictor for nonadherence to NPWT. This finding may encourage wound care specialists and patients with sensitive skin to start a dialogue about the risk of skin irritation in their choice of wound therapy. This study is a first step in the preselection of candidate determinants predicting nonadherence to NPWT. The next step should be a prediction study using larger datasets resulting in higher EPVs.

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Chapter 5 | The association of potential prognostic determinants to nonadherence to NPWT:
An exploratory prospective prognostic study

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Table S1 Complete case analysis

Univariable analysis of determinants and non-adherence to NPWT (n=259)

Baseline determinants					
Determinant	Non-adh*	Adherence**	OR	95 % CI	p***
Etiology					
Surgical wounds	16	119		0.72	
Traumatic wounds	2	40	2.69	-17.48	0.20
Hard to heal wounds	13	69	0.71	0.32 – 1.59	0.40
Age (years)			1.00	0.98 – 1.03	0.78
Age (decade)			1.04	0.79 – 1.35	0.78
Age					
≤ 65	15	99			
> 65	16	129	1.22	0.57 – 2.60	0.60
Device					
Portable	29	198			
Non- portable	2	30	2.20	0.62 – 4.02	0.30
Location Wound					
Foot and Leg	17	149			
Other	14	79	0.68	0.32 – 1.47	0.32
Sex					
Male	15	140			
Female	16	88	0.59	0.28 – 1.26	0.17
Wound-dimensions (cm ³)			1.00	1.00 – 1.00	0.97
Wound-dimensions (100 cm ³)					
Wound dimensions			1.00	0.97 – 1.09	0.97
≤ 35	16	108			
> 35	15	120	1.19	0.56 – 2.53	0.66
Potential prognostic determinants					
Determinant	Non-adh*	Adherence**	OR	95 % CI	p***
Activity pattern					
Low(1-3)	11	79			
High (4-5)	20	149	1.04	0.46 – 2.24	0.93
Autonomy					
Low(1-3)	18	154			
High (4-5)	13	74	0.66	0.31 – 1.46	0.30
Coping with anxiety					
Low(1-3)	25	186			
High (4-5)	6	42	0.94	0.38 – 2.66	0.90
Coping with pain					
Low(1-3)	7	50			
High (4-5)	24	178	1.04	0.39 – 2.44	0.94
Cultural Background					
Dutch	29	213			
Other	2	15	1.02	0.27 – 6.69	0.98
Expectations of NPWT					
Low(1-3)	7	47			
High (4-5)	24	181	1.12	0.43 – 2.56	0.80

Chapter 5 | The association of potential prognostic determinants to nonadherence to NPWT:
An exploratory prospective prognostic study

Table S1 Complete case analysis (continued)

Potential prognostic determinants					
Previous experience with NPWT					
Yes (Positive, Negative and Neutral)	3	45			
No	28	183	0.44	0.10 – 1.30	0.19
Previous positive experience with NPWT					
Yes	2	29			
No (Not, Negative and Neutral)	29	199	0.47	0.07 – 1.69	0.32
Handiness technique					
Low (1-3)	19	100			
High (4-5)	12	128	2.03	0.95 – 4.48	0.07
Having a sensitive skin					
Yes	19	93			
No	12	135	2.30	1.08 – 5.09	0.03
Heard of negative experience with NPWT from others					
Yes	1	6			
No	30	222	1.23	0.06 – 7.57	0.85
Highest level of education					
Primary and secondary education	13	108			
Vocational and higher education	18	120	0.80	0.37 – 1.70	0.57
Illness experience					
Low (1-3)	27	205			
High (4-5)	4	23	0.76	0.27 – 2.73	0.63
Knowledge and understanding NPWT					
Low (1-3)	6	70			
High (4-5)	25	158	0.54	0.19 – 1.30	0.20
Limitation of taking a shower					
Low (1-3)	17	125			
High (4-5)	14	103	1.00	0.47 – 2.16	1.00
Setting where NPWT is given					
At home	19	149			
Not at home	12	79	0.84	0.39 – 1.86	0.66
Social support					
Yes	28	215			
No	3	13	0.56	0.17 – 2.57	0.39
Work status					
At work	8	66			
Not at work	23	162	0.85	0.34 – 1.93	0.72
Prognostic health system determinants					
Determinant	Non-adh*	Adherence**	OR	95 % CI	p***
Alternatives discussed					
Yes	15	76			
No	16	152	1.88	0.87 – 4.01	0.10
Confidence in healthcare team					
Low (1-3)	1	16			
High (4-5)	30	212	0.44	0.02 – 2.29	0.44

Table S1 Complete case analysis (continued)

Prognostic health system determinants					
Consistency in therapy advice					
Low (1-3)	5	36			
High (4-5)	26	192	1.02	0.33 – 2.65	0.96
Decision for NPWT made as a Shared Decision					
Yes	24	135			
No	7	93	2.36	1.02 – 6.14	0.06
Relation between NPWT wound care specialist and patient					
Low (1-3)	2	18			
High (4-5)	29	210	0.80	0.12 – 2.99	0.78
Relation between NPWT subscriber and patient					
Low (1-3)	1	12			
High (4-5)	30	216	0.60	0.03 – 3.21	0.63
Support from care team					
Low (1-3)	3	13			
High (4-5)	28	215	1.77	0.39 – 5.92	0.39

Non-adh, Non-adherence; OR, Odds Ratio; 95 % CI, Confidence Interval; p, p-value; **NPWT**, Negative Pressure Wound Therapy

*Non-adherence – termination of NPWT on request of the patient (table 2)

**Adherence – goal achieved, or termination advised by NPWT wound care specialist or other reasons (table 2)

*** Summary Waldtest

6

Preferences of patients treated with negative pressure wound therapy in relation to shared decision making and participation in wound care, a qualitative study using thematic analysis

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Submitted to Journal of Wound Care June 20, 2022. Under Review.

ABSTRACT

Aims

To explore the experiences and preferences of patients with wounds, treated with negative pressure wound therapy (NPWT) regarding shared decision making and patient participation.

Methods

Semi-structured interviews with 10 adults treated with NPWT. Interview topics included shared decision making and patients' active participation in wound treatment. Thematic analysis was applied to identify themes.

Results

Four themes emerged: (1) Having a wound makes patients uncertain and thus influences quality of life; (2) NPWT influences patients' daily lives; (3) Patients consider professional treatment decisions most important in decision making processes; (4) Self-management of wounds is accepted by patients only for low-complexity well-healing wounds under supervision.

Conclusion

Participants emphasized their worries about the future and the impact of the wound / -treatment on their families. After being thoroughly informed, participants preferred that healthcare professionals decide on the treatment choice. In addition, participants and/or their relatives did not want to actively participate in complex wound care. In addition to expressing a need for qualified wound care professionals, participants reported that they did not want to be or feel responsible for the wound treatment.

Shared decision making and active patient participation are underused and underexposed topics in wound care. Patients' recognition of the importance of their personal preferences can facilitate shared decision making.

INTRODUCTION

Patients with a wound experience physical, psychological, social, and financial consequences that significantly affect their daily quality of life (QoL) and overall well-being.^[1, 2] Self-motivation and self-control in wound care have been demonstrated to improve patient QoL.^[1] Thus, stimulating patient participation in wound care can provide value for a patient.^[1] Patient involvement in wound management requires the right patient having access to the right services and information, which will give them the knowledge and confidence to make informed decisions about their own care.^[1] In this process of shared decision making, a health care professional and patient jointly collaborate to make a healthcare decision after discussing the options, benefits, and harms, and considering the patients' values, preferences, and circumstances.^[3] Although the principles of value-based health care dictate a general implementation of shared decision making, this process has not been widely applied in the daily practice of wound care.^[3] Studies of the use of shared decision making tools for diseases like breast or colonic cancer have led to strong recommendations that guide clinical practice, because these diseases have been extensively studied.^[4] However, in the field of wound care, high-quality evidence is lacking for many of the most commonly utilized treatment options,^[5] which makes it even more important to discuss patients' preferences.

Lack of therapeutic evidence is particularly apparent for the widely used wound treatment modality negative pressure wound therapy (NPWT).^[6, 7] Prior research has found that NPWT can have major effects on the physical, psychological, and social domains of patient QoL.^[8] The Cochrane database emphasizes the lack of rigorous evidence regarding the effectiveness of this therapy when applied to leg ulcers, pressure ulcers, and surgical wounds healing by secondary intention.^[9-11] This wide field of unknown knowledge hampers the implementation of shared decision making in wound care.

To increase knowledge in this area and stimulate shared decision making in wound care, patients' preferences regarding wound care must be explored. However, eliciting and translating patient preferences in wound care is challenging.^[4] Patient involvement in treatment decisions requires a patient to be able to make decisions with knowledge and confidence. Extensive information about the possibilities of care, combined with the availability and accessibility of supporting services, are quintessential for this process.^[1] To stimulate shared decision making, each patient's preferences regarding wound care should be explored in different stages of treatment.^[12] A recent editorial claimed that the principle of patient-centered care can be simplified to: "What does the patient want?"^[13] The key questions of whether a patient has a preference for a specific treatment, wants to make a treatment choice themselves, and/or wants to implement wound care treatment themselves, rather than being dependent on healthcare professionals,

must be addressed, particularly since active patient participation in dressing changes is uncommon during NPWT.^[14]

This study aims to explore the experiences and preferences of patients with wounds treated with NPWT regarding shared decision making and patient participation.

METHODS

This study was conducted according to the Critical Appraisal Skills Programme (CASP) and reported according to applicable criteria of the COnsolidated criteria for REporting Qualitative research (Coreq; see Supplementary table S1).^[15, 16] The Medical Research Involving Human Subjects Act (WMO) only applies to research that involves an infringement of the physical and/or psychological integrity of the subject; thus, official approval of this project by a Medical Ethics Review Committee was not required, and this project was granted a waiver from the Medical Ethics Review Committee (waiver nr. W19 385 # 19.450). Participants did not receive compensation for participating in this study.

Study design and setting

A qualitative study was conducted at a general hospital in the Netherlands that has 450 beds, two surgical units, and a wound expertise center. The wound expertise center, under the leadership of a clinical nurse specialist in wound care, treats approximately 600 patients with wounds each year, including those who are admitted and those treated in the outpatient clinic. The main wound types treated are diabetic foot ulcers and wounds caused by vascular insufficiencies. Patients are treated by a multidisciplinary team that includes a (vascular) surgeon, podiatrist, plaster technician, and rehabilitation specialist.

Participants and recruitment

Eligible participants who had completed NPWT treatment were asked to participate in this study and provided verbal and written informed consent. All participants were adults (≥ 18 years) who had any type of wound that had been treated with NPWT less than a year prior to the time of the interview. The NPWT treatment for all patients was initiated in the hospital and continued in the home care setting. As part of their wound treatment, patients received follow-up care at the wound expertise center.

Eligible participants were asked to participate in the study by the nurse specialist either in person at the outpatient clinic or by phone. Participation in the study was voluntary. Purposeful criterion sampling was used to ensure the sample was varied in baseline characteristics such as age, gender, and work status and to identify and select information-rich cases.^[17] The sample size was set at ten participants provided data saturation had been reached by the end of the initial interviews.

Data collection

A semi-structured interview topic list was developed based on prior research^[1, 12, 18] and existing knowledge within the interdisciplinary study group (i.e., two nurse scientists, two surgeons, and two nurse specialists; see Appendix 2). The first author [AHJJ] conducted the interviews, guided by the topic list. The first three interviews were pilot interviews to test the topic list. After the pilot interviews, one question was added to the topic list: “What do you need for shared decision making / active participation in wound treatment?” Data from the pilot interviews were not included in this study.

The main research questions this study addresses are as follows:

- a. How do patients experience the impact of their wound and wound treatment on the psychological domain of quality of life?
- b. To what extent do patients wish to participate in the choice of treatment and the wound care itself?

Interviews were conducted face-to-face, either at home or in the hospital, depending on the participants’ preference. All interviews were audio recorded with full consent of the patient. The interviewer took notes during the interview to improve the credibility of the data.^[19] The trustworthiness of the interview data was established through the sampling approach (i.e., variation) and by generating a nonjudgmental atmosphere during the interview.^[20, 21] Only the participant was present during the interview. All others (e.g., caregivers, relatives) were asked to leave the room to ensure participants could speak freely.

First, participants were asked to share their experiences of living with a wound and NPWT. Next, the patient’s experiences and wishes regarding patient participation in shared decision making about therapy and wound care were discussed. The final part of the interview examined the patient’s experiences receiving health care, and the final question asked whether the patient would choose to receive NPWT in the future. Baseline characteristics were collected for each participant, as well as relevant information about medical history and the wound.

Data analysis

The interview recordings were transcribed verbatim. The first five interviews were transcribed manually by the interviewer, and the last five were transcribed using an online transcription program (Amber-script, <https://www.amberscript.com>).^[22] All transcripts were manually checked by the first author [AHJJ]. Data collection and analysis occurred concurrently to enable constant comparison of emerging themes (both within and between narratives) with the existing literature, allowing for model refinement.^[23] After transcription, two authors [AHJJ and AJ] independently coded the transcripts. No new aspects emerged during the final interviews; thus, theoretical saturation was reached, and no further interviews were required.

The interviewer and first coder of the interviews [AHJJ] has a master's degree in Nursing Practice and Health and Social Care. She is a nurse specialist in wound care and works at the hospital in which the patients were treated. At the time of the interviews, she did not have a professional relationship with any of the interviewees. The interviewer was formerly the primary healthcare professional for one of the participants, and the other patients were treated by colleagues at the hospital. The second coder of the interviews [AJ, third author), has a master's degree in Nursing Practice and Wound Healing and Tissue Repair and is a nurse specialist at another hospital in The Netherlands. She had no professional relationship with any of the participants. A third member of the research team [AME] with experience in qualitative research supervised the data collection and analysis process as a quality check to ensure the validity of the results.^[24]

A thematic analysis was performed to identify, analyze, and report patterns (themes) within the data.^[25] Thematic analysis involves a six-step process: (1) familiarizing oneself with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report.^[26] Steps 1 and 2 were carried out independently by two researchers [AHJJ and AJ]. After coding the transcripts, the transcribed interviews, code list, and field notes were extensively reviewed. Axial coding was performed to identify emerging themes. Steps 3, 4 and 5 were carried out by three researchers [AHJJ, AJ and AME].

RESULTS

Between January 2020 and August 2021, 11 patients fulfilled the eligibility criteria and were asked to participate, one of whom declined. Therefore, 10 patients with (healed or unhealed) wounds that had been treated with NPWT participated in the study. Data saturation was reached after these 10 interviews. Baseline characteristics of the participants are presented in Table 2. One interview was conducted in the hospital and the other nine interviews in the participants' homes. The time between patients' date of ceasing NPWT and the interview date ranged from 3–171 days (median: 115 days; interquartile range: 50.5). The duration of the interviews ranged from 45–90 minutes.

The thematic analysis identified four major themes: (1) Having a wound makes patients uncertain and thus influences quality of life; (2) NPWT influences patients' daily lives; (3) Patients consider professional treatment decisions most important in decision making processes; and (4) Self-management of wounds is accepted by patients only for low-complexity, well-healing wounds under supervision.

Table 1 Baseline characteristics of the participants

Participant	Gender	Age	Wound aetiology	Duration of NPWT in days	Social status	Work status
1	female	76	Necrotectomy and bursectomy olecranon right	27	Living alone	Retired
2	female	68	Amputation hallux / metatarsal phalanx I right	26	Married with children (living away from home)	Has not worked
3	male	59	Laparotomy with decompression abdomen, removal of mesh, phasix mesh placed	36	Married with two children, one living at home	Employed (now on sick leave)
4	male	45	Removal osteosynthesis material ankle right, debridement	25	Living alone	Employed
5	male	84	Trans meta tarsal amputation radius I, II, III because of ischemic left leg and necrosis fore foot	14	Married with children (living away from home)	Retired
6	male	70	Debridement necrotic part gastrocnemius medial left	46	Married with children (living away from home)	Retired
7	male	62	Amputation trans meta tarsal IV left	8	Married with children (living away from home)	Incapacitated
8	male	70	Necrotectomy and cleavage wound lower arm right	4	Married with children (living away from home)	Retired
9	male	58	Drainage cellulitis/abcess pretibial scars after former external fixation tibia (pilon tibial fracture)	27	Married with children (living away from home)	Independent entrepreneur
10	male	63	Ventro-medial sheet osteosynthesis after open pilon tibial fracture right for what wound debridement and short sheet osteo synthesis dital fibula and bridging externa fixation	80	Married with children (one living in huis next to him)	Independent entrepreneur

NPWT Negative Pressure Wound Therapy

Having a wound makes patients uncertain and thus influences quality of life

All participants who were treated with NPWT mentioned the significant impact of having a wound on their daily lives. Some participants explicitly mentioned worries about the future, including whether the wound would heal and whether they would be able to live their normal lives again.

As one patient said:

“That was my biggest concern, that I couldn’t walk at all. That I had lost my balance...”

[Participant 2]

Another patient mentioned:

“I worried whether the wound would heal...maybe I become an invalid.... Life is nice, but then you have to be able to do something...” [Participant 3]

Most participants set goals during their treatment, including to be able to work again, walk again, play golf, go shopping, or babysit their grandchildren. When their goals were not achieved, they adjusted them. Setting goals stimulated patients to progress in their recovery and stay positive.

“Of course, you also want to move forward. And I also want to see my grandchild grow up. That encourages you to go for it...” [Participant 2]

Some participants felt resigned and expressed confidence that in time, their lives would return to normal. Participants noted that they needed a certain amount of time to learn to cope with their wound and its consequences. One patient indicated that he and his family drew tremendous strength and confidence from their faith.

“But then I just get angry, and if I dive into the holy books, then I get peace again. Then I think, maybe that had to happen to me.” [Participant 3]

Having a wound impacted not only patients’ lives but also the lives of their family members. This impact led some participants to a feeling of guilt.

“And my daughter also deteriorated. She saw daddy not doing well...She was getting worse at school, with driving lessons. And that hurts...That gives an emotional sense of guilt...” [Participant 3]

The roles in family relationships changed, which also made participants feel bad and sad. Participants realized how difficult their health situation was for their family members and felt gratitude for the love and care they received from them. For some participants, their wound and health condition resulted in an earlier-than-expected takeover of their company by their children:

“My children are now taking over the company early. Things now happen that I think: if I had been there I would have done that differently...” [Participant 10]

“During her lunch break, she came to visit me. She helped me with everything. And then we are the poor souls because we have that wound, but it is much harder for them.” [Participant 7]

Participants found it difficult to deal with their wound and the accompanying inconveniences. Anxiety, sadness, and dreariness were mentioned as predominant emotions. Patients also described their dependence on home care nurses as a limitation with regard to their skills (which were rated variably among the different nurses) and the amount of time they needed to stay at home to receive care.

“If they said I’ll be there between 2:30 or 4:30, you can hardly leave in the afternoon.”
[Participant 3]

“But there are also nurses who really pay attention to it... and that really meant a lot to me.” [Participant 7]

Negative pressure wound therapy influences patients’ daily life

Participants mentioned that not only having a wound, but also receiving NPWT treatment, had a major impact on their daily lives. Several participants described the weight of the device, the noises that accompanied the treatment, difficulties with (un)dressing, and the short tube length as annoying.

“Then you had to lift that thing between your chair and legs...lots of hassle” [Participant 7]

Two participants slept apart from their partner because of the humming sound of the pump. The need for the patient to remember to take the pump with them when walking or going to the restroom and to charge it regularly resulted in a constant awareness of treatment and being attached to a device. Several participants also mentioned the pain of dressing changes. For two participants, this pain led to a premature cessation of therapy on their own request.

“And then it [the foam] had to be changed. I’ve been through a lot, but that, that hurt so much...” [Participant 8]

Participants reported feeling anxious about being treated with NPWT. The main reasons for their anxiety were that they worried about (the consequences of) loosening foils, hearing alarm sounds and not knowing what to do, knowing when to contact the home care nurse in case of wound deterioration, and worrying whether or not the home care nurse would come. Being attached to a NPWT device also restricted participants’ social activities. Due to the COVID-19 pandemic and resulting lockdown in the Netherlands, participants were already restricted in their social activities, which made the social limitations caused by NPWT less noticeable than otherwise.

“I’ve been playing with my golf buddies for years. I miss it so much...” [Participant 5]

Participants indicated that they had confidence in the NPWT treatment. As treatment proceeded, they actively searched for practical solutions for problems such as the short length of the tube and where and how to carry the device. Although participants felt increasingly comfortable with NPWT as therapy proceeded, they all reported feeling relieved when the NPWT ended.

“I really liked it when the pump was gone.” [Participant 3]

Patients consider professional treatment decisions most important in decision making processes

Participants did not feel a need to make a shared decision about their treatment with their healthcare professional. Participants expressed that they want open and honest communication with their healthcare professional, and they want to be thoroughly informed of the treatment options available. Subsequently, they prefer the healthcare professional to give concrete advice and ultimately make a treatment choice for them.

“I’d prefer to have more information about the options, these are the pros and cons.”
[Participant 5]

“I don’t have to decide for myself. I just want to get some advice. And I will follow that advice.” [Participant 2]

Participants felt incapable to choose a treatment option for themselves, because they felt they had too little knowledge about wound healing and treatments. Even after discussing the treatment options with the healthcare professional, they preferred the professional to advise them and decide which treatment to follow. Participants saw the healthcare professional as an expert and were willing to follow his or her advice, regardless of their own preferences.

“But I do think that it will be very difficult for the average patient. Because yes, I am not a specialist. I think you should let people who are specialized in that decide, because I don’t want that.” [Participant 9]

Several participants mentioned that it would be ‘not appropriate’ to make a collaborative decision; rather, the patient should follow the specialist’s advice.

“But not to really make a decision. That is not right, I think, as a patient. I didn’t learn for it.” [Participant 7]

All participants indicated a need for information regarding what treatment options exist, what NPWT is, the limitations of each treatment option, and what the treatment process looks like. They prefer to be thoroughly informed, despite their wish to be advised by a healthcare professional and not make a treatment choice themselves.

“For a layman, the explanation should have been very good, what does a vacuum pump do, what are the limitations.” [Participant 4]

If a patient had a prior experience with NPWT, he or she could indicate the nature of this experience (e.g., good or bad); however, those patients would still prefer to follow the specialist’s advice rather than make their own treatment decision. When asked, several participants indicated that despite the burden of NPWT, they would prefer to do it again if needed, because they believed it resulted in faster wound healing than standard wound care,

“Yes, then I think I would opt for the pump. Because yes, well--it has gone faster with it.” [Participant 6]

Self-management of wound care is accepted by patients only for low-complexity, well healing wounds under supervision

Few participants or their relatives actively participated in wound care treatment. This was only done in cases for which conventional wound treatment (i.e., not NPWT) was prescribed. Participants indicated that they were willing to participate in their wound care under certain conditions. First, they must be able to see and reach the wound. The wound and the treatment process must not be complex, meaning that wound healing must have been initiated and the wound must not be infected, deteriorating, or too big. Participants considered prior experience in wound treatment to be a prerequisite to perform such treatment themselves. In addition to these conditions, participants preferred support from home care or healthcare professionals in the hospital, and they felt that a wound care specialist should perform debridements.

“I prefer home care, and if I had gradually seen and learned all that, then maybe myself. When the wound is healing. And then back up from the hospital.” [Participant 9]

Participants considered NPWT treatment too complicated to self-administer; therefore, none of the participants preferred to take an active role in dressing changes.

“Changing the pump yourself, that’s impossible.” [Participant 6]

Participants did not want to take responsibility for the bandage changes or the healing process. Expertise in wound care was rated as more important than autonomy.

“I have that confidence in them [home care nurses]. I can do that myself, but if I didn’t do it right afterwards, then I have to blame myself.” [Participant 10]

Several participants mentioned the need for debridement of the wound. It was a painful but necessary process, and they felt they would not have done it thoroughly, like the home care nurses did.

“You will think it will be good like this. But those wound care nurses, they continue until it’s gone.” [Participant 7]

Two participants mentioned that they are entitled to wound care because they pay for health insurance, so they want to receive it. One patient mentioned that he asked his wife to change the bandages, but she refused to take on the role of caregiver.

“Well, my wife indicated: I’m your partner and no, not a care giver.” [Participant 8]

DISCUSSION

Having a wound significantly impacts a patient’s quality of life. Participants emphasized their worries about the future, including whether the wound would heal and whether they would be able to live their normal lives again, as well as the impact of the wound on their families. These feelings of uncertainty about the future echo the findings of other studies regarding the impact of wounds of different etiologies on patient quality of life.

^[27-29] In addition to the impact of having a wound, receiving NPWT also has a physical, psychological and social impact on patients' daily lives.^[8, 14, 30]

Despite the quality-of-life impacts of NPWT, shared decision making about wound treatment was not preferred by the study participants. A prospective prognostic study of the association of potential prognostic determinants to non-adherence to NPWT found that shared decision making was associated with premature termination of NPWT.^[31] Participants in the present study wanted to be thoroughly informed about treatment options; however, they preferred to let the healthcare professional decide on their treatment option. This deferred decision from patient to healthcare professional has been observed in other studies of shared decision making,^[32, 33] including in (palliative) cancer treatment.^[34, 35] Researchers have found that patients diagnosed with a serious illness are unlikely to seek an active role in selecting their medical treatment.^[35] Many patients undervalue their contribution to the decision-making process due to a belief that the highly rated medical knowledge of their healthcare professional makes their own personal knowledge and participation in shared decision making superfluous.^[36] Some patients believe that asking questions is inappropriate and could undermine the status of the healthcare professional. Conversely, patients' recognition of the important contribution of their own personal preferences and understanding that it is acceptable to ask questions facilitates shared decision making. Patients require knowledge and power to participate in shared decision making.^[36]

The patient's family is also affected by the wound and wound treatment.^[37] The present study findings confirm the importance of family members to help patients cope with life with a wound. However, most participants in this study and/or their relatives did not want to actively participate in (complex) wound care. A systematic review of patient and family engagement found that some patients and their families preferred to play a passive role in care.^[38, 39] However, the study participants also indicated they had received few opportunities to engage in such care and felt disempowered.^[38] Increased family participation in care could be achieved by providing communication and caregiver support to patients and their families to strengthen caregiver competency and teach caregivers new skills.^[40] Informal care can carry a burden, but it can also have positive effects for patients and family members, such as personal growth, fun and reward, enjoyment of care, and patient and caregiver satisfaction. The positive and negative impacts of family caregiving should be discussed with the patient and their family members.^[41] Future research could examine whether the role of the family is regularly discussed with patients and their families at the onset of NPWT treatment and during therapy. Some family members in the present study did participate in patient care, but only in cases of standard wound care.

Participants clearly expressed that they preferred their wounds to be treated by professionals with skills and expertise in wound care. Wounds have a significant impact

on patient quality of life; thus, it is logical that patients would want their wounds to be treated as efficiently as possible. In addition to the preference for qualified healthcare professionals to treat their wounds, participants did not want to be or feel responsible for wound treatment and healing. The systematic review mentioned earlier found that some patients and their families believed their ability to trust that they were being provided with competent care was more important than their wish to take on a leadership role in their care.^[38] Patient involvement in wound care is enhanced through nurse-patient relationships in which the patient's viewpoint is given equal weight to that of the practitioner. Based on these findings, more effort should be made to communicate with patients about their wishes and provide opportunities for patients to actively participate in wound care.^[42, 43]

Strengths and limitations

In this study, a thematic analysis was conducted to gain insight into patients' experiences and preferences regarding shared decision making and patient participation during NPWT treatment. Thematic analysis provides a robust systematic framework for coding qualitative data to identify patterns across the dataset in relation to the research question.^[44] Semi-structured interviews enabled each participant to provide an in-depth perspective of their experiences and preferences. Data saturation was achieved, denoting the transferability of responses. Individual characteristics influence health literacy;^[45] thus, patients of different ages with different wounds and work statuses were recruited. However, results from ten interviews cannot be generalized to represent all patients with wounds treated with NPWT. Notably, generalizability is not the goal of qualitative studies.^[46] An objective analysis was achieved by having the data coded by a second author from another institution and discussing the themes among three authors from three institutions.

Some limitations of the study must be acknowledged. The interviews were conducted during a one-and-a-half-year period due to the COVID-19 pandemic. During the initial year-long data collection period, there were several lock-down periods in the Netherlands, which restricted the ability to conduct face-to-face interviews. The research team determined that switching to telephone interviews would have a greater impact on the results than extending the study period; thus, the study period was extended. The relatively long data collection time enabled the research team to concurrently conduct data collection and analysis, which enabled the team to compare emerging themes to the existing literature and refine the explored themes.^[23] The COVID-19 pandemic itself may have influenced study participants' well-being.^[47] However, the interview questions asked about patients' experiences and impact of their wounds and wound treatment; thus, the influence of the COVID-19 pandemic on the study findings is likely negligible.

In addition, the interviewer was known by some interviewees, which may have affected their responses. However, most participants had been treated by the interviewer's colleague rather than the interviewer, which makes the results more reliable.

Conclusion

This qualitative study provides valuable insight into the experiences and preferences of patients with wounds treated with NPWT. Through thematic analysis, four major themes were identified; (1) Having a wound makes patients uncertain and thus influences quality of life; (2) NPWT influences patients' daily life; (3) Patients consider professional treatment decisions most important in decision making processes; and (4) Self-management of wound care is accepted by patients only for low-complexity, well healing wounds under supervision.

These themes must be addressed to provide patient-centered care. More effort should be made to communicate with patients about their wishes and provide opportunities to actively participate in wound care decisions and treatment. Future studies could explore the needs of patients with wounds treated with therapies other than NPWT.

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Chapter 6 | Preferences of patients treated with NPWT in relation to shared decision making and participation in wound care, a qualitative study using thematic analysis

Table S1 Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description	Page in article
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	7
2.	Credentials	What were the researcher's credentials? <i>E.g. PhD, MD</i>	8,9
3.	Occupation	What was their occupation at the time of the study?	8,9
4.	Gender	Was the researcher male or female?	8,9
5.	Experience and training	What experience or training did the researcher have?	8,9
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	9
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? <i>e.g. personal goals, reasons for doing the research</i>	8,9,18
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? <i>e.g. Bias, assumptions, reasons and interests in the research topic</i>	8,9,18
Domain 2: study design			
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis</i>	9
Participant selection			
10.	Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>	7
11.	Method of approach	How were participants approached? <i>e.g. face-to-face, telephone, mail, email</i>	7
12.	Sample size	How many participants were in the study?	7
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	9
Setting			
14.	Setting of data collection	Where was the data collected? <i>e.g. home, clinic, workplace</i>	9

Table S1 Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist (continued)

No	Item	Guide questions/description	Page in article
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	8
16.	Description of sample	What are the important characteristics of the sample? <i>e.g. demographic data, date</i>	Table 2, 26,27
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	7 Appendix 1, 28
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	-
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	8
20.	Field notes	Were field notes made during and/or after the interview or focus group?	8
21.	Duration	What was the duration of the interviews or focus group?	9
22.	Data saturation	Was data saturation discussed?	9
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	-
Domain 3: analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	9
25.	Description of the coding tree	Did authors provide a description of the coding tree?	-
26.	Derivation of themes	Were themes identified in advance or derived from the data?	9,10
27.	Software	What software, if applicable, was used to manage the data?	-
28.	Participant checking	Did participants provide feedback on the findings?	-
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? <i>e.g. participant number</i>	10-16
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	10-16
31.	Clarity of major themes	Were major themes clearly presented in the findings?	10-16
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	-

Chapter 6 | Preferences of patients treated with NPWT in relation to shared decision making and participation in wound care, a qualitative study using thematic analysis

Supplement 2: Topic List

Introduction:	
Introduce myself, purpose of interview, approach, anonymity, duration, recording, feedback for verification	
Baseline characteristics	
Questions	Topics
Opening questions	Wound etiology, duration of wound, how long ago, wound closed?
What is it like to live with a wound?	<ol style="list-style-type: none">1. Emotions / worries?2. Impact (on daily and social life)
What are / were your goals?	<ol style="list-style-type: none">1. Short and long term goals2. Priority
What does patient participation mean to you?	<ol style="list-style-type: none">1. Conditions for participation (knowledge, needs, selfcare, confidence)2. Communication with health care professionals, sharing knowledge, actively participating, self-management wound care
What do you need for shared decision making / active participation in wound treatment?	<ol style="list-style-type: none">3. Preferences participation4. Autonomy (self-direction, dependence on others)5. What is needed for shared decision making / active participation in wound treatment
How did you experience the care provided?	<ol style="list-style-type: none">1. Professionalism / involvement / respect / empathy2. Autonomy (self-direction, dependence on others)
Closing:	
Thank you, if they want to be kept informed of the results, then ask for email address).	

7

Promising results in wound care with a new Rapid Capillary Action Dressing; A case series study

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Wounds international, 12(3), 20. [12]

ABSTRACT

This case series aimed to describe treatment effects and experiences of patients who switched from first Negative Pressure Wound Therapy (NPWT) to a rapid capillary action dressing (RCAD; VACUTEX™). Ten consecutive patients who prematurely terminated NPWT were recruited. Mean time to complete wound closure was 87.3 days (SD 38.3). The main reasons for terminating NPWT were maceration of the skin caused by the film and patient discomfort. All patients preferred RCAD, mainly because of better mobility and no noise, compared to the NPWT device. RCAD appears to be a promising treatment modality.

INTRODUCTION

Skin wounds are an important health concern. Based on data from developed countries, it is estimated that approximately 1 to 2 % of the population will experience a hard-to-heal wound during their lifetime.^[1] These wounds impose a significant and often underappreciated burden to the individual, the healthcare system and the society as a whole.^[2]

To reduce the burden of wounds and improve quality of life (QoL), adequate wound treatment is necessary. Healthcare professionals continuously seek and demand for innovative and effective wound care products, which can be a challenging task as there is insufficient evidence for many treatment options.^[3,4] Negative Pressure Wound Therapy (NPWT) is based on the principle that a negative pressure inside the wound can suction fluids and approximate wound edges.^[5] This therapy has been used for many years in the treatment of acute and hard-to-heal wounds.^[6]

Despite the potential benefits of NPWT, there is also some evidence that patients experience harm. It appears that NPWT can have a negative impact on QoL and can lead to serious restrictions in the physical, psychological and social domain of QoL.^[6] These restrictions even lead a significant amount of patients to request a premature termination of NPWT.^[7]

A treatment modality which may overcome these negative side effects, is a rapid capillary action dressing (RCAD). VACUTEX™ (Protex Healthcare, Roeselare, Belgium) consists of three layers, namely two 100% polyester filament outer layers, and a 65% polyester and 35% cotton woven inner layer.^[8] The inner layer, in contact with the wound, is able to lift and transport necrotic and sloughy tissue. The middle layer wicks away the exudate laterally across the fabric and the outer layer draws the exudate from the saturated middle layer.^[9] This soft and conformable RCAD can be cut to size and placed in layers on the surface of the wound.^[8] The RCAD provides a capillary pressure of -70 to -75 mmHg in the wound.^[10] This may be sufficient as another study showed that the maximum biological effects of NPWT on the wound are obtained at the level of 80 mmHg.^[11,12] Therefore, RCAD could be a valuable alternative to NPWT in terms of better tolerance by the patient and comparable time to achieve complete wound healing.

A quick search in MedLine Pubmed (up to March 2021), yielded seven studies on RCAD, six of them published before 2004. Therefore, further investigation and description of this treatment modality is needed. This case series aimed to describe the treatment effects and the experiences of patients who switched from first NPWT to RCAD. The results of this study can be used to generate hypotheses for future studies.

MATERIALS AND METHODS

This study is reported according to applicable criteria of the Case Report Guidelines (CARE).^[13] The Medical Research Involving Human Subjects ACT (WMO) does not apply to our research project because there is no infringement of the physical and/or psychological integrity of the patients.^[14]

This case series study prospectively recruited ten consecutive patients treated in a teaching hospital in the Netherlands between June 2019 and October 2019. Patients were eligible if they prematurely terminated NPWT, either requested themselves or by the wound care specialist. They provided written and verbal informed consent regarding participating in this study, taking pictures of the wound and publication of the results/pictures. Data were collected and noted in the patient chart over the wound healing. When NPWT was terminated, treatment was continued with RCAD (VACUTEX™). In all cases, RCAD was used in the same way. Depending on the depth of the wound, multiple layers of RCAD were applied up to skin level. One slightly larger layer was put on top of the other dressings, with an overlay of ± 1 centimeter on the surrounding skin. See figure 1. The dressings were cut 2 millimeters smaller than the wound enabling approximation of the wound edges. The RCAD was covered with an absorbent dressing. The RCAD was changed two times a week, the absorbent dressing every day.

Figure 1 Schematic representation of the application of RCAD



The reasons for premature termination of NPWT were noted. Wound dimensions at the start of the NPWT therapy, length of the treatment with NPWT and with RCAD, and time to complete wound closure were recorded. After hospital discharge, all patients were admitted to the rehabilitation centre, located near the hospital. Patients were followed up by the hospital's wound care consultant until complete wound closure. Wound closure was defined as 100% epithelialization of the wound surface with no discernable exudate and without drainage or dressing.^[15] Patients' experiences with NPWT and RCAD were noted.

RESULTS

Ten patients were included in this study. None of the patients declined participation. Nine men and one woman were included, with 11 wounds of different aetiologies. All wounds were postoperative wounds; four toe/partial foot amputations, three abdominal wounds, one lower leg wound, two groin wounds. One wound was a heel pressure ulcer (after surgical debridement). The baseline characteristics are described in table 1. One patient was lost to follow-up, one patient died and one patient had still an open wound at time of writing. The other eight wounds were healed.

Treatment effects

All patients received NPWT according to the local protocol, with the aim to continue this therapy until granulation tissue reached the skin level. The Vacuum Assisted Closure® (V.A.C.®) Therapy device (Kinetic Concepts Inc., San Antonio, TX, US) was used in all 10 patients. Dressings were changed two times a week. Continuous negative pressure levels of -125 mmHg were used in all patients.^[16] Median duration of NPWT was 14 days (IQR 24). The NPWT was discontinued, either by the patients themselves or the wound care specialist. Reasons for premature termination of NPWT are described in table 2. Four cases are shown in Figures 2-5 and the other cases can be found in Appendix 1.

Figure 2. Case 4 was a 73-year old man with two abdominal wounds.



Left to right: At start of NPWT; Start of RCAD on upper wound; Upper wound closed

Figure 3. Case 5 was a 70-year old man with right forefoot amputation. Left to right: At start of NPWT; Start of RCAD; Superficial wound, hypergranulation, so RCAD was stopped and Terracortril started



Table 1 Baseline characteristics

Case	Gender	Age	Wound etiology / location	Smoking	BMI	DM	CVA /TIA	HF	Malignancy	PAOD	Intervention(s)
1	Male	71	Amputation toes 4-5 right foot, wound left open	Unknown	19.9	No	Yes	No	No	Yes	PTA ATA and ATP right foot
2	Male	71	Abdominal wound with mesh, fascia closed, wound left open	Stopped	25.7	Yes	No	Yes	Adeno-carcinoma	No	*Hemicolectomy right *Laparotomy: seam leakage, abdominal compartment syndrome. Abthera, *Close fascia with Biomesh
3	Male	76	Postoperative wound infection left knee	No	22.9	No	Yes	Yes	No	Yes	*Endovascular treatment of Femoral Popliteal artery stenosis with stent on the right and PTA of popliteal artery on the right, *Infragenual femoral-popliteal bypass right with silver coated 6mm prosthesis.
4	Male	73	Abdominal wound (top and bottom)	Stopped	31.5	No	No	No	No	No	*Acute Aortic Abdominal Aneurysm, open procedure. Open abdominal treatment with Abthera. Abthera removed, Fascia closed, leaving VAC in subcutis
5	Male	70	Fore foot amputation	No	37.4	Yes	No	No	No	Yes	*PTA: covered kissing stents AIC on both sides. Fore foot amputation right
6	Female	77	Amputation hallux right	No	25.1	Yes	No	No	No	No	*Amputation TMT 1 right, approximating closed. *Open original amputation wound and shorten MT1; Apply VAC.
7	Male	80	Infection vascular prosthesis groin	Stopped	22.9	No	No	No	No	Yes	Sartorius plastic left groin + VAC
8	Male	73	Infection vascular prosthesis groin	Stopped	23.5	No	No	No	No	Yes	*Bifurcation prosthesis *Removal of left groin seam aneurysm gelsoft rifampicin-soaked bifurcation prosthesis. *Drainage abscess, infection groin
9	Male	94	Pressure ulcer heel	No	27.8	Yes	Yes	Yes	No	Yes	Wound debridement left heel
10	Male	78	Partial amputation toes 2, 3, 4 and 5 right foot	No	33.1	Yes	No	No	No	Yes	*PTA Popliteal artery, Peroneal artery and ATP right. *Partial amputation TMT 2 to 5 right

AIC: Common Iliac Artery; ATA: Anterior Tibial Artery; ATP: Posterior Tibial Artery; BMI: Body Mass Index; CVA: Cerebral Vascular Accident; Dig: digitus; DM: Diabetes Mellitus; HF: Heart Failure; PAOD: peripheral arterial obstructive disease; ; PTA: Percutaneous Transluminal Angioplasty; TIA: Transient Ischemic Attack; TMT: trans metatarsal; VAC: Vacuum Assisted Closure

Table 2 Results

Case number	Wound dimensions at start (length x width x depth, cm)	Length Negative pressure wound therapy (day/s)	Negative pressure wound therapy	Reason for terminating therapy	Duration RCAD (days)	Wound dimensions at end treatment with rapid capillary action dressing	Reason for terminating therapy	Duration alternative therapy until wound closure
1	12 x 8 x 3	4	maceration		78	3 x 1,5	wound at skin level, only protection needed	28
2	6 x 5 x 1	33	maceration, no progression		78	3 x 3	wound at skin level, hypergranulation, much exudate	still open
3	13 x 3,5 x 2,5 undermining 6	5	many blood clots		47	closed		
4	16 x 5 x 4	9	wound at skin level		17	closed		
	8 x 4 x 7	23	discomfort		44	closed		
5	10 x 3 x 2	9	maceration		70	6 x 1.5 x 0	hypergranulation	14
6	5 x 2 x 2,5	10	maceration hypergranulation		43	2,8 x 0,5 x 0,2	wound at skin level and too narrow for RCAD	lost to follow up
7	6 x 2 x 1	17	maceration leakage		31	0,5 x 1,5	Inexperience with RCAD, relieve of seroma, hypergranulation	Died
8	8 x 2,2 x 1	58	discomfort maceration leakage		22	3,5 x 1 x 0,5	bottom part of the wound was closed	22
9	6 x 5 x 0,7	14	discomfort maceration		115	closed		
10	10,5 x 3 x 3	49	maceration		85	closed		

NPWT Negative Pressure Wound Therapy

All patients continued their wound treatment with RCAD (i.e., VACUTEX™) after discontinuation of NPWT. Four patients (with five wounds) continued RCAD until complete wound closure, and six patients switched wound therapy when the granulation tissue reached skin level. Mean duration of treatment with RCAD was 57.3 days (SD 30.3). In case of exposed tendon it was overgrown with tissue during treatment with the RCAD. In two cases the tendon was kept moist with a hydrogel beneath the RCAD. During the treatment with the RCAD, wounds of three patients (case 2, 5 and 7) developed hypergranulation.

In all patients, the dressing was soaked with tap water before removing. None of the patients indicated pain at dressing changes. No residual particles of the dressing were seen. Although all wounds were hard-to-heal, all but one showed prosperous wound healing. Mean time to complete wound closure was 87.3 days (SD 38.3).

Figure 4. Case 8 was a 73-year old man with an infected vascular groin prosthesis. Left to right: At start of NPWT; Start of RCAD; Wound nearly closed.



Figure 5. Case 3 was a 76-year old man with postoperative wound infection in his left knee. Left to right: At start of NPWT; Blood clots led to termination of NPWT and start of RCAD; Wound nearly closed, unfortunately leg was later amputated after bypass infection.



In seven cases (case 1, 2, 5, 6, 7, 9, 10), despite correct application of the NPWT, the pump could not handle the amount of exudate which resulted in maceration of the skin, alarms, or the film to coming off. This resulted in premature termination of this therapy. No skin maceration was seen during the treatment with RCAD.

“Everything was soaking wet, and that the pump was roaring and my clothes and chairs got dirty so I could not go anywhere, horrible”-Patient

In case 3, there were many blood clots at the first bandage changes of NPWT, that the wound care specialist decided to terminate the therapy (figure 5).

Experiences of patients: NPWT versus RCAD

Case 4, 8 and 9 experienced a high level of discomfort during NPWT and indicated the wish to terminate this therapy. All three patients mentioned restrictions in mobilizing. Because of the pump and the tube, they needed help with transfers and walking. They were annoyed that they had to be constantly aware that they were attached to a pump. When treatment was switched to RCAD, all three patients indicated they felt more free and independent.

As well as the restrictions in movement, cases 8 and 9 indicated the dressing changes during NPWT were very painful. With RCAD, they experienced no pain. With wounds located in the groin and at the heel, they experienced more comfort from the dressing itself during treatment with RCAD. All ten patients mentioned the reduced freedom of movement, the noises of the pump and the burden of carrying it with them as very uncomfortable and indicated a relief to be able to stop NPWT.

“Luckily I got rid of that hum and squeak.”- Patient

DISCUSSION

This case series indicates that RCAD (i.e., VACUTEX™) is a promising treatment modality if NPWT does not suffice. The patients in this case series treated with both treatment modalities preferred RCAD, mainly because of the freedom of movement and the absence of pump noises.

Although strong evidence of effectiveness of RCAD is still lacking, this case series indicates that RCAD might be an interesting treatment modality to consider when the results of NPWT are insufficient and/or when the patients indicates the wish to stop NPWT. When making a clinical decision on treatment using an evidence based practice approach, the best evidence from well-designed studies, clinicians’ expertise and a patients’ preferences and values should be integrated.^[17] Because evidence on the effectiveness of RCAD is still lacking, patients’ preferences become even more important and should be considered.

The conjoint analysis of Vermeulen et al. (2007) showed that little pain during dressing changes, short duration of hospitalization, and quick wound healing were the most preferred attributes of an “ideal” wound dressing for local wound care, in the opinion of doctors, nurses and patients.^[18] Participants in this case series clearly stated their preference for RCAD over NPWT. Most wounds showed marked wound healing with RCAD without the inconveniences of the NPWT treatment.

It was remarkable that three out of 11 wounds showed hypergranulating tissue during the use of RCAD. Hypergranulation can be defined as excess of granulation tissue that fills the wound bed to a greater extent than what is required and goes beyond the height of the surface of the wound resulting in a raised tissue mass.^[19] To date, there is no consensus on how to manage these wounds [20]. One of the treatment options is ‘wait and see’, because hypergranulation is often transient and will resolve itself.^[20,21] In this case series, according to standard protocol, it was decided to stop RCAD and start with Terracortril (containing oxytetracycline and hydrocortisone). In all three patients, the hypergranulation disappeared. We do not know whether this would have happened if we had continued the treatment with the RCAD. In further studies on RCAD, hypergranulation as secondary outcome should be considered.

In this case series it should be taken into account that there might be a carry-over effect. All the included patients in this case series were first treated with NPWT, which may have given the wound a start in healing. Perhaps RCAD should be used in a step-down model: start with NPWT and when the wound shows signs of healing, switch to RCAD. However, experiences in our wound centers show also promising results of RCAD as a replacement for NPWT. Russell et. al. studied the differences between RCAD and standard protocol in time to a clean wound bed. The preliminary results of that small multicenter randomised trial (35 participants) suggested that RCAD may be a useful new treatment for dealing with sloughy, devitalised and exudating wounds.^[9] However, the authors did not study time to complete wound healing and did not compare RCAD with NPWT. Also patients’ experiences with RCAD compared to standard protocol were not considered. Further experimental research on this RCAD as an alternative to NPWT is recommended.

Conclusion

This is, to our knowledge, the first case series utilising RCAD in patients with hard-to-heal wounds. Although case series do not provide robust evidence in terms of efficacy of one treatment above another, they are valuable because they illustrate cases in true clinical practice and have high external validity.^[23] The promising results of this case series indicate the value of conducting an RCT comparing the efficiency of RCAD compared to NPWT. In this RCT, one could hypothesize that RCAD results in less skin problems, higher patient satisfaction and possibly faster wound healing rates.

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Chapter 7 | Promising results in wound care with a new Rapid Capillary Action Dressing: A case series study

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Appendix 1 Cases



Case 1 was a 71-year-old male after an amputation of toes 4 and 5 right foot, wound left open. From left to right: At the start of NPWT; Start of RCAD; Epithelialisation phase, wound at skin level, RCAD was stopped.



Case 2 was a 71-year-old man with an abdominal wound with biomesh, fascia closed, wound left open. From left to right: At the start of NPWT; Start of RCAD; Superficial wound, hypergranulation, high exudate, RCAD continued.



Case 6 was a 77-year-old woman with an amputation of hallux right. From left to right: At the start of NPWT; At the start of RCAD; on discharge home, continue RCAD.

Chapter 7 | Promising results in wound care with a new Rapid Capillary Action Dressing; A case series study



Case 7 was an 80-year-old man with an infection of the vascular prosthesis in the left groin. From left to right: At the start of NPWT; At the start of RCAD; overgrown Sartoriusplasty with hypergranulation, continue SCWW; Superficial wound, hypergranulation, start Terracortril



Case 9 was a 94-year-old man after a nettoyage wound on the left heel (pressure ulcer). From left to right: At first dressing change of NPWT; Start of RCAD; On discharge home, wound at skin level, continue RCAD.



Case 10 was a 78-year-old man after a partial amputation of TMT 2 to 5 right foot, wound left open. From left to right: At the start of NPWT; At the start of RCAD; On discharge home, wound at skin level, continue RCAD.

8

General Discussion

With this thesis we aimed to provide insight in the experiences and preferences of patients with wounds, treated with negative pressure therapy (NPWT). Knowing these experiences and preferences will facilitate health care providers (HCPs) in the future to inform patients more thoroughly about treatment options and facilitate the conversation in an Evidence Based Practice (EBP) and Shared Decision Making (SDM) way. In this way, HCPs together with patients, will be able to choose a wound therapy which suits each individual patient best.

The insights we gained with this thesis fits very well in the new paradigm of appropriate care which is launched by the Dutch Health Care Authority (Nederlandse Zorgautoriteit (NZa)).^[1] Appropriate care is a way of working together that ensures that everyone can receive fundamental care in the future. It is based on four basic principles to keep care good, accessible and affordable; (1) only provide care that really works for patients (EBP); (2) organize care as nearby the patient as possible; (3) decide together with the patient (SDM); (4) focus more on health and quality of life, and less on medicalization.^[1]

In this final chapter, the main findings of our studies are discussed to put our research in wider perspective. Methodological considerations of the studies are presented in order to provide correct interpretation of the results. Subsequently, the impact of the study on our daily practice is discussed, comprising recommendations regarding future research.

Main findings

Our experience that relatively many patients ceased their NPWT treatment prematurely on their own request was confirmed by a retrospective chart study (Chapter 4). This study revealed that over one fifth of the patients with postoperatively infected abdominal wounds asked to cease this therapy because they felt too restricted by it in their daily activities. A systematic review of quantitative studies on the impact of NPWT on the QoL showed that patients treated with NPWT experienced a deterioration in their QoL in the first week of treatment. After that week, QoL was experienced equal to Standard Wound Care (SWC) (Chapter 2). The systematic review of quantitative studies gave more insights in what this decreased QoL (chapter 3) entails. We were able to identify four themes; (1) Reduced freedom of movement caused by an electric device; (2) Decreased self-esteem; (3) Increased social and professional dependency and (4) Gaining self-control.

Having confirmed that NPWT can have a huge impact on daily activities and QoL a multimethod study was conducted to find out which patient-, treatment-, and health care factors are associated with nonadherence to NPWT, i.e., leading to premature cessation of therapy (Chapter 4). A narrative review yielded 25 general determinants of nonadherence to healthcare related therapies such as wearing stockings, diet, compression therapy. In a national survey in the Netherlands, wound care nurses indicated which of these general determinants they estimated as also applicable to nonadherence

to NPWT. (Chapter 4) With the selected determinants an association cohort study was performed in 16 hospitals in the Netherlands. In a multivariable analysis, having a sensitive skin appeared to be significant associated with nonadherence to NPWT. (Chapter 5). Making the decision of therapy in a shared decision way also showed an association with nonadherence. A case series of ten patients treated with a capillary dressing after being treated with NPWT, indicated that this dressing could be a valuable alternative or follow-up to NPWT (Chapter 7).

Interviewing ten patients about their experiences and preferences in SDM and patient participation provided valuable insights. After thematic analysis, four major themes were identified: (1) having a wound makes patients uncertain and thus influences QoL, (2) NPWT influences daily life, (3) professional treatment decisions are considered most important, and (4) self-management is accepted only in low-complex well-healing wounds under supervision (Chapter 6) .

General discussion

As said in the introduction, evidence based medicine (EBM) involves the integration of clinical expertise, patients' values, and the best available evidence in making patient care decisions.^[2] The current lack of rigorous evidence on NPWT when applied on leg ulcers, pressure ulcers and surgical wounds healing by secondary intention^[3-5] emphasizes the value of the patients' preferences of treatment. Considering the sparse evidence of superior effectiveness of NPWT over SWC, more effort should be made by HCP to discuss the benefits and harms of the different treatment choices with the patients. In wound care, this shared decision making is specifically a task to be performed by (wound care) nurses. The nursing profession has evolved over time from a more task-oriented role to an autonomous nursing role characterized by patient-specific care planning, critical thinking, patient advocacy and care coordination.^[6] Nurses are educated and suitable to explore and address patients' values and preferences. Besides knowledge, skills and communication skills, also trust plays an important role in building up a relationship.^[7] In a correlational evaluation on patient-clinician relationship to adherence to antiretroviral medication, the level of trust placed in the nurse (by the patient) was associated with better adherence to the medical treatment.^[8] It needs time to build trust, and time is scarce in the outpatient clinic. However, by integrating communication into routines, communication and relationship building with patients seems to take no extra time.^[9] Additionally, nurses should recognize the value of short, iterative interaction as quality communication for getting to know their patients and providing patient-centered care.^[9] Knowing the patients in front of you, being aware of their context, their preferences, enables HCPs to give personalized information about the pro's and cons of treatment options and facilitates a well-informed and well considered treatment choice in a shared decision way. In our qualitative study (Chapter 6) patients indicated that they did not

want to make the treatment choice themselves. They preferred to be well informed about treatment options, followed by a treatment choice made by the HCP. This traditional relationship between a HCP and a patient is more of a paternalistic model, with all the decisions based on the expertise and knowledge of the HCP.^[10] Patients may prefer to leave the decision to the HCP, because they don't have the courage or confidence to decide themselves.^[11] SDM is one of the principles of appropriate care which is a spearhead for the coming years to keep care good, affordable and accessible. This thesis revealed that SDM needs attention for further up-take. For example patients need knowledge and power to participate in SDM.^[12] Therefore, more effort should be made on a two-way communication to support patient involvement.^[10] Results from a recent descriptive exploratory study revealed that nurses routinely incorporate elements of SDM in their care.^[13] Specifically listening, taking time to talk to patients, actively request the patient's input in care decisions, and paying attention to the patient's preferences in care are core competences of nurses.^[13] Patients need to become aware of the importance of their contribution to the SDM process, and feel that it is acceptable to ask questions.^[12] HCPs need to facilitate and support this contribution in an open conversation.

Beside the emotional benefits for patients, SDM also results in lower health care costs.^[14] Well-informed preference-based patient decisions leads to more cost-effective healthcare, because of reduced utilization of health care facilities.^[15] The other way around is studied by Hughes et al. (2018). Their evaluation study revealed that poor SDM was associated with higher healthcare use, thus higher healthcare costs.^[16] Therefore, SDM should be seen as appropriate care, i.e., a way of working together that ensures that everyone can receive fundamental care in the future.

The above also applies for active patient participation (PP). NPWT is applied to patients with a variety of complex wounds. These patients often move through the care system, receiving care from different organizations. This raises the need for good discharge planning, documentation, skilled HCPs and excellent communication.^[17] In the light of appropriate care, we need to provide adequate care at the best location for the patient. The emergence of wound expertise clinics in which different HCPs work together in a team, is a welcome development. In the care for patients with diabetic foot problems, working in teams of different HCPs has been proven beneficial in terms of better care, less complications and less costs.^[18-20] Working together in a committed, well-educated team, over the borders of institutions would improve care delivery.^[21] In the Netherlands there is a trend of upcoming "primary care plus" (anderhalve lijnszorg): care at the interface of complex or chronic primary care and simple secondary care. The primary care plus, as a derivative of integrated care^[22], combines the accessibility of (in this scope) primary wound care with the specific knowledge and diagnostics of secondary wound care. It is a way to improve healthcare in a sustainable way.^[23] However, effective multidisciplinary teamwork calls for good collaboration between HCPs

themselves, and between HCPs and patients as well.^[24] In our qualitative study on SDM and PP, patients preferred not to be actively participate in wound care itself. Participants indicated that they prefer educated, skilled HCPs to take care of their wounds. This seems understandable given the burden and impact their wounds and treatments have on their QoL. However, also here an open two-way communication between patient and HCP is essential to explore the patients preferences and competences to actively participate in their wound care. The Fundamentals of Care (FOC) (e.g., active listening, being empathetic, helping patients to cope, working with patients to set, achieve, and evaluate progression of goals) are requisite in this process to deliver genuine patient-centered care.^[25] HCPs should communicate with their patient what their needs, worries and possibilities are, and together come to a level of participation that comforts this particular patient best. The empowerment of patients in wound care depends on the extent to which patients feel and are enabled to perform dressing changes themselves. This in turn depends on the extent to which they are informed about their options and possibilities with regard to self-care. Thus, make the patient realize that they have a role and a responsibility in the care for their wounds, what the possibilities are, the (dis) advantages of self-care and that they can receive professional support if preferred. The HCP and patient together consider what is important for the patients in their lives; self-care or professional care or a combination. This is the true meaning of ‘shared decision’ and patient-centered care.

The development of a wound treatment decision aid could be considered, to allow patients to make careful treatment choices.^[26] Decision aids are known to provide information about (in this case wound) treatment and actively involve patients in the treatment choice, by providing evidence-based information on the disease, treatment options, and their associated benefits, harms, and scientific uncertainties.^[27] A systematic review of 105 studies on decision aids for treatment or screening decisions found that patients who used a decision aid had greater knowledge and felt more clear about their values, had less decisional conflict and were more actively involved in the decision making process.^[28] Whether this involvement in the decision making process will result in a more active patient participation in wound care, is still unknown. Decision aids are only effective if the HCP is prepared to make shared decisions and is willing to take the patient’s preference seriously in the decision-making process. Only then can a decision aid help the patient to understand the options and support the decision on the most appropriate choice.

We need to try to avoid low-value care, i.e., care that is unlikely to benefit the patient given the harms, costs available alternatives, or preferences of the patients.^[29] Regarding the latter, it appeared to be quite difficult to find out what patients with wounds prefer for treatment. The impact of NPWT can be huge, differing between patients. However, NPWT has been selected as the treatment of choice for more than 10 million wounds

worldwide^[30], suggesting its effectiveness. At the same time, there is only evidence on the effectiveness of NPWT on diabetic foot wounds after amputation^[31], robust evidence of effectiveness of NPWT over SWC when applied on wounds with different etiologies is still lacking. Thereby, Peinemann et al (2008) found in their systematic review that one manufacturer of the NPWT-devices sponsored the majority (68%) of the conducted RCT's on NPWT.^[32] This may have its effect on the methodology used and conclusions drawn.^[33, 34] Another issue is the possibility of publication bias.^[35, 36] Peinemann et al (2008) in their systematic review, identified 28 unpublished RCT's on NPWT covering at least 2755 planned or analyzed patients.^[32] Inclusion of unpublished data may affect conclusions regarding the intervention.^[37]

Question remains why NPWT is so popular. Maybe the increasing favor of using electronic gadgets in health is related to this popularity.^[38] Good marketing skills of the negative pressure devices companies may also add to the appreciation of this therapy.^[39] Besides this, the early clinical results of case reports and small series were impressive, prompting surgeons to apply this technology to a wide range of wounds.^[40] Thereby, the mechanism of actions of NPWT, e.g., macro- and micro-deformation, fluid removal, optimizing wound environment, angiogenesis and granulation tissue formation, are well-studied factors in promoting wound healing.^[40-42] Despite the exciting results that many have achieved, HCPs should be aware that NPWT is not a cure for all wounds, and not all patients are suitable for this therapy. The preference of HCPs for one treatment above the other may never be leading in treatment choice. The patient should be at the center of EBP and all decision-makings. Choice of therapy should be made in collaboration with HCP and patient, after being well informed and considering the specific needs and preferences of the patient.

Having a sensitive skin, as indicated by the patients themselves, appeared in a multi-variable analysis to be the only factor associated with nonadherence to NPWT (Chapter 5). This seems surprising, given the result of our retrospective study in which over one fifth of the patients treated with NPWT wished to cease this therapy because they felt to restricted by it in their daily lives. Also most of the participants of the qualitative studies (systematic review Chapter 3 and qualitative study Chapter 6) did not indicate skin problems as reasons for the experienced burden of NPWT. Maybe the fact that participants were aware of being studied in our prospective association study, restricted them in being open about their experienced burden. There might have been a Hawthorne effect, i.e., a change in behavior as a motivational response to the interest, care, or attention received through observation and assessment.^[43] Also, participants in the association study might felt it as not appropriate to indicate the allocated treatment as not suitable for themselves. The reason for the discrepancy between the results of our studies remains unclear. Nevertheless, having a sensitive skin is one of the factors that should be explored before starting wound therapy. When patients indicate to have a sensitive

skin, and prefer NPWT for the treatment of their wounds, the possibility of occurrence of skin irritation, and also alternative wound treatments should be discussed. When, after the SDM-conversation, the treatment choice for NPWT is made, a skin friendly drape, which is recently developed^[30], should be considered for use to decrease the chance of skin irritation. More frequent dressing changes could be considered.

Impact on daily practice

Currently, SDM and EBP are hot topics. Recently even more, by the launch of the paradigm of appropriate care by the Dutch Healthcare Authority.^[1] Chewning et al. found in their systematic review on patients' preferences for SDM that most patients preferred to be involved in decision making.^[44] Shared decision making is seen as beneficial to their knowledge of treatment options and satisfaction about decision making, especially when they feel involved.^[45] This 'feeling of being involved' might be the most important aspect of SDM. HCPs should make more effort to facilitate a two-way conversation. The patients need to understand their wound treatment options and associated risks and benefits. The HCPs need to know their patients, their preferences and their abilities. After sharing this knowledge, in two ways, the HCP and the patient together can explore the capabilities of the patient to decide and to participate in wound care treatment. Knowing that NPWT can have a huge impact on daily life activities and the experienced QoL emphasizes the importance of SDM. NPWT is a valuable treatment option, but not suitable for each patient. By sharing knowledge and preferences, the HCP and patient together find out before starting the wound therapy what suits this patient best. In this way we can avoid low-valued care, unnecessary costs, and provide real patient-centered care.

Methodological considerations

The focus of our research was the impact of NPWT on the QoL of patients. We used a variety of research designs, each design chosen as considered most suitable to answer the different research questions. Overall, our research is done in the scope of the patients' perspective. We are convinced that our research gives valuable insights in the patients' perspectives and preferences regarding wound care treatment, specifically the NPWT treatment.

The order in which we conducted the studies turned out to be logical and meaningful. Although published later, we started with the retrospective study to confirm our assumption that a substantial percentage of our patients (with postoperatively infected abdominal wounds) premature ceased NPWT because they felt too restricted by it in their daily lives. The systematic reviews gave us information on whether this problem is also recognized in general, and what the experiences of patients treated with NPWT entail. Further research was conducted to explore which factors are associated with a

premature cessation of therapy at the patients request. All the knowledge we gained from the former studies could be used to formulate the right questions in the topic list of the interviews of the qualitative study. Thereby, having found that NPWT can have a huge impact on the quality of patients' lives, resulted in the requirement for a study on an alternative treatment as we did in the case series on the capillary dressing.

Although specifically asked to the patients, it might have been hard to distinguish between the experienced impact of the wound and impact of the treatment on their daily lives. Most aspects mentioned, are specifically related to NPWT, such as the noises, the alarms en being attached to a medical device by a tube. However, having a wound itself does have a huge impact on patients. This might have influenced their overall coping with a treatment. Having to deal with a wound, comorbidities and the uncertainties that accompanies this might have lowered their coping capabilities to also having to deal with the wound treatment. Being aware of this emphasizes the need to keep the discomfort of the wound treatment as small as possible, with the fastest result (i.e., wound healing).

The confidence patients have in their HCPs, as well as the currently still seen paternalistic relationship between patients and HCPs, makes it sometimes hard to explore the real patients experiences and feelings. As participants mentioned in the interviews, they will follow the HCP's advice regardless their own preferences. This phenomenon might have influenced the results of the studies. Patients might not have indicated their wishes to premature cease NPWT, because they felt this would be inappropriate, as if they questioned the treatment choice of the HCP.

The last two years the world had to deal with the Covid-19 pandemic.^[46] Also our research activities have been influenced by Covid-19. The pressure the pandemic put on the HCPs, resulted in lack of attention to our pilot study on the comparison of NPWT and a capillary dressing on time to complete wound healing and experienced QoL, in the participating hospitals. This resulted in only seven patients included in over a half year time and we decided to premature cease this study. Beside the impact on the pilot study, Covid-19 might have influenced the experienced QoL of the participants in our qualitative study. We specifically asked for experiences due to the wound and the therapy, but we do not know whether or not our participants' experiences were influenced by living in this difficult time. Also in our research team things changed due to the pandemic. Meetings went from face to face to online. Our attention had to be divided between concerns for our families, our many patients and our research. However, the pandemic didn't influence our passion for research and did not restricted any of our team members to keep on going.

FUTURE RESEARCH

Our association study was a first step, but further prospective research on predictive determinants to nonadherence to NPWT is required. The results of this prognostic study could be used to develop a decision aid for choosing between NPWT and standard wound care, based on evidence-based information on both treatment options, and their associated benefits and harms. As mentioned in the discussion, only when HCPs are willing to invest in a real two – way conversation, giving the patient the possibility and strength to decide on treatment choice en PP, the development of such a tool is useful.

More high quality research about the effectiveness of NPWT, compared to standard wound care, should be performed. Also potential alternatives to NPWT, such as the capillary dressing of our case series, should be studied for their (cost-)effectiveness. Restart our pilot study would provide meaningful information whether a capillary dressing could be a valuable alternative to NPWT.

Research about the patients' preferences in wound care on NPWT, and on other wound care treatment options regarding treatment choice and PP is needed. Evaluation research on received care of wound treatments e.g., what are the patients' values, what do they consider important in wound treatment, should be performed. Only when we know what the priorities in wound care outcomes are for patients, we can address them en talk about real patient-centered care.

CONCLUSION

With this thesis we aimed to provide insight in the experiences and preferences of patients with wounds, treated with negative pressure therapy. We found that NPWT can have a huge impact on the QoL of patients. HCPs need to inform patients more thoroughly about treatment options and the pro's and cons of each treatment. More effort should be made in exploring the patients preferences regarding treatment and PP. By this two-way conversation, i.e., the HCP informs the patients about the treatment options and the patient informs the HCP about their preferences and capabilities, patient and HCP will come to a wound treatment that suits each individual patient best.

Our research fits in the four principles of appropriate care; working together that ensures that everyone can receive fundamental care in the future.^[1] The first principle is to only provide wound care that really works for patients. We acknowledged the sparse rigid evidence for NPWT, as well as for other wound care treatments. This lack of evidence on treatment options emphasizes the importance of exploring and addressing the patients preferences. The need for professional wound care treatment is linked to the second principle; organize care as close as possible. The complexity of wound

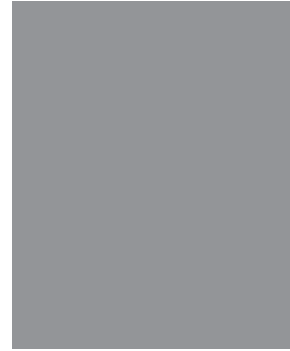
care and the different HCPs involved in this care, asks for good interprofessional communication and collaboration. In many cases, wound treatment can be performed at home, provided the availability of skilled home (wound) care nurses and accessibility of specialized wound care HCPs in wound expertise centers. In our research we paid extensive attention to the third principle of fundamental care; decide together with the patient. More effort should be made to a two-way conversation to inform the patient thoroughly about the treatment options, and to explore the patients preferences in wound treatment and in PP. Finally, our research adds to the fourth principle, more emphasis on health and quality of life, and less on medicalization. When we acknowledge the impact a wound and wound treatment can have on the patients' experiences QoL, and explore and address the patients' preferences in wound treatment, patients will feel empowered. This will result in an improvement in sense of self, a better HCP – patient relationship and probably better health care outcomes.

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Summary

Negative pressure wound care therapy (NPWT) is a widely accepted and commonly used treatment modality for open wounds. However, robust evidence is lacking regarding the effectiveness of NPWT for wound healing. It is critical to explore patients' experiences and preferences regarding this treatment choice, because this information will enable healthcare professionals (HCPs) to more thoroughly inform patients about treatment options and facilitate conversations about treatment decisions using an evidence-based practice (EBP) and shared decision making (SDM) approach. This approach will enable HCPs to work together with patients to choose the wound therapy that best suits each individual patient. The primary aim of this thesis is to provide insight regarding the experiences and preferences of patients treated with NPWT.

Although NPWT is frequently used, some patients decide to prematurely cease the treatment due to its negative effects on their quality of life (QoL). To obtain more insight regarding the impact of NPWT on patients' QoL, **Chapter 2** of this thesis presents a systematic review of quantitative studies and explores whether the impact of treatment on patient QoL differs between NPWT and standard wound care (SWC).

This systematic review includes five articles of moderate to high quality (median MINORS-score: 75%; range: 58–96%), all of which include observations that patient QoL improved after therapy, regardless of which therapy was used. Patients who had NPWT experienced a decreased QoL during the first week of treatment, possibly due to anxiety, after which they reported a similar or increased QoL compared to that of patients who received SWC. These findings suggest an association between NPWT and increased patient anxiety.

Chapter 3 presents an additional systematic review of qualitative studies to understand what factors affect QoL scores among patients treated with NPWT. Five qualitative studies with good methodological quality are included in this review, representing the experiences of 51 individual patients.

Four major themes emerged from content analysis. First, patients experienced less freedom of movement because they were attached to an electric device. Second, patients reported decreased self-esteem due to NPWT treatment because being attached to a device constantly reminded them of their wound. The shame of the wound and the inconveniences of the treatment altered patients' sense of themselves. The third theme observed in content analysis was an increase in social and professional dependency that resulted in patients feeling unable to fulfill their normal role in the family. Professional assistance by HCPs who were familiar with NPWT was considered a requisite by patients. The final observed theme was that over time, patients' tolerance for NPWT increased as they gained control over their situation and themselves. This review indicates that NPWT has substantial effects on the physical, psychological, and social domains of patient QoL.

Chapter 4 presents a multi-method study. First, we retrospectively measured the number of patients in the study hospital with a postoperatively infected abdominal wound who prematurely ceased NPWT on their own request because due to experienced restrictions in their daily lives. In all, 20% of patients ($n = 17$) chose to prematurely cease NPWT. To gain additional insight as to the factors that determine this nonadherence (i.e., cessation of therapy upon patient request before the treatment goal is reached), a narrative review was conducted to identify general determinants of nonadherence to healthcare-related therapies. A narrative review of 22 studies identified 23 determinants that might influence patient nonadherence. The potential determinants identified in the narrative review were included as questions in an e-survey distributed to 620 wound care nurses in the Netherlands. For each determinant drawn from the narrative review and the retrospective study (total of 26 potential determinants), wound care nurses were asked to indicate on a 10-point scale how decisive they consider this determinant for patient nonadherence to NPWT.

In all, 22% of the wound care specialists ($n = 136$) completed the survey. The highly relevant determinants of (non)adherence to NPWT identified by survey respondents included confidence in the healthcare team, consistency in therapy advice, coping with pain, former negative experiences with NPWT, normal activity pattern, social support from family or friends, and support from the healthcare team. Religion was the only potential determinant that was scored as not highly relevant.

In **Chapter 5**, the 25 potential prognostic determinants identified in chapter 3 are assessed for their predictive value in determining nonadherence to NPWT. A multi-center exploratory prognostic cohort study was conducted, including 264 patients treated with NPWT. Knowing which (patient-, treatment-, and healthcare-related) factors are associated with premature cessation of therapy will facilitate SDM and support patient-centered choice of therapy. Data for 25 potential prognostic determinants of nonadherence were collected using a web-based case record form. The primary outcome was nonadherence to NPWT, defined as premature termination upon patient request. Logistic regression analyses were used to explore the association between the potential determinants and nonadherence.

A total of 16 hospitals (1 academic hospital, 3 teaching hospitals, 10 general hospitals, and 2 private centers) in the Netherlands participated in this study. Nonadherence to NPWT was found in 32 of 264 patients (12.1%). Univariable analyses identified 6 candidate prognostic determinants: sensitive skin (odds ratio: 2.32; 95% confidence interval: 1.10–5.10; $p = .03$), shared decision to use NPWT (odds ratio: 2.43; 95% confidence interval: 1.06–6.30; $p = .05$), handiness with technique (odds ratio: 1.80; 95% confidence interval: 0.86–3.89; $p = .13$), alternatives discussed (odds ratio: 1.78; 95% confidence interval: 0.83–3.75; $p = .13$), patient knowledge and understanding of NPWT (odds ratio: 0.50; 95% confidence interval: 0.18–1.20; $p = .15$), and previous experience with NPWT

(odds ratio: 0.42; 95% confidence interval: 0.10–1.24; $p = .17$). In the multivariable analysis, only sensitive skin appeared to be a significant determinant of nonadherence (odds ratio: 2.20; 95% confidence interval: 1.02–4.85; $p = .05$). Patients who have sensitive skin may have an increased risk of premature termination of NPWT. Making shared decisions about therapy was also associated with nonadherence.

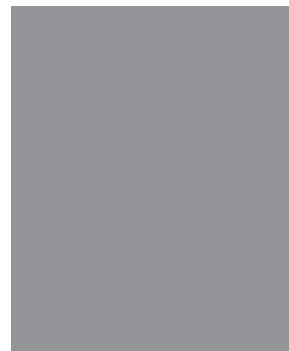
Chapter 2, 3, 4 and 5 of this thesis examine different aspects of the impact of NPWT on patient QoL. In medical practice, it is generally understood that patient participation in decision making influences adherence and QoL. However, it is unclear if this association holds true among patients with wounds. Therefore, **Chapter 6** presents a qualitative study that investigates the experiences and preferences of patients treated with NPWT regarding their treatment choice and participation in wound care. In semi-structured interviews, 10 adult patients who were treated with NPWT were invited to share their experiences and preferences regarding SDM and patient participation (PP) in wound care. A purposive sampling approach was chosen to identify and select information-rich cases. All interviews were recorded and transcribed verbatim. A thematic analysis was applied to identify, analyze, and report themes within the data.

Four themes emerged from the qualitative interviews: (1) Having a wound makes patients uncertain and thus influences QoL; (2) NPWT influences patients' daily lives; (3) Professional treatment decisions are considered most important and (4) Self-management of wounds is accepted by patients only in low-complexity well healing wounds under supervision. Participants specifically emphasized their worries about the future and the impact of the wound and treatment on their families. Participants did not prefer SDM in wound treatment choice. After being thoroughly informed, they still preferred the HCP to decide on the treatment choice. Additionally, participants and/or their relatives did not want to actively participate in complex wound care. Participants referred to a need for qualified wound care professionals and expressed that they did not want to be nor feel responsible for the wound treatment.

Because NPWT reduces freedom of movement for patients, alternative wound treatment products were examined. These products are equally effective but do not include the inconvenience of an electric device. **Chapter 7** presents the results of a case series on a potential alternative to NPWT. This case series describes treatment effects and experiences among patients who switched from NPWT to a rapid capillary action dressing (RCAD; VACUTEX™). For the case series study, 10 consecutive patients were prospectively recruited in a teaching hospital in the Netherlands between June 2019 and October 2019. Patients were eligible if they had prematurely terminated NPWT, either upon their own request or that of the wound care specialist. Data on wound healing were collected and noted in the patient chart. When NPWT was terminated, treatment was continued using an RCAD.

The mean time to complete wound closure was 87.3 days (SD: 38.3). The main reasons for terminating NPWT were maceration and irritation of the skin (caused by the exudate and the film) and patient discomfort. All patients preferred the RCAD treatment due to their increased mobility with this treatment and the relative absence of noise compared to NPWT. The case series findings indicate that RCAD could be a valuable alternative or follow-up treatment to NPWT.

Finally, **Chapter 8** presents a summary of the findings of the studies in this thesis and discussion of the implications for nurses and other HCPs. SDM is considered beneficial for patient knowledge about treatment options and satisfaction with decision making, especially when they *feel* involved. Based on the study findings, the “feeling of being involved” may be the most important aspect of SDM for patients; thus, HCPs should make an effort to facilitate two-way conversations. Patients need to understand their wound treatment options and the associated risks and benefits, and HCPs need to understand their patients’ preferences and abilities. By sharing knowledge and preferences, the HCP and patient can work together to determine the wound therapy that best suits the patient. This approach can help HCPs avoid low-value care and unnecessary costs and provide truly patient-centered care.



Samenvatting

Negatieve druktherapie (NDT) is een algemeen aanvaardde en veelgebruikte behandelmethode voor patiënten met wonden. Er is echter nog steeds geen robuust bewijs voor de effectiviteit van NDT. Hierdoor wordt het nog belangrijker om de ervaringen en voorkeuren van patiënten met betrekking tot de behandelkeuze te onderzoeken. Wanneer zorgprofessionals op de hoogte zijn van deze ervaringen en voorkeuren, stelt dat hen in staat om patiënten grondiger te informeren over behandelingsopties en het behandelgesprek op een evidence-based practice (EBP) en shared decision making (SDM) manier te voeren. Op deze manier kunnen zorgprofessionals samen met patiënten een wondbehandeling kiezen die het beste bij elke individuele patiënt past. Doel van dit proefschrift was dan ook om inzicht te verschaffen in de ervaringen en voorkeuren van patiënten met wonden, behandeld met NDT.

Hoewel NDT vaak wordt gebruikt, besluiten sommige patiënten voortijdig te stoppen met NDT vanwege de negatieve effecten hiervan op de door hen ervaren kwaliteit van leven (KvL). Om meer inzicht te krijgen in de impact van NDT op de KvL van patiënten hebben we in **Hoofdstuk 2** een systematische review van kwantitatieve studies beschreven. In deze review hebben we onderzocht of de invloed van de gekozen therapie op de KvL van patiënten verschillend is tussen NDT en standaard wondzorg.

Deze systematische review van vijf geïncludeerde artikelen van matige tot hoge kwaliteit (mediane MINORS-score was 75% (58%-96%)), liet zien dat de KvL verbeterde aan het einde van de therapie, onafhankelijk van de ingezette therapie. NDT leidde in de eerste behandelweek tot een lagere KvL, mogelijk door angstgevoelens. Na de eerste week werd een vergelijkbare of betere KvL gerapporteerd, in vergelijking met standaard wondzorg. NDT zou geassocieerd kunnen zijn met een verhoogde mate van angst.

In **Hoofdstuk 3** hebben we een aanvullende systematische review gedaan van kwalitatieve studies, omdat we wilden begrijpen welke aspecten van de behandeling met NDT de KvL-scores beïnvloedt. Vijf kwalitatieve onderzoeken met een goede methodologische kwaliteit, waarin de ervaringen van 51 individuele patiënten zijn verwerkt, werden geïncludeerd.

Na Content Analysis kwamen vier grote thema's naar voren. Als eerste; patiënten ervaarden minder bewegingsvrijheid door het vastzitten aan een elektrisch apparaat. Het tweede thema was dat patiënten een verminderd zelfbeeld door de NDT rapporteerden, doordat het vastzitten aan een apparaat hen constant aan hun wond herinnerde. De schaamte van de wond en de ongemakken van de therapie gaf hen een verminderd gevoel van eigenwaarde. Het derde thema van de content analysis was een toegenomen sociale en professionele afhankelijkheid wat bij patiënten resulteerde in een beperking in het vervullen van hun normale rol binnen het gezin. Professionele hulp door zorgverleners die bekend waren met NDT, werd als een vereiste beschouwd. Het laatste thema was dat na verloop van tijd patiënten NDT beter leken te verdragen, doordat ze meer

controle over hun situatie en over zichzelf verkregen. Uit deze review blijkt dat NDT grote effecten heeft op de fysieke, psychologische en sociale domeinen van KvL van patiënten.

Hoofdstuk 4 beschrijft een multimethods onderzoek. Eerst hebben we retrospectief het werkelijke aantal patiënten in het onderzoeksziekenhuis met een postoperatief geïnfecteerde buikwond dat voortijdig stopten met NDT op eigen verzoek vanwege ervaren beperkingen in hun dagelijks leven, gemeten. We vonden dat 20% (n=17) van deze patiënten voortijdig en op eigen verzoek stopte met NDT. Om meer inzicht te krijgen in wat deze therapieontrouw zou kunnen bepalen (d.w.z. stopzetting van de therapie op verzoek van de patiënt, voordat het doel is bereikt), werd een narrative review uitgevoerd. Het doel van deze narrative review was het identificeren van algemene determinanten van therapieontrouw. Deze narrative review van 22 studies identificeerde 23 determinanten die therapie(on)trouw zouden kunnen beïnvloeden. Met de resultaten van deze narrative review is een emailenquête gehouden onder wondzorgverpleegkundigen in Nederland. De algemene determinanten uit de narratieve review zijn als vragen toegevoegd in deze enquête, en werd gestuurd naar 620 wondzorgverpleegkundigen in Nederland. Per algemene determinant verkregen uit de narratieve review en de retrospectieve studie (totaal 26 potentiële determinanten), werd wondzorgverpleegkundigen gevraagd om op een 10-puntsschaal aan te geven hoe bepalend zij deze determinant vonden met betrekking tot therapieontrouw aan NDT.

Tweëntwintig procent (n = 136) wondzorgverpleegkundigen vulden de enquête in. Vertrouwen in het zorgteam, consistentie in therapieadviezen, omgaan met pijn, eerdere negatieve ervaringen met NDT, een normaal activiteitenpatroon, sociale steun van familie of vrienden en steun van het zorgteam werden geïdentificeerd als zeer relevante determinanten van therapie(on)trouw naar NDT. Religie was de enige potentiële determinant die als minder relevant scoorde.

In **Hoofdstuk 5** werden de 25 geïdentificeerde potentiële prognostische determinanten uit hoofdstuk 3 beoordeeld op hun voorspellende waarde voor therapieontrouw aan NDT. Er is een multicenter exploratory prognostic cohortonderzoek uitgevoerd, waarin 264 patiënten die behandeld werden met NDT zijn geïnccludeerd. Wanneer we meer weten over welke (patiënt-, behandelings- en zorggerelateerde) factoren geassocieerd zijn met een voortijdige stopzetting van de therapie, zal dat SDM en het maken van een patiëntgerichte keuze voor behandeling vergemakkelijken.

Met behulp van een web-based dataprogramma werden de gegevens over 25 mogelijke prognostische determinanten van therapieontrouw verzameld. De primaire uitkomstmaat was therapieontrouw bij NDT, gedefinieerd als voortijdige beëindiging van NDT op verzoek van de patiënt. Middels logistische regressieanalyses werd de associatie tussen de potentiële determinanten en therapieontrouw onderzocht.

Zestien ziekenhuizen (1 academisch ziekenhuis, 3 topklinische ziekenhuizen, 10 algemene ziekenhuizen en 2 particuliere centra) in Nederland namen deel aan dit on-

derzoek. Bij 32 van de 264 patiënten (12,1%) werd therapieontrouw aan negatieve druktherapie gevonden. Univariabele analyses identificeerden 6 kandidaat prognostische determinanten: het hebben van een gevoelige huid (odds ratio: 2.32; 95% betrouwbaarheidsinterval 1.10-5.10, $p = .03$), beslissing voor negatieve druk wondtherapie genomen als een gedeelde beslissing (odds ratio: 2.43; 95% betrouwbaarheidsinterval 1.06-6.30, $p = .05$), handigheid met techniek (odds ratio: 1.80; 95% betrouwbaarheidsinterval 0.86-3.89, $p = .13$), alternatieven worden besproken (odds ratio: 1.78; 95% betrouwbaarheidsinterval 0.83-3.75, $p = .13$), kennis en begrip van wondtherapie met negatieve druk (odds ratio: 0.50; 95% betrouwbaarheidsinterval 0.18-1.20, $p = .15$) en eerdere ervaring met wondtherapie met negatieve druk (odds ratio: 0.42; 95% betrouwbaarheidsinterval 0.10-1.24, $p = .17$). In de multivariabele analyse bleek alleen het hebben van een gevoelige huid een significante determinant van therapieontrouw te zijn (odds ratio: 2.20; 95% betrouwbaarheidsinterval 1.02-4.85, $p = .05$). Patiënten met een gevoelige huid kunnen een verhoogd risico op voortijdige beëindiging van negatieve druktherapie hebben. Het maken van een keuze voor de te volgende behandeling op een SDM manier toonde ook een associatie met therapieontrouw.

De eerste hoofdstukken van deze thesis onderzochten de verschillende aspecten van de impact van NDT op de KvL van patiënten bestudeerd. We weten dat het over het algemeen belangrijk is om patiënten te betrekken in de besluitvorming, omdat dit de therapietrouw en de kwaliteit van leven positief beïnvloedt. Het is echter onduidelijk of dit ook het geval is bij patiënten met wonden. Daarom beschrijft **Hoofdstuk 6** een kwalitatieve studie waarin de ervaringen en voorkeuren van patiënten, behandeld met NDT, met betrekking tot behandelkeuze en deelname aan wondzorg, onderzocht zijn. In semi-gestructureerde interviews werden tien volwassen patiënten die voor hun wonden met NDT waren behandeld, uitgenodigd om hun ervaringen en voorkeuren met betrekking tot SDM en patiëntenparticipatie (PP) in wondzorg te delen. Er werd gekozen voor een doelgerichte steekproefkeuze om informatierijke casussen te identificeren en te selecteren. Alle interviews zijn opgenomen en woordelijk uitgetypt. Er werd gebruik gemaakt van thematic analysis om thema's binnen de data te identificeren, analyseren en te beschrijven.

Uit de ervaringen van patiënten kwamen vier thema's naar voren: (1) Het hebben van een wond maakt patiënten onzeker en beïnvloedt daarmee de KvL; (2) NDT beïnvloedt het dagelijks leven van patiënten; (3) Het maken van de beslissing voor de te volgen therapie door de zorgprofessional wordt als het belangrijkste beschouwd en (4) Patiënten participatie, het zelf verzorgen van de wond, wordt door patiënten alleen geaccepteerd bij laagcomplexen, goed genezende wonden onder supervisie van zorgprofessionals. De deelnemers aan het onderzoek benadrukten specifiek hun zorgen over de toekomst en de impact van de wond en van de behandeling op hun families. De deelnemers gaven niet de voorkeur aan gedeelde besluitvorming bij de keuze van hun wondbehandeling.

Na grondig te zijn geïnformeerd, wilden de deelnemers toch dat de zorgprofessional een definitieve behandelkeuze zou maken. Ook wilden deelnemers en/of hun naasten niet actief deelnemen aan het uitvoeren van complexe wondzorg. Naast de behoefte aan gekwalificeerde wondzorgprofessionals, gaven deelnemers aan dat ze de verantwoordelijkheid voor de wondbehandeling/-genezing niet wilden dragen.

Omdat NDT de bewegingsvrijheid van patiënten vermindert, werd gezocht naar alternatieve wondbehandelingsproducten, die even effectief zijn, maar niet de ongemakken zoals een elektrisch apparaat, hebben. In **Hoofdstuk 7** worden de resultaten getoond van een casiserie over een mogelijk alternatief voor NDT. Deze casusreeks beschrijft de behandelingseffecten en van patiënten die overstapten van NDT naar de wondbehandeling met een 'snelle capillaire werking verband' (SCWV; VACUTEX™). Voor deze casiserie werden prospectief 10 opeenvolgende patiënten die tussen juni 2019 en oktober 2019 in een academisch ziekenhuis in Nederland werden behandeld, geïnccludeerd. Patiënten kwamen in aanmerking voor participatie in de studie als ze NDT voortijdig beëindigden op eigen verzoek, of op advies van de zorgprofessional. Gegevens over de wondbehandeling en -genezing werden verzameld en genoteerd in het patiëntendossier. Na beëindiging van de NDT werd de behandeling voortgezet met een capillair verband (SCWV).

De gemiddelde tijd tot volledige wondsluiting was 87,3 dagen (SD 38,3). De belangrijkste redenen voor het beëindigen van NDT waren maceratie en irritatie van de huid veroorzaakt door vocht onder folie, en het ervaren ongemak door de patiënt. Alle deelnemende patiënten gaven de voorkeur aan het capillair verband boven NDT, voornamelijk omdat ze hiermee mobieler waren en het verband in tegenstelling tot NDT geen geluid maakte. Deze case serie liet zien dat dit capillair verband een waardevolle vervolghtherapie op NDT, of een mogelijk alternatief voor NDT zou kunnen zijn.

In **Hoofdstuk 8** worden de bevindingen van de studies in dit proefschrift en de implicaties voor verpleegkundigen en andere zorgprofessionals samengevat en besproken. Gedeelde besluitvorming (SDM) draagt bij aan meer kennis bij patiënten over de behandelopties en de tevredenheid over de besluitvorming, vooral wanneer zij zich betrokken voelen. Dit 'gevoel van betrokkenheid' is misschien wel het belangrijkste aspect van SDM. Zorgprofessionals zouden meer moeite moeten doen om het zorgverlenersgesprek in twee richtingen te laten verlopen: de patiënten moeten hun wondbehandelingsopties en de bijbehorende risico's en voordelen begrijpen. De zorgprofessionals moeten hun patiënten, hun voorkeuren en hun capaciteiten kennen. Door kennis en voorkeuren te delen zoeken de zorgprofessional en de patiënt samen, voor de start van de wondtherapie, uit wat het beste bij deze specifieke patiënt past. Op deze manier vermijden we 'low-value-care' en onnodige kosten, en bieden we echte patiëntgerichte zorg.



Research data management

The data obtained during my PhD at the Radboud University Medical Center have been stored at the secured drive Z394343 op VDIPR512-0372.

All folders are named in accordance with the chapters in this thesis. Every folder consists of at least the research proposal, the documents for the medical ethics committee, data analysis scripts, databases with raw and transformed research data, and the manuscript. The promotor of my PhD has access to this data. Access can be requested via the management of the Scientific Institute for Quality of Healthcare (IQ healthcare), Radboudumc, Nijmegen, the Netherlands. Data of the association study have been stored online in Castoredc, the electronic data capture system supported by the Radboudumc. All databases are provided with the original scientific publications or are available from the first author at reasonable request.

All studies were performed in accordance with the Good Clinical Practice principles and the Netherlands Code of Conduct for Research Integrity. We followed the International Committee of Medical Journal Editors (ICMJE) criteria for authorship. All studies involving human subjects were performed in accordance with the Declaration of Helsinki. The Medical Ethics committee for Research Involving Human Subjects Region Arnhem and Nijmegen, Nijmegen, the Netherlands has given approval to conduct the Pecan study (2020-6095), which is premature terminated and not included in this thesis. No ethical consideration was requested for the systematic reviews in **Chapters 2 and 3**, for the retrospective chart study / narrative review / e-survey in **Chapter 4** and the case series study of **Chapter 7**. Full ethical consideration was waived by the Ethics Committee of Arnhem and Nijmegen for the study in **Chapter 5** (2019-5108) in accordance with the Dutch Medical Research with Human Subjects Law. Full ethical consideration of the study of **Chapter 6** was waived by Medical Ethics Review Committee Amsterdam Medical Center (waiver nr. W19 385 # 19.450).

The studies of Chapter 2, 3, 4, 5 and 7 are published, the study of Chapter 6 is submitted and under review. The data and informed consent forms will be stored for 15 years after termination of the particular study. Re-use of the data obtained in our studies is only possible with a renewed informed consent by the study participant as stated in the informed consent. Anonymous use of data or use for educational purposes are possible, if renewed informed consent is considered unreasonable. The datasets analyzed during these studies are available from the corresponding author on reasonable request.



Portfolio

PhD portfolio of Sandra Janssen

Department: Scientific Institute for Quality of Healthcare (IQ healthcare) Radboud University, Nijmegen Graduate School: Radboud Institute for Health Sciences PhD period: 01-01-2018 – 31-21-2022 Promotor(s): Prof. H. Vermeulen Copromotor(s): Dr . A.M. Eskes, dr. T.S. de Vries Reilingh	
Training activities	Hours
Courses	
- GSL - Introduction Day (2018)	8.00
- RIHS - Introduction course for PhD candidates (2018)	15.00
- GCP (2018)	16.00
- Didactische basisprincipes (2018)	12.00
- RU - Digital Tools (2018)	4.00
- Enquetes maken die werken (2018)	4.00
- RU - Scientific Writing for PhD candidates (2019)	84.00
- RU - Statistics for PhD's by using SPSS (2019)	60.00
- Klinische predictiemodellen (2019)	18.00
- Introductiecursus kwalitatief onderzoek in de gezondheidszorg (2020)	13.50
- IMM - The Art of Presenting Science (2020)	33.00
- RU - Academic English Conversation and Pronunciation (2021)	43.00
- Radboudumc - Scientific integrity (2021)	20.00
- GCP (2022)	0.00
Seminars	
- Positief symposium over negatieve druk (2019) (organization symposium and oral presentation)	10.00
Conferences	
- EWMA 2018 (2018) (oral presentation)	24.00
- AAEFDU (2018) (oral presentation)	12.00
- EWMA 2019 (2019) (poster presentation)	19.00
- EWMA 2020 (2020) (oral presentation)	21.00
- 4th international conference on wound care, tissue repair and regenerative medicine (2021) (oral presentation)	7.00
- WUWHS (2022) (oral presentation)	35.00
- EWMA 2021 (2022) (oral presentation)	7.00
Other	
- PhD meetings (2018)	2.00
- PhD meetings (2018)	2.00
- PhD meetings (2018)	2.00
- EWMA curriculum for nurses EQF level 7 (2019)	0.00
- Bestuurslid V&VN Wondexpertise (2022)	56.00

Teaching activities	
Lecturing	
- Teacher (2021)	80.00
- Teacher (2021)	40.00
- Teacher (2022)	50.00
Supervision of internships / other	
- Supervision (2018)	80.00
- Supervision student wondopleiding (2018)	80.00
- Supervision MANP student (2019)	80.00
- Supervision HBO-V student (2019)	80.00
- Supervision student wondopleiding (2019)	120.00
- Supervision student wondopleiding (2020)	40.00
- Supervision student wondopleiding (2020)	60.00
- Supervision MANP student (2020)	40.00
- Supervision student wondopleiding (2021)	40.00
- Supervision student wondopleiding (2022)	40.00
Total	1,418.50



List of publications

INTERNATIONAL PUBLICATIONS

2016

Janssen, A. H., Mommers, E. H., Notter, J., de Vries Reilingh, T. S., & Wegdam, J. A. (2016). Negative pressure wound therapy versus standard wound care on quality of life: a systematic review. *Journal of wound care*, 25(3), 154–159.

2020

Janssen, A. H., Wegdam, J. A., de Vries Reilingh, T. S., Eskes, A. M., & Vermeulen, H. (2020). Negative pressure wound therapy for patients with hard-to-heal wounds: a systematic review. *Journal of wound care*, 29(4), 206–212.

Holloway, S., Pokorná, A., Janssen, A., Ousey, K., & Probst, S. (2020). Wound Curriculum for Nurses: Post-registration qualification wound management–European qualification framework level 7. *Journal of wound care*, 29(Sup7a), S1-S39.

2021

Janssen, A. H. J., Wegdam, J. A., de Vries Reilingh, T. S., Vermeulen, H., & Eskes, A. M. (2021). Which determinants are considered to be important for adherence to Negative Pressure Wound Therapy: A multimethods study. *Journal of tissue viability*, 30(2), 250–255.

Janssen, A. H. J., Rijploeg, J., Wegdam, J. A., de Vries Reilingh, T. S., Vermeulen, H., & Eskes, A. M. (2021) Promising results in wound care with a new rapid capillary action dressing: a case series study. *Wounds International*, 12(3), 20-25

2022

Janssen, A. H. J., van Bruggen-van der Lugt, A. W., Wegdam, J. A., de Vries Reilingh, T. S., van Dieren, S., Vermeulen, H., & Eskes, A. M. (2022). The association of potential prognostic determinants to nonadherence to negative pressure wound therapy: An exploratory prospective prognostic study. *Surgery*, 172(1), 349–357.

Chadwick, P., Janssen, S., Cvjetko, I., & Wright, E. (2022) Excellence in diabetic foot ulcer management: accelerate healing with topical oxygen therapy. *Wounds International* 13(3), 39-44

NATIONAL PUBLICATIONS

2018

List of publications

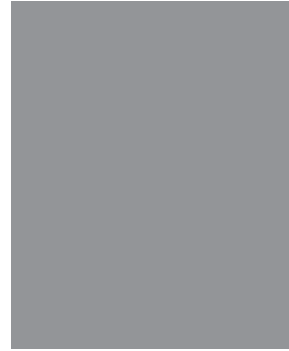
Janssen, S., Wegdam, J., de Vries Reilingh, T., Vermeulen, H., & Eskes, A. (2018). De relatie tussen vroegtijdig staken negatieve druktherapie en de ervaren kwaliteit van leven. *WCS Nieuws*, 34(4), 24-30.

2019

Janssen, S. (2019). Richtlijn littekenbreuk. *WCS Nieuws* 35(4), 20-23.

2021

Janssen, S. De impact van negatieve druktherapie. (2021) *TVZ verpleegkd prakt wet* **131**, 46-47



Dankwoord

Graag wil ik iedereen bedanken die heeft meegewerkt aan het tot stand komen van dit proefschrift. Een aantal mensen wil ik in het bijzonder noemen.

Hester Vermeulen, toen ik besloten had om te gaan promoveren, wist ik dat ik jou graag als promotor wilde. En daar heb ik ook geen moment spijt van gehad. De chirurg die mij begeleid had tijdens mijn Master, had enige twijfels, maar na ons eerste gezamenlijke gesprek in Nijmegen was hij volledig 'om' en zei hij dat hij volledig begreep waarom ik jou graag als promotor wilde. Je hebt me altijd het gevoel gegeven dat je er vertrouwen in had, dat we aan iets moois bezig waren. Van jou hoorde ik voor het eerst over de 'trias academica', en dat was/is precies wat ik wilde: werken met patiënten met wonden, les geven in wondzorg en onderzoek doen op het gebied van wondzorg. Ik heb genoten van de PhD bijeenkomsten en het rondje 'successen delen' daar vond ik zo typerend voor jou. Ik heb enorm veel respect voor jou als mens, en voor de carrière die je gemaakt hebt. Dank voor je steun, je laagdrempelige benaderbaarheid en alles wat ik van je geleerd heb.

Anne Eskes, als copromotor heb jij het meeste voor mij betekend. Elke vraag die ik had, elk stuk wat ik geschreven had, elke keer weer beantwoordde jij mijn vragen snel, kritisch en opbouwend. Door jouw kennis en enthousiasme werd mijn enthousiasme alleen maar groter. Het waren soms zware jaren, maar niet een keer ben ik moedeloos geworden. Dit komt met name door de professionele maar ook persoonlijke begeleiding die ik van jou heb mogen ontvangen. Ik heb veel geleerd op het gebied van onderzoek, met name door het sparren met jou (en Hester), het heen en weer sturen van stukken, de opbouwende kritieken en onze (Teams)gesprekken. Anne, ik ben heel blij en dankbaar dat Hester jou als copromotor voorstelde en hoop dat we in de toekomst samen onderzoek kunnen blijven doen. Je bent geweldig.

En dan 'de mannen', zoals Anne en ik jullie meestal noemden: **Johannes Wegdam** en **Tammo de Vries Reilingh**, chirurgen van het Elkerliek ziekenhuis. Hoe gezegend ben je als je mag promoveren met twee chirurgen die in je geloven en je steunen. Jullie hebben me zo vaak verteld dat jullie trots op me zijn dat ik het geloof. De avonden sparren bij Johannes thuis, en in het ziekenhuis, zal ik nooit vergeten. Druk met zijn eigen promotie maar (zeker in het begin) toch tijd vrij maken voor mijn traject. Johannes kritisch, soms van links naar rechts schietend in zijn gedachten en wensen, maar altijd positief. Het heeft mij mede gevormd en me sterker gemaakt in mijn conversaties. Tammo, jij hebt me het gevoel gegeven dat ik altijd bij je terecht kon/kan, dat je er voor me bent. Dank voor je steun op verschillende gebieden. Ik weet dat jullie het heel druk hebben, en er was de afgelopen jaren veel gaande in de GE groep. Desondanks hebben jullie mij het gevoel gegeven gewaardeerd te worden, en mede dat maakt dat ik elke dag met plezier in het Elkerliek ziekenhuis kom werken.

Door de jaren heen heb ik verschillende collega's gehad. Vorig jaar is **Jennifer Boereboom** mijn directe collega geworden. Zij begint in september aan de MANP opleiding.

Jennifer, ik ben zo blij dat jij ons team bent komen versterken. We worden allebei blij van samen werken, van samen sparren en ook af en toe samen klagen. Maar vooral ook samen lachen en blijven leren en genieten van onze successen. Elke tevreden patiënt maakt dat wij nog meer van ons werk houden. Nu ben ik klaar met mijn studie en kan ik me gaan richten op het begeleiden van jou tijdens je MANP opleiding.

Op de poli chirurgie in het Elkerliek ziekenhuis hebben we fantastische **polikliniek assistenten**. Elk succesje wat ik behaalde, zoals een publicatie, werd met veel enthousiasme en waardering door jullie mede gevierd. Altijd hebben of maken jullie tijd voor een praatje, voor hulp waar nodig. Jullie zijn leergierig en vrolijk. Het is een genot om elke dag met jullie samen te mogen werken.

Tijdens mijn PhD traject heb ik twee directe leidinggevende gehad, de eerste jaren **Tessa Brederode** en later (en nu) **Anne-Marie Pompen**. Dankjewel dames voor jullie interesse in waar ik mee bezig ben geweest. Ik weet dat jullie het niet altijd allemaal geheel begrepen, maar jullie waardering heb ik zeker gevoeld. Ook mijn sector manager **Steeff Hoeks** wil ik bedanken voor het realiseren van 5 onderzoeksuren per week in mijn dienstverband. Boeien, binden, behouden hoor ik je nog zeggen: nou dat is gelukt.

Dite de Jong, arts-assistent in het Elkerliek ziekenhuis, heel erg bedankt voor de mooie plaatjes die jij gemaakt hebt voor mijn inleiding. Dat je dit tijdens je vakantie, en je verhuizing, hebt willen doen is echt heel lief en daar ben ik je zeer dankbaar voor.

Bij verschillende onderzoeken heb ik samengewerkt met anderen. **Alita Jaspar**, hoe ontzettend leuk vond ik het dat jij meteen ja zei toen ik je vroeg om de interviews mee te coderen. Het artikel is nog 'under review' maar ik ben ervan overtuigd dat we iets moois geschreven hebben. Ik waardeer jou enorm als collega en hoop dat we in de toekomst nog meer projecten samen mogen doen.

Andrea van der Bruggen, als afstudeeropdracht van de studie Master Evidence Based Practice in Health Care heb jij meegewerkt aan de Helmond studie. Ik heb veel geleerd van de analyses die je gedaan hebt, dankjewel. **Janet Rijploeg**, dankjewel voor de mooie casussen voor de case series study. We hebben er een mooi artikel van kunnen maken.

Al mijn **collega's in Nederland**, die op een of andere manier mee hebben gewerkt aan de totstandkoming van deze thesis: dankjewel. Alle respondenten op mijn enquête, alle collega's die mee hebben gewerkt aan de Helmond studie en aan de Pecan studie (vroegtijdig gestopt en niet opgenomen in deze thesis), mijn V&VN bestuursmaatjes: allemaal heel, heel erg bedankt voor jullie bijdragen, werk, moeite en fijne gesprekken!

Lieve **Leda en Bregje**, jullie staan tijdens mijn verdediging naast me...zoals jullie altijd naast me staan. Onze vriendschap betekent heel veel voor mij. Afspraken uitstellen omdat ik het te druk had, een reisje nog niet plannen omdat ik de datum van mijn verdediging nog niet weet; jullie hebben altijd begrip. Ik kan altijd alle problemen met

jullie bespreken en het mooie is dat het daarna eigenlijk nauwelijks nog problemen zijn. Jullie gingen mee naar Birmingham om mijn Master's certificaat te halen (ik krijg nog tranen in mijn ogen als ik er aan denk dat jullie dit gedaan hebben) en nu zijn jullie mijn paranimfen. Dank voor onze vriendschap, it means the world to me!

Papa en mama, jullie hebben mij altijd gesteund, in alles. Een dochter die na haar Atheneum een MBO opleiding tot verpleegkundige ging volgen, mensen vonden daar iets van. Jullie vonden het alleen maar fijn dat ik mijn hart volgde. Alle opleidingen daarna, en zeker deze laatste betekende dat ik soms mijn studie voor een bezoekje aan jullie liet gaan. Nooit hebben jullie daarover geklaagd. Ik heb alleen maar support, bewondering en heel veel liefde mogen ontvangen. De inhoud van alle artikelen die ik jullie heb laten lezen was jullie niet altijd even duidelijk, maar dat maakte jullie niet minder trots. Ik ben jullie heel dankbaar, en hou oneindig veel van jullie.

Bram en Luuk, mijn zonen...inmiddels jongvolwassenen. Jullie zijn mijn grootste goed, mijn grootste liefdes. We hebben van te voren besproken wat het zou betekenen als ik weer, en deze keer ruim 4 jaar, zou gaan studeren. Jullie kennen me als geen ander en weten hoe graag ik dit doe/gedaan heb. Het begrip dat jullie al die jaren hiervoor gehad hebben is onbetaalbaar. Dankjewel dat jullie me altijd gesteund hebben. Dankjewel dat jullie bij mijn verdediging zijn. Dankjewel dat ik jullie moeder mag zijn. Ik ben zo trots op jullie allebei. Jullie geven mijn leven zin, meer dan wat, welke thesis ook.

Hoe moet je een liefde die pas op een later moment in je leven is gekomen, en je altijd neemt zoals je bent, bedanken? **Marc**, ik heb geen woorden om uit te drukken hoe dankbaar ik je ben. Jij kent me, jij voelt me aan en jij laat me mijn gang gaan. Als ik het druk had deed je de was, liet je de hond uit, kookte je. Ik hoefde er niet eens om te vragen. Je las met veel interesse en vaak met iets minder begrip mijn artikelen. Je bent trots op me en ik ben trots op jou. Ik laat het hierbij, je weet wat ik voel en bedoel.



Curriculum Vitae

Sandra (Alexandra Helena Jacoba) Janssen werd geboren op 18 maart 1970 te Rotterdam. Zij groeide op in Gemert, waar ze in 1989 haar Atheneum diploma behaalde aan het toenmalig Macropedius College. Daarna wist ze zeker dat ze verpleegkundige wilde worden. Na het Atheneum lag de HBO-V wellicht voor de hand, maar ze wilde zo snel mogelijk aan de slag als verpleegkundige, dus het werd de in-service opleiding tot A-verpleegkundige in het toen nog streekziekenhuis Helmond-Deurne (huidige Elkerliek ziekenhuis). In 1993 behaalde ze haar diploma. Inmiddels was ze verhuisd naar Aarle-Rixtel, slechts een paar kilometer verwijderd van het ziekenhuis. Na haar diplomering werkte ze op de interne afdeling, en later op de chirurgische afdeling. Bij de chirurgie lag haar hart, en in 1995 haalde ze haar diploma oncologie verpleegkundige om de zorg voor oncologie patiënten op de chirurgische afdeling te verbeteren.

Soms gebeuren er dingen die later lijken 'zo te moeten zijn'. Sandra beseftte dat ze zich verder wilde verdiepen in haar vak. Zoekende naar een mogelijkheid hiertoe maakte een ongeluk tijdens het tafeltennissen dat ze niet tot haar pensioen aan bed zou kunnen blijven werken. Tegelijkertijd maakte het concept 'consulent' zijn opkomst in de Nederlandse zorginstellingen. Verpleegkundigen kozen voor aandachtsgebieden om zich verder te verdiepen in een bepaald onderdeel van de verpleegkunde en deze kennis over te dragen aan collegae. Sandra startte eind 1998 als consulent met twee aandachtsgebieden: oncologie en wond-/decubituszorg. Het Elkerliek ziekenhuis pakte het consulentenschap professioneel aan, en de consulenten hebben allen de incompany training 'verpleegkundig consulent' gevolgd, gegeven door de Hogeschool Arnhem/Nijmegen (HAN). Daarnaast volgde zij vele trainingen en scholingen op het gebied van wondzorg.

Na een aantal jaren beide consulentenschappen vorm te hebben gegeven, netwerken te hebben gebouwd en scholingen te hebben gegeven werd haar steeds meer duidelijk dat de wondzorg haar echte passie was. Toen ze in 2001 haar oudste zoon Bram kreeg en minder ging werken, was de keuze dan ook makkelijk gemaakt: Sandra stopte met het consulentenschap oncologie en stortte zich volledig op de wondzorg. Ze was inmiddels bestuurslid van de beroepsvereniging Nederlandse Vereniging van Decubitusconsulenten (NVDC, later overgegaan in V&VN wondconsulenten). In 2001 startte de eerste Master of Advanced Nursing Practice (MANP) opleidingen in Nederland. Het heeft een paar jaar geduurd voor het Elkerliek ziekenhuis toestemde om deze opleiding te gaan volgen, maar in 2004 was het zo ver: Sandra volgde als eerste verpleegkundige in het Elkerliek ziekenhuis de MANP opleiding aan de Fontys Hogeschool in Eindhoven / Tilburg. Inmiddels was ook haar tweede zoon Luuk geboren. Na deze opleiding zette zij het wondexpertisecentrum in het Elkerliek ziekenhuis op. Omdat veel wonden gerelateerd zijn aan vaatproblematiek, haalde ze in 2010 haar diploma voor de Vasculaire Specialisatie. Inmiddels gaf Sandra ook les op de twee wondopleidingen in Nederland, aan de

zorgacademie Radboudumc in Nijmegen en de zorgacademie van het Erasmus mc in Rotterdam.

Tijdens de MANP opleiding is de liefde voor onderzoek ontstaan. Om zich verder in het doen en beoordelen van onderzoek te bekwamen, volgde Sandra in 2013 / 2014 met goed gevolg de Master Health & Social Care aan de Universiteit van Birmingham. Deze Universiteit bood toentertijd een verkorte Master aan voor Verpleegkundig Specialisten. Zij deden dit al een paar jaar in Deventer / Enschede en 2013/2014 was de pilot in Rotterdam. Deze studie, met maar vier studenten in een groep en twee zeer bevlogen professoren uit Birmingham, was een genot om te volgen. Vanuit deze opleiding kwam de wens om verder te gaan met onderzoek. En waarom dan niet in een PhD traject? De chirurgen van het Elkerliek waren enthousiast, en in 2018 startte Sandra haar PhD met als onderwerp de impact van negatieve druktherapie op de kwaliteit van leven van patiënten. De trias academica is compleet: patiëntenzorg, educatie en onderzoek. En dit alles met 1 doel voor ogen: een zo goed mogelijke zorg voor de patiënten met wonden.

Inmiddels werkt Sandra ook in het Regionaal Expertise Team Wondzorg wat ze samen met de twee grootste eerste lijns zorg aanbieders opgezet heeft. Ze is voorzitter van V&VN wondexpertise en geeft les aan de wondopleidingen. Ze werkt nog steeds met heel veel zin, fulltime, in het wondexpertisecentrum van het Elkerliek ziekenhuis, alwaar ze ook uren beschikbaar gesteld heeft gekregen voor het opzetten en deelnemen aan wetenschappelijk onderzoek.

“Tell me and I forget. Teach me and I remember. Involve me and I learn.” -*Benjamin Franklin*

