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NPWT Resource Use Compared With Conventional Wound Treatment in Subcutaneous Abdominal Wounds With Healing Impairment After Surgery

SAWHI Randomized Clinical Trial Results

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Objective: To compare resource utilization of NPWT and CWT for SAWHI after surgery

Summary of Background Data: NPWT is widely used in the management of complex wounds but high-level evidence of its resource use remains sparse.

Methods: The multicenter, multinational, randomized clinical SAWHI study enrolled a total of 539 consecutive, compliant adult patients with SAWHI after surgery without fascial dehiscence between August 2, 2011, and January 31, 2018. Patients were randomly assigned to NPWT and CWT stratified by study site and wound size using a centralized web-based tool. Evaluation of direct resource use comprised inpatient and outpatient time, personnel and material for wound treatment, and associated wound-related procedures. The resource use analysis was primarily based on the per protocol population (NPWT 157; CWT 174).

Results: Although treatment length within 42 days was significantly shorter in the NPWT arm {Mean [Standard deviation (SD)] NPWT 22.8 (13.4); CWT 30.6 (13.3); $P < 0.001$ *U*-test}, hospitalization time was shorter with CWT [Mean (SD) NPWT 13.9 (11.1); CWT 11.8 (10.8); $P = 0.047$ *U*-test]. Significantly more study participants were outpatient with CWT [N=167 (96.0%)] than with NPWT [N = 140 (89.2%) ($P = 0.017$)]. Time for dressing changes per study participant [Mean (SD) (min) NPWT N = 133, 196 (221.1); CWT N = 152, 278 (208.2); $P < .001$ *U*-test] and for wound-related procedures [Mean (SD) (min) NPWT 167 (195); CWT 266 (313); $P < 0.001$ *U*-test] was significantly lower with NPWT.

Conclusions: NPWT reduces resource use and maybe an efficient treatment alternative to CWT for SAWHI after surgery.

Keywords: abdominal wound, conventional wound treatment, negative pressure wound therapy, resource use, surgical wound, wound healing, wound treatment

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Wound complications are one of the leading causes of postoperative morbidity worldwide, with mortality affecting 1%–4% of patients after gastrointestinal surgery.[1,2] Impaired wound healing in the acute setting is typically caused by surgical site infections (SSIs), wound dehiscence (without infection), and peri-wound maceration.[2–5] Dependent on the extent and infection status of the resulting lesion, adapted wound treatment is necessary. Subcutaneous abdominal wound healing impairment (SAWHI) after surgery requires immediate treatment to prevent fascial dehiscence and progression into deeper tissue layer and underlying organs.

Wound complications not only affect the patient's health status, quality of life, and mortality, but are associated with a negative economic impact. Economic impact is best reported for SSIs. SSIs, regardless of severity, increase hospitalization time [6,7] and incur considerable extra healthcare costs associated with additional hospital days and treatment.[8] To reduce hospitalization time, patients are frequently transferred to the home care setting, resulting in a resource use shift.[9] A substantial number of resources are used in outpatient facilities and home care.[9,10]

Negative pressure wound therapy (NPWT) represents a clinical wound care innovation that is not only a potentially effective alternative to conventional wound treatment (CWT),[11–15] but can also help reduce resource use.[10] Published literature examining the use of NPWT in wounds of various origin demonstrated that NPWT could reduce rehospitalizations, associated surgical procedures, dressing changes, personnel commitments, hospitalization and treatment time, and time until subsequent surgery.[16–21] However, there is an increasing demand for quality outcome data to support the economic decision-making process with attention to resource use efficiency and assessment of consequence rather than simplistic cost arguments, particularly in postsurgical wounds.[10,22] To best of our knowledge, no prospective study published to date compared the resource use of NPWT and CWT in SAWHI after surgery.

For SAWHI after surgery treated with NPWT, we previously reported significantly shorter wound closure time but an increased number of wound-related adverse events, whereas QoL was not significantly different from CWT.[23,24] The aim of this evaluation was to compare inpatient and outpatient direct and indirect resource use of NPWT and CWT in SAWHI after surgery.

METHODS

Study Design

This resource use evaluation was performed as an add on to the randomized clinical SAWHI trial which was conducted in 34 abdominal surgical departments in Germany, Belgium, and the Netherlands. The study protocol (Supplement) and the informed consent documents were approved by the lead ethical committee of the Witten/Herdecke University. The study was registered with the ClinicalTrials.gov Identifier: NCT01528033.

Participants

Adult patients (age ≥18 years) with spontaneous wound dehiscence, reopened suture, or open wounds that could not be closed by primary intention after abdominal surgery were screened for study participation. A minimum wound size was required for correct application of the NPWT device, which was applicable for both treatment arms due to randomization. Inclusion, randomization, debridement or thorough wound cleansing, and treatment start were to be performed within 48 hours after diagnosis of the SAWHI. A nonclosable defect of the abdominal fascia was an exclusion criterion. Patients expected to be incompliant with the protocol and study-related requirements, or participating in another trial, which was thought to interfere with the study procedures, patient's compliance, wound healing, or targeted end points, were excluded. Patients were also excluded when receiving concomitant therapies or procedures deviating from the standard clinical wound care or had investigational character within 30 days before screening or with the need for concomitant therapies or procedures directly affecting wound healing. Pregnant women and patients with any pre-existing or ongoing organ system failure, which could not be stabilized or solved by appropriate medical treatment, with unremovable necrotic tissue present, with nonenteric and unexplored fistulas or malignancy of the wound were not allowed to participate. The use of any other NPWT device on the study wound within ≤8 days before screening was an exclusion criterion.

The initially defined wound size limitation was deleted because this was not in line with clinical practice and led to difficulties with patient inclusion.

Randomization and Masking

After providing written informed consent, patients were randomly allocated to NPWT or CWT in a 1:1 ratio using a computer-generated list created by the trial statistician located on a centralized web-based tool hosted by a professional information technology service. The randomization list consisted of permuted blocks of variable length, which were randomly arranged. Patients were stratified by study site and wound size ($\leq 60\,cm^3$ and $>60\,cm^3$). Each registered investigator received individual access to the tool without knowing the randomization sequence, which ensured allocation concealment. The investigators were responsible for adequately implementing the assigned therapy. Neither study participants, medical staff, nor resource use outcome assessors were blinded to the treatment assignment.

Procedures

At baseline, patients received an extensive examination of the study wound, actual surgical history, and overall health status. After wound debridement or thorough wound cleansing, study treatment started either in-hospital or outpatient and was to be continued in outpatient care whenever possible.

In the intervention arm, commercially available CE-marked NPWT systems (V.A.C. Therapy, KCI, now part of 3M Company, San Antonio, TX) and consumables, were used at the discretion of the clinical investigator and according to manufacturer's instructions. Mainly reticulated open cell foam (ROCF, V.A.C. GRANUFOAM, KCI) dressings were used as indicated for dehisced wounds. Polyvinyl alcohol (V.A.C. WHITEFOAM, KCI) dressings were used for superficial and sensitive wounds. ROCF silver (V.A.C. GRANUFOAM SILVER, KCI) dressings were used for wounds with need for a barrier to bacterial penetration. NPWT as interim therapy was discontinued once the condition of a wound was suitable for closing, either by epithelialization or surgically.

The control therapy was CWT, which was any local wound treatment regularly used in the respective study site that did not have an experimental status or was NPWT. CWT was applied according to the hospitals' local clinical standards and guidelines, based on the individual needs of the wound in the process of healing, and with special attention paid to exudate amount and local infection status.

In both treatment arms, wound-related procedures were performed when considered clinically necessary. Wounds were closed either surgically or by secondary intention. In the NPWT arm, secondary healing was achieved with CWT dressings after NPWT was discontinued.

Study visits were performed weekly until the end of maximum study treatment time at day 42. All study participants were followed until 132 days after randomization.

Quality assurance of the data collection was ensured by 100% monitoring of the study data documented in the case report forms. Clinical research associates visited the study sites regularly with the frequency of visits adapted on the number of patients randomized per study site.

Outcomes

Resource use parameters assessed included time, personnel (physician, nurse, nursing assistance, and relatives), and material. Evaluation of care and treatment periods included inpatient and outpatient treatment length, length of hospital stay, time to first discharge from hospital, and hospital readmissions. Time, personnel, and material required for dressings changes were documented within booklets for inpatient and outpatient care. Wound treatment material was placed in bags belonging solely to the patient treated. Each material entry was documented in the booklets with category, name, size, unit, and amount.

Wound-related procedures were documented with date of performance and time and human resources used. Surgical wound closure and wound closure by secondary intention were documented with number of study participants, location, anesthesia performed, time and human resources used, and associated procedures performed (wound cleansing and lavage, debridement, wound drainage application, and performance of secondary suture, skin graft or flap).

Indirect resource use included the period of working disability, and mobility and leisure activities at baseline and at the end of the active study treatment period after 42 days or during the wound closure confirmation visit.

In addition to the clinical effectiveness analysis, the number of closed wounds within 132 days was determined. The criteria defined in the study protocol for complete, verified wound closure lasting at least 14 days were not applied. Any wound closure documented by the clinical investigator that did not conflict with another documented outcome was considered. Other than a priori planned, direct nonmedical resource use (transport; care and housekeeping services) was not assessed due to problems of the study participants to provide the information.

Statistical Analysis

Assuming a complete wound closure rate of 50% in the CWT arm and a minimum difference of 12.5% between the treatment arms after 42 days, 492 study participants were calculated to be necessary to achieve 80% power ($\beta = 0.2$) with $\alpha = 0.05$.[23,25] Due to 1 planned interim analysis after 250 participants completed 42 days, α was adjusted using the O'Brien-Fleming method ($\alpha = 0.005$ for the interim analysis and $\alpha = 0.048$ for the final analysis), which led to a marginally increased sample size of 498 participants.[24] Interim results did not show the predefined positive effect at P less than 0.005 or a negative effect at a P less than 0.05 level for NPWT. The study was continued without sample size adjustment.

Resource use analysis was primarily based on the per protocol (PP) population representing study participants without treatment changes and with complete documentation, excluding patients

violating inclusion and exclusion criteria, with unauthorized treatment changes, deviations from the recommended frequency of NPWT dressing changes, early treatment termination, or without valid documentation until wound closure confirmation or end of maximum treatment time. However, the results of the modified intention-to-treat (ITT) population including all randomized participants with a valid baseline and at least 1 post baseline wound assessment (Fig. 1) were analyzed secondarily, since this study population corresponds to real-life.

Resource use parameters are presented descriptively with mean and standard deviation, (minimum and maximum) per study participant or per treatment procedure as applicable. Statistical significance was determined using the Chi-squared or Mann-Whitney *U* test, respectively, with an alpha level of .05. SPSS statistical software, version 23 (IBM Inc, Armonk, NY), was used for all analyses.

RESULTS

Between August 2, 2011, and January 31, 2018 539 patients were randomized in 34 study sites with the last patient follow-up visit on June 11, 2018. Recruitment was completed. 331 study participants were analyzed in the PP population. The patient flow according to Consolidated Standards of Reporting Trials (CONSORT), including inpatient and outpatient care periods is provided in Figure 1. Reasons for screening failures and exclusion from the ITT and the PP population were previously reported.[24]

Demographics and Baseline Characteristics

Demographics and baseline characteristics of the PP population relevant for resource use analyses are provided in Table 1 and eTable 1 and 2 in the Supplement, http://links.lww.com/SLA/D161. Wound volume was slightly lower in the CWT arm. The mean number of comorbid diagnoses per study participant were the same in both treatment arms. More study participants with CWT had cardiovascular and endocrine/metabolic comorbidities at baseline. Details on the mandatory last and final wound pretreatment procedure performed before initiation of study treatment are provided in eTable 3 in the Supplement, http://links.lww.com/SLA/D161.

Inpatient and Outpatient Care and Treatment Periods

In the PP population, total treatment length within 42 days was significantly shorter in the NPWT arm (mean difference 7.8 days; $P < 0.001$), with the extended treatment in the CWT arm predominantly conducted during outpatient care (Table 2). Total outpatient treatment time was significantly shorter in the NPWT arm (mean difference 6.2 days; $P = 0.017$). Hospitalization time was 2.1 days shorter with CWT ($P = 0.047$) (Table 3). In the CWT arm, 6.8% less study participants were treated exclusively inpatient and 4.2% more participants were discharged from hospital within 42 days, but in case of hospital discharge, time to discharge was only marginally longer in the NPWT arm (mean difference 0.9 days; $P = 0.306$). Overall, 6.8% more study participants with CWT than with NPWT were treated outpatient. Hospital readmissions were approximately the same in both treatment arms (difference 0.6%; $P = 0.875$). After day 42, 164 study participants [NPWT 60 (38.2%); CWT 104 (59.8%)] were still in care.

More information on treatment periods and care status is available in Table 2, Table 3, and Figure 1. In study participants remaining with open wounds after 42 days, treatment was continued during follow up (eTable 4 in the Supplement, http://links.lww.com/SLA/D161).

Surgical Wound Closure and Wound Closure by Secondary Intention

Within 42 days, surgical wound closure was performed in 103 of 331 (31.1%) study participants [NPWT 69 of 157 (44.0%); CWT 34 of 174 (19.5%)] (eTable 5 in the Supplement, http://links.lww.com/SLA/D161). In 66 of 331 (19.9%) participants [NPWT 31 of 157 (19.8%); CWT 35 of 174 (20.1%)] wounds were closed by secondary intention. Whereas surgical wound closure in the CWT arm was approximately evenly distributed between the inpatient and outpatient settings, the majority of surgical wound closure in the NPWT arm was performed in the hospital. Wound closure by secondary intention was predominantly achieved in the outpatient setting in both treatment arms. Additional information on the surgical wound closure procedure is provided with eTable 6 in the Supplement, http://links.lww.com/SLA/D161.

Post Hoc Analysis of Wound Closures Within 132 Days

In the PP population, for a total of 288 of 331 (87.0%) study participants [NPWT 140 of 157 (89.2%); CWT 148 of 174 (85.1%)] a closed wound was documented within 132 days (Chi-squared test; $P = 0.266$) (eTable 7 in the Supplement, http://links.lww.com/SLA/D161). Time to this first wound closure documentation was significantly shorter in the NPWT arm [median 35 (95% confidence interval 29.2–40.8) days] than in the CWT arm [median 57 (95% confidence interval 46.6–67.4) days, $P < 0.001$].

Time, Human Resources, and Material Required for Dressing Changes and Wound-related Procedures

In the NPWT arm, significantly fewer dressing changes were performed (mean difference 10.1) with a significantly lower time expenditure per study participant (mean difference 81.7 minutes) in total and in both care settings (Table 4). Physician contacts were significantly less frequent with NPWT (mean difference 2.7, $P = .011$) (eTable 8 in the Supplement, http://links.lww.com/SLA/D161). However, their time spent per study participant was nearly the same in the treatment arms (mean difference 3.4 minutes, $P = 0.585$). Nurse contacts and their total time expenditure were significantly lower with NPWT (mean difference 7.7, $P < 0.001$ and 69.1 minutes, $P = 0.001$, respectively). In both treatment arms, more dressing changes were performed outpatient than inpatient. CWT dressing changes following NPWT in case of wound closure by secondary healing, were mainly performed outpatient (eTable 9 in the Supplement, http://links.lww.com/SLA/D161).

Dressing material and wound dressings used during inpatient and outpatient care are listed in eTable 10 in the Supplement, http://links.lww.com/SLA/D161.

Significantly fewer wound-related procedures per study participant (mean difference 16.1, $P < 0.001$) with a correspondingly lower time expenditure (mean difference 99 minutes, $P < 0.001$) were performed in the NPWT arm (Table 5). The number of procedures involving nurses, assistant physicians, and specialist physicians was higher with CWT than with NPWT (eTable 11 in the Supplement, http://links.lww.com/SLA/D161). Time for nurses per study participant was significantly lower in the NPWT arm (mean difference 49 minutes, $P = 0.038$). Time expenditure for assistant and specialist physicians was not significantly different between the treatment arms.

More details on dressing changes and wound-related procedures with separate consideration of the post NPWT CWT period, and information on dressing material and wound dressings used during inpatient and outpatient care are provided in Table 4, Table 5, and in eTables 11–14 in the Supplement, http://links.lww.com/SLA/D161.

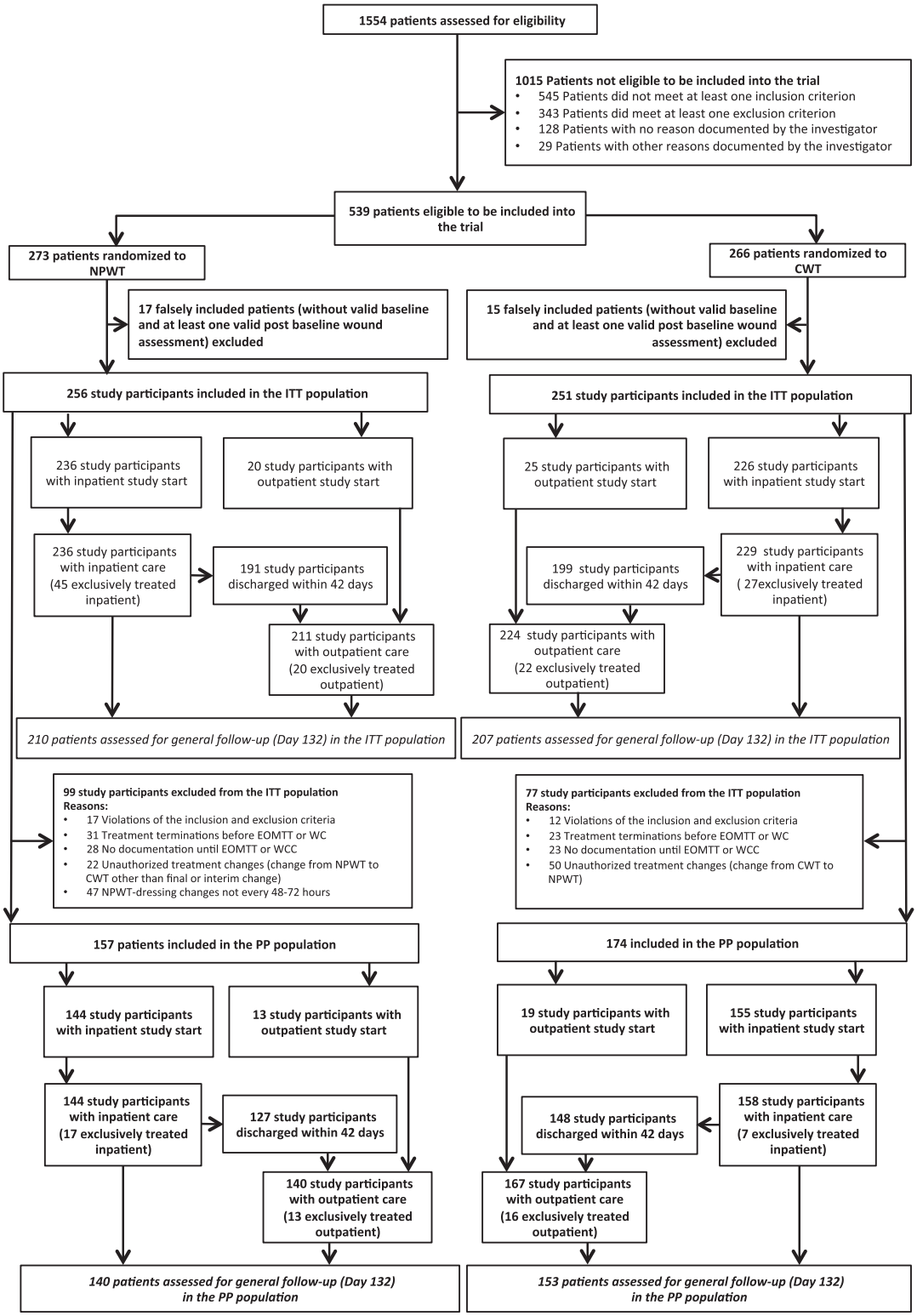

FIGURE 1. Study Participant flow diagram in the subcutaneous abdominal wound healing impairment (SAWHI) randomized clinical trial. Patient flow diagram according to consolidated standards of reporting trials (CONSORT), including reasons for exclusions from the per protocol (PP) population and distribution of study participants across treatment sectors (inpatient and outpatient care). CWT indicates conventional wound treatment; EOMTT, end of maximum treatment time; NPWT, negative pressure wound therapy; WC, wound closure; WCC, wound closure confirmation.

TABLE 1. Demographics and Selected Baseline Parameters of the PP Study Population

Randomized Treatment Arms	NPWT	CWT
Study participants in the PP population, no.	157	174
Age in years, median (IQR) [min-max]	64 (19) [26–88]	66 (18) [26–91]
Sex, male/female, no. (%)	96 (61.1)/61 (38.9)	92 (52.9)/82 (47.1)
Study participants with documented comorbidities, no.	149	160
Diagnoses per study participant, mean (SD) [min-max]	4.2 (2.6) [1–16]	4.2 (2.9) [1–16]
Diagnoses per body system/study participants with diagnosis, no.:		
Cardiovascular	134/88	155/102
Respiratory	32/25	29/24
Gastrointestinal	195/107	222/111
Renal, genitourinary	48/40	46/37
Metabolic, endocrine	84/56	95/71
Neurologic	6/6	23/17
Dermatologic	12/12	8/6
Hematologic	16/14	17/15
Musculoskeletal	20/15	22/19
Head, eyes, ears, nose, throat	10/8	7/5
Psychiatric	9/9	5/5
Other	55/40	47/33
Reason for initial hospitalization no.		
Elective surgery	77	87
Diagnostic procedure	6	4
Acute setting	38	39
Emergency	37	44
Hospitalization time before screening (d)		
Mean (SD) [min-max]	11 (7) [0–35]	13 (11) [0–81]

CWT indicates conventional wound treatment; IQR, interquartile range; NPWT, negative pressure wound therapy; PP, per protocol; SD, standard deviation.

Indirect Resource Use: Working Disability and Activities of Daily Living

A total of 64 study participants with employment status available at the end of the active study treatment time were gainfully employed [NPWT 26/118 (22.0%); CWT 38/137 (27.7%)]. The duration of work disability was similar in both treatment arms (mean (standard deviation) [Min-Max] NPWT N = 24, 40.4 (5.6) [25–45]; CWT N = 31, 38.3 (10.5) [4–45]); $P = 0.592$; Mann-Whitney *U*-test).

TABLE 2. Treatment Periods Within 42 d in the PP Population

Randomized Treatment Arms/Statistical Significance	NPWT	CWT	*P*-value (Test Used)
Study participants in the PP population, no.	157	174	NA
Length of treatment (d), no.	157	174	
Mean (SD)	22.8 (13.4)	30.6 (13.3)	<0.001 (U)
Min-Max	3–42	2–42	
Length of NPWT (d), no.	157	NA	
Mean (SD)	14.6 (9.1)	NA	NA
Min-Max	1–42	NA	
Length of CWT (d), no.	64	174	
Mean (SD)	20.2 (9.3)	30.6 (13.3)	NA
Min-Max	3–41	2–42	
Study participants with inpatient NPWT, no.	144	0	NA
Length of inpatient NPWT			
Mean (SD)	10.1 (6.6)	NA	NA
Min-Max	1–30	NA	
Study participants with inpatient CWT, no.	33	159	NA
Length of inpatient CWT (d)			
Mean (SD)	9.1 (6.9)	11.9 (10.0)	NA
Min-Max	1–25	1–42	
Study participants with outpatient NPWT, no.	65	0	NA
Length of outpatient NPWT (d)			
Mean (SD)	12.7 (8.3)	NA	NA
Min-Max	1–35	NA	
Study participants with outpatient CWT, no.	56	138	
Length of outpatient CWT (d)			
Mean (SD)	17.4 (9.7)	24.9 (11.7)	NA
Min-Max	1–39	1–42	

CWT indicates conventional wound treatment; NA, not applicable; NPWT, negative pressure wound therapy; PP, per protocol; SD, standard deviation; U, Mann-Whitney *U* test.

TABLE 3. Care Status Within 42 d in the PP Population

Randomized Treatment Arms/Statistical Significance	NPWT	CWT	*P*-value (Test Used)
Study participants in the PP population, no.	157	174	NA
Study participants with inpatient care, no. (%)	144 (91.7%)	158 (90.8%)	0.769 (C)
Length of hospital stay (d)			
Mean (SD)	13.9 (11.1)	11.8 (10.8)	0.047 (U)
Min-Max	0–42	0–42	
Study participants exclusively treated inpatient, no. (%)	17 (10.8%)	7 (4.0%)	NA
Length of hospital stay for study participants exclusively treated inpatient			
Mean (SD)	32.1 (9.5)	37.6 (7.6)	NA
Min-Max	17–42	25–42	
Length of hospital stay excluding study participants exclusively treated inpatient, no.	140	167	
Mean (SD)	11.6 (9.1)	10.7 (9.5)	0.219 (U)
Min-Max	0–40	0–41	
Study participants with inpatient start and discharged until end of study treatment period of 42 d, no. (%)	127 (80.9%)	148 (85.1%)	NA
Time until first discharge from hospital (d), no.	127	148	
Mean (SD)	12.9 (8.3)	12.0 (8.0)	0.306 (U)
Min-Max	2–41	2–42	
Study participants with outpatient care, no. (%)	140 (89.2%)	167 (96.0%)	0.017 (C)
Length of outpatient care (d)			
Mean (SD)	19.3 (12.2)	25.5 (12.2)	<0.001 (U)
Min-Max	0–42	0–42	
Study participants exclusively treated outpatient, no. (%)	13 (8.3%)	16 (9.2%)	NA
Number of study participants with hospital readmission within 42 d, no. (%)	18 (11.5%)	19 (10.9%)	0.875 (C)

C indicates Chi-squared test; CWT, conventional wound treatment; NA, not applicable; NPWT, negative pressure wound therapy; PP, per protocol; SD, standard deviation; U, Mann-Whitney *U* test.

Study participants were less mobile after 42 days than at baseline, and outdoor leisure activities and sports decreased (Table 6).

Evaluating ''Real-life'' With the ITT Population

In the ITT population, due to treatment changes NPWT was also performed in some study participants in the CWT arm. Length of hospital stay was shorter in the CWT arm but, other than in the PP population, the difference between the treatment arms was not significant. All other care and treatment results show no relevant deviations from those in the PP population. Time and human resources used for dressing changes and wound-related procedures were similar to those the PP population. Further details on the results of the ITT population are provided in eTables 15–29 in the Supplement, http://links.lww.com/SLA/D161.

DISCUSSION

In the SAWHI study, treatment length within 42 days was significantly shorter with NPWT than with CWT. This corresponds to the previously reported finding that NPWT was superior to

TABLE 4. Time Required for Dressing Changes Within 42 d in the PP Population

Randomized Treatment Arms/Statistical Significance	NPWT	CWT	*P*-value (Test Used)
Study participants in the PP population, no.	157	174	NA
Number of dressing changes per study participant, no.	133	152	
Mean (SD)	10.7 (10.4)	20.8 (13.0)	<0.001 (U)
Min-Max	1–80	1–72	
Time required for dressing changes per study participant (min), no.	133	152	
Mean (SD)	195.8 (221.1)	277.5 (208.2)	<0.001 (U)
Min-Max	5–2098	10–1315	
Inpatient dressing changes per study participant, no.	119	130	
Mean (SD)	5.5 (6.1)	10.6 (10.3)	<0.001 (U)
Min-Max	1.0–48.0	1.0–71.0	
Time required for inpatient dressing changes per study participant (min), no.	118	130	
Mean (SD)	109.8 (122.1)	128.8 (128.4)	0.234 (U)
Min-Max	10.0–951.0	5.0–765.0	
Outpatient dressing changes per study participant, no.	82	118	
Mean (SD)	9.4 (10.8)	15.0 (11.3)	<0.001 (U)
Min-Max	1.0–78.0	1.0–47.0	
Time required for outpatient dressing changes per study participant (min), no.	81	118	
Mean (SD)	161.5 (243.7)	215.6 (186.0)	0.010 (U)
Min-Max	5.0–2053.0	3.0–888.0	

CWT indicates conventional wound treatment; NPWT, negative pressure wound therapy; PP, per protocol; SD, standard deviation; U, Mann-Whitney *U* test.

TABLE 5. Wound Related Procedures Performed Within 42 d in the PP Population

Randomized Treatment Arms/Statistical Significance	NPWT	CWT	*P*-value (Test Used)
Number of study participants in the PP population	157	174	NA
Number of study participants with wound related procedures	156	173	NA
Wound related procedures per study participant, no.	157	174	
Mean (SD)	20.5 (17.5)	36.6 (28.0)	<0.001 (U)
Min-Max	0–124	0–174	
Total time expenditure per study participant (min)			
Mean (SD)	167 (195)	266 (313)	<0.001 (U)
Min-Max	0–1060	0–2019	
Study participants with inpatient wound related procedures, no.	137	150	NA
Inpatient wound related procedures per study participant, no.	157	174	
Mean (SD)	9.7 (13.6)	16.2 (21.8)	0.013 (U)
Min-Max	0–124	0–119	
Time expenditure per study participant (min)			
Mean (SD)	85 (119)	107 (178)	0.365 (U)
Min-Max	0–920	0–1294	
Study participants with outpatient wound related procedures, no.	117	151	NA
Outpatient wound related procedures per study participant, no.	157	174	
Mean (SD)	10.5 (12.6)	19.8 (19.8)	0.001 (U)
Min-Max	0–57	0–104	
Time expenditure per study participant (min)			
Mean (SD)	80 (143)	154 (270)	0.001 (U)
Min-Max	0–990	0–1952	

CWT indicates conventional wound treatment; NA, not applicable; NPWT, negative pressure wound therapy; PP, per protocol; SD, standard deviation; U, Mann-Whitney *U* test.

conventional dressings in achieving complete closure.[24] Moreover, in the post hoc analysis on wound closure throughout the observation period, we showed that although the wound closure rate became more similar between the treatment arms within 132 days, the time to first wound closure documentation was significantly shorter in the NPWT arm.

Intersectoral wound treatment was realized with the majority of study participants starting treatment in hospital and being discharged within 42 days. The assumed substantial number of resources used in outpatient facilities and home care,[9] was shown also to be applicable for patients with SAWHI after surgery. Length of hospital stay was 2 days shorter with CWT. Findings of studies with other indications which showed NPWT to shorten the hospitalization period, could not be confirmed for the specific patient group included in the SAWHI-study.[17–21] Significantly more study participants with CWT were treated as outpatients. Participants with NPWT were less often discharged and more often exclusively treated in hospital. If study participants were discharged from hospital, time to first discharge was similar with NPWT and CWT. Hospital readmissions were also equally represented in the treatment arms. More wounds were closed surgically than by secondary intention. Surgical wound closure was more common in the NPWT arm and was mainly performed during inpatient care, which could explain the longer hospital stay while the total treatment time was longer in the CWT arm. However, neither study participants, medical staff, nor resource utilization assessors were blinded to treatment assignment, which

TABLE 6. Mobility and Leisure Activities at Baseline and After End of Study Treatment in the PP Population

Randomized Treatment Arms	NPWT		CWT	
Study Participants in the PP Population, no.	157		174	
Survey date	Baseline	End of Study Treatment Time After 42 d or at Wound Closure Confirmation	Baseline	End of Study Treatment Time After 42 d or at Wound Closure Confirmation
Mobility*				
Study participants with information available, no.	157	115	174	132
Bedridden or mobilized in a wheel chair, no.	5	6	8	7
Able to move freely within home, no.	18	8	15	13
Able to leave home, no.	134	102	152	114
Leisure activities*				
Study participants with information available, no.	156	113	171	130
Indoor activities, no.	29	31	44	37
Outdoor activities, no.	106	74	95	88
Recreational sports, no.	31	9	51	12
Competitive sports, no.	1	1	1	0

*Multiple answers possible.
CWT indicates conventional wound treatment; NPWT, negative pressure wound therapy; PP, per protocol.

may have introduced bias in objective assessment, particularly in the clinical decision to discharge from the hospital with NPWT. Because the overall frequency of comorbidities was the same in both treatment arms and even more cardiovascular and metabolic/endocrine diagnoses occurred in the CWT arm, comorbidities at baseline can be excluded as a cause of prolonged hospitalization time with NPWT.

In both care settings, the number of dressing changes and the associated time consumption were significantly lower with NPWT. CWT dressing changes after NPWT to achieve wound closure by secondary intention, which by their nature are more frequent and require less effort than NPWT changes, made a relevant contribution to outpatient care.

Significantly more wound related procedures per study participant with a correspondingly higher time expenditure were necessary with CWT. Dressing changes and wound-related procedures required more personnel in the CWT arm with nurses being the major human resource used. The majority of resources were used in the outpatient sector, but a simple resource use-shift rather than decreasing the overall time consumption, because NPWT is thought to demand less frequent but more complex and time-consuming dressing changes than CWT,[10] could not be confirmed in this study.

Limitations

As with the analysis of effectiveness and safety of the SAWHI study, the treatment and observation period of 42 days is also a limitation for the resource use analysis. We previously reported that more than 50% of the wounds were still open after 42 days. The small amount of data available before the start of the study severely limited the possibility of an adequate assessment of the required treatment and observation period to close the majority of the wounds. To address this, an additional post hoc analysis of wound closures within 132 days was performed that captured all wound closures regardless of whether they met the study protocol criteria for a complete, sustained, and verified wound closure or not. Nonetheless, the evaluation of resource utilization remains limited to 42 days and may require adjustment in further cost analyses.

Material use was not sufficiently documented in the SAWHI trial. The planned analysis was not possible to be performed, but is limited to a simple listing of dressings used per treatment arm. Information on optimal material use for subsequent cost analyses may be derived from other resources.

Another limitation of this study is the lack of evaluation of intensive care unit days.

No formal cost analysis was performed which, if you think globally, is more of an opportunity than a limitation. The economic status of different countries is a major problem when analyzing disease state cost.[10] Unlike previous studies, which typically present country-specific unit costs for personnel, inpatient accommodations, and supplies based on the prevailing billing system, our study presents resource use results that can be used as the basis for any economic analysis worldwide.

Country-specific cost analyses from the perspective of the relevant actors in the respective health care system, incorporating other relevant data sources, are the next step in using the study data presented here.

CONCLUSIONS

To our knowledge, the SAWHI trial is the first RCT to report that NPWT reduces treatment time and results in less resource use for dressing changes and wound-related procedures for SAWHI after surgery. NPWT maybe an efficient treatment alternative to CWT, which needs to be demonstrated in a subsequent cost analysis.

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