Single use negative-pressure wound therapy compared to standard care in patients after carbon dioxide laser surgery for hidradenitis suppurativa

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Abstract
Negative pressure wound therapy is a commonly used treatment modality for surgical wounds healing by secondary intention. In an open, split side study with 12 patients, we compared low negative pressure wound therapy to conventional foam dressing the first postoperative week after carbon dioxide laser vaporization of hidradenitis suppurativa lesions. The primary outcome was time to complete wound healing, comparing the two intervention sites. Secondary endpoints included perception of pain during intervention period and patient registered impact of the regimes on daily life activities. Low negative pressure wound therapy the first postoperative week tended to reduce the time to complete wound healing. Patients reported significant lower pain levels from wounds treated with a negative pressure wound device the first postoperative week. Eleven out of 12 study participants had a preference to the negative pressure wound therapy regime to a conventional regime with foam dressings.

KEYWORDS
carbon dioxide laser, negative-pressure wound therapy, patient-reported outcomes

1 | INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic skin disease characterized by painful, deep-seated, inflamed nodules, abscesses and, in the later stages, tunnels and scarring in apocrine gland-bearing areas of the body. Treatment of HS varies widely and includes both surgical and medical treatments.1 Carbon dioxide (CO2) laser vaporization of recurrent HS-lesions is an efficient surgical therapeutic option for both physician- and patient-derived outcomes.2,3 After vaporization of recurrent HS-lesions, postoperative wounds are left for secondary intention healing. Surgical wounds healing by secondary intention are costly and take time to heal. Foam dressings are best studied as alternatives to gauze and appear to be preferable in terms of pain reduction, patient satisfaction and nursing time.4 Negative pressure wound therapy (NPWT) is a commonly used treatment modality for surgical wounds healing by secondary intention.5 NPWT may have a positive effect on wound healing by removing exudate, reducing infections and increasing tissue perfusion.6

Wound healing options after skin excision and laser treatments of hidradenitis lesions left to heal by secondary intention, have been reviewed,7 but studies assessing effectiveness of low pressure NPWT after CO2-laser surgery are still missing. Therefore, we conducted this study to compare NPWT-treatment to conventional foam dressing the first postoperative week after CO2-laser surgery in regards to time to complete wound healing, patient reported pain from wound beds and impact on daily life activities between the regimes.

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Dermatologic Therapy. 2022;35:e15483.
https://doi.org/10.1111/dth.15483
2 | METHODS

This study was approved by the Regional Committee for Medical and Health Research Ethics, North Norway (approval # 2014/1094). It was performed without any support, financial or otherwise, from the makers of the PICO unit.

2.1 | Trial design

This was an open, prospective, single-center slit-side clinical trial designed to determine whether application of a negative pressure dressing (PICO, Smith & Nephew, Norway) is superior to a standard surgical foam dressing in regards to patient reported outcomes related to healing time and subjective preference of each post-operative regime.

2.2 | Participants

Sixteen patients undergoing elective bilateral scanner-assisted carbon dioxide laser surgery as described by Lapins et al. in local or general anesthesia for symmetrical lesions for HS Hurley stage II and III were enrolled in the study and informed consent was obtained. The lesions were located in the armpits or groins/lower abdomen and morphologically similar postoperative wounds (circumference, depth, and location) were included. The size of postoperative wounds could not exceed a total area greater than 150 cm² or have a maximum diameter >15 cm.

2.3 | Interventions/randomization

After CO₂-laser treatment, wounds were left open for secondary intention healing. Wound surface area as described by Kundin. After informed consent, a single use ultra-portable NPWT-device (PICO®, Smith & Nephew) Nursing Unit was assigned in one treatment intervention area (left side) and conventional treatment with silicone foam bandages (Cutimed Siltec®, BSN Medical) on the contralateral intervention area (right side). Patients received oral and written instructions regarding the use of the NPWT device. After the first week, wounds on both sides were covered with silicone foam bandages until the wound cavity was fully granulated to the level of the skin surrounding the wound. Thereafter, petrolatum gauze was used as dressings until the wound was fully healed. If the wound cavity was fully granulated upon discontinuation of the disposable NPWT device, petrolatum gauze was used secondly. Wounds were inspected daily and bandages replaced if oozing, after gentle rinsing with tap water a hand shower or with saline.

2.4 | Outcomes

The primary outcome was time to complete wound healing, comparing the two intervention sites. Secondary endpoints included perception of pain, recording experienced pain sensation related to the interventions using visual analogue scale (VAS) at day 3 of intervention and on discontinuation of intervention phase (day 7). VAS is a validated method of assessing pain after day surgery. The perception of pain is typically most intense after the fifth postoperative day, based on feedback from CO₂ laser operated patients. Therefore, these time points for registration of these data were chosen. Another secondary endpoint was patient registered outcomes on how the different dressings did impact on daily life activities such as social activities, choice of clothing, physical activity, house work, and sleep. Responses comprised a 3-point scale (pleased, satisfied, and dissatisfied) regarding the impact of therapy on activities of daily living in self-completed questionnaires, and the numeric range of non-validated scoring system was from 0 to 18.

The patients were also requested to subjectively select the preferred wound care regime for the initial postoperative week.

2.5 | Statistical methods

Descriptive statistics were used to compare the baseline characteristics of the trial participants. Differences between groups in total healing time, VAS scores and patient reported score of daily activities were explored using the Wilcoxon signed rank test. A binomial test was also used for testing a binary outcome for shorter time to complete healing comparing the two treatment regimes. Survival functions were plotted with Kaplan–Meier curve on the basis of time-to-event strategy. For all tests, the level of significance was set at *p* < 0.05. All statistical analyses were performed using SPSS statistics 26.

3 | RESULTS

Sixteen patients were included in the study, four study participants did not return the patient report form, and were thus lost to follow-up. Among the 12 participants that completed the end-point registration, there was an expected predominance of female participants (10 of 12). One patient failed to report the time for complete wound healing.

The median postoperative wound size in NPWT-sites was 7.0 cm² (maximum 38.7; minimum 1.1) and in conventional sites 7.3 cm² (maximum 42.8; minimum 2.8) (Table 1).

For the primary outcome, patient reported time to complete wound healing, 9 out of 11 reported that the wound where the NRWT-unit was used the first postoperative week healed before the wound treated with conventional foam dressings. At the NPWT-site, the median time to complete healing was 21 days (maximum 146; minimum 17), compared with a median of 43 days (maximum 80; minimum 11) at the conventional dressing site. This change was not statistically significant (*p* = 0.10). However, using a binomial test, NPWT was significantly better than conventional treatment (*p* = 0.033, data not shown). Survival curves for time to complete wound healing also demonstrated how most wounds healed faster using the NPWT-regime (Figure 1).
The patients’ own rating of experienced pain from postoperative wounds measured by VAS (1–10) was lower at the NPWT-site at postoperative day 3 with a median of 1 (maximum 5; minimum 0) compared to the conventional dressing-site with a median of 2.5 (maximum 7; minimum 0) \( (p < 0.05) \). A significant difference was reported at postoperative day 7 with a median of 2 (maximum 9; minimum 0) \( (p < 0.02) \). Interestingly, all patients reported equal or lower scores for pain for the NPWT-site at all registrations (data not shown).

When requested which regime the participants preferred the first postoperative period, 11 out of 12 study participants had a preference to the NPWT-regime over the conventional regime.

### 4 | DISCUSSION

Compared to conservative foam dressings, low pressure NPWT the first postoperative week tended to reduce the time to complete wound healing after CO₂-laser vaporization of HS lesions. Albeit the difference is not statistically significant in a non-parametric test, 9 out of 11 wounds healed in a shorter time using the NPWT compared to conventional treatment. Furthermore, treatment with NPWT leads to improvement in self-assessed pain perception from postoperative wounds compared to conventional foam dressings the first postoperative week. Patients in this study reported significant lower levels of VAS pain both at day 3 and day 7 in the low-pressure NPWT-treated wounds. Patients in our study prefer the NPWT-regime to conventional dressings postoperatively, and a high patient satisfaction with the use of this device has been shown in previous studies.\(^{11-13}\)

Data on benefit of the NPWT treatment is conflicting, but it seems to be safe, and there is an indication of greater benefit of NPWT in comparison with standard wound therapy in wounds healing by secondary intention.\(^{5,14,15}\) Our results are in line with findings from recent meta-analysis, showing advantages of NPWT to standard wound therapy with regard to wound closure. The positive results from our study encourages larger interventional studies to confirm NPWT as a superior postoperative wound bed treatment after CO₂-laser surgery.

### ACKNOWLEDGMENTS

Ellen Emanuelsen and Oddrun Olsen helped out with registration of baseline data, photodocumentation, and application of dressings. The author thanks professor Tom Wilsgaard Department of Community Medicine, UiT The Arctic University of Norway for kind help with the statistics.

### CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Grimstad Ø. Single use negative pressure wound therapy compared to standard care in patients after carbon dioxide laser surgery for hidradenitis suppurativa. Dermatologic Therapy. 2022;35(6):e15483. doi:10.1111/dth.15483