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Use of Negative Pressure Wound Therapy Systems after radical vulvectomy for advanced vulvar cancer

RUNNING TITLE: Negative pressure wound therapy after vulvectomy

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ABSTRACT

A retrospective cohort study was performed to evaluate the efficacy of negative pressure wound therapy in improving vulvectomy healing. Women who underwent radical vulvectomy with complete inguofemoral lymphadenectomy for advanced vulvar cancer were divided into two groups according to immediate postoperative care: patients treated with negative pressure wound therapy using the device applied on the site of the wound (including vulva and inguinal region), and patients receiving conventional care. Eighteen patients were included in the study. Seven (38.9%) women were treated with negative pressure wound therapy immediately after the surgery and were included in the intervention group, and 11 (61.1%) patients were included in the control group. Women who received negative pressure wound therapy had significantly lower length of stay in the hospital (14.2 ± 4.7 vs 17.1 ± 6.1 days, mean difference -6.90 days, 95% confidence interval -11.91 to -1.89), and significantly lower length for wound healing (-31.90 days, 95% confidence interval -43.48 to -20.32). In conclusion, the utilization of the negative wound pressure therapy may contribute to reduce hospitalization after radical vulvectomy for vulvar cancer. Large and well-designed randomized trials with cost effectiveness analyses are needed to confirm these findings.

KEY WORDS: cosmetic, patient satisfaction, wound, disinfection, skin closure.

INTRODUCTION

The gold standard treatment for advanced vulvar cancer is radical en bloc vulvectomy with inguinofemoral node dissection.^{1,2} This surgical approach is associated with a high rate of early-onset complications, including infection and wound dehiscence. Gaarenstroom et al. reported data on 101 consecutive patients who underwent radical vulvectomy. They found a 76% overall rate of complications, such as wound dehiscence (17%), infection (39%) of the groin, lymphocyst formation (40%), and lymphedema (28%).³

Several therapies have been studied as adjuvant to wound healing in patients undergoing radical vulvectomy.^{1,4,5} Negative pressure wound therapy (NPWT) is a novel method of wound management.⁶ It is a therapeutic technique using a suction pump, tubing, and a dressing to remove excess exudate and promote healing. Negative pressure dressing appears to stimulate fibroblast migration and proliferation, two key elements in the inflammatory response.⁶

The aim of this study was to evaluate the efficacy of NPWT in improving vulvectomy healing.

MATERIAL AND METHODS

Study design

This was a single center, retrospective, cohort study. Clinical records of all consecutive women who underwent radical vulvectomy with complete inguinofemoral lymphadenectomy for advanced vulvar cancer from January 2017 to January 2020 were collected in a dedicated database. Patients were divided into two groups according to immediate postoperative care: patients treated with closed NPWT immediately after the surgery, and patients receiving conventional care.

NPWT was applied using the device (Prevena KCI) applied on the site of the wound, including vulva and inguinal region. The dressing was placed on the fresh wound left partially unsutured, and remained in place for 4-5 days at which time dressing was changed under local anesthesia (Figure 1). The scar was partially unsutured on a 1-cm medial part to introduce a thin foam. NPWT was started within 24 h of surgery. The subatmospheric pressure was gradually set at 100–125 mmHg, according to patient tolerance, over a course of approximately ten minutes. Subatmospheric pressure was then maintained constant.

Women in the control group were those who received standard care with perineal irrigation with 0.9% sodium chloride serum and air drying and did not receive NPWT. Drains to collect lymphatic fluid were used in both groups.

All women included in the study received en Bloc radical vulvectomy with complete bilateral inguinofemoral lymphadenectomy. The vulvectomy was performed to remove the primary lesion to the depth of the perineal fascia with a 2-cm circumferential margin.

Study outcomes

The primary outcome was the mean length of stay in hospital. Secondary outcomes were wound infection, wound edge necrosis, wound dehiscence, and length for complete wound healing in days.

Wounds were defined infected if they demonstrated purulent drainage, localized fever, spreading erythema. Infected wounds were treated with antibiotics and/or opening/debridement of the wound

Wound dehiscence was defined as rupture of the wound along the surgical incision.

Complete wound healing was defined as complete epithelization of the wound.

Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) v. 19.0 (IBM Inc., Armonk, NY, USA).

Data are shown as means \pm standard deviation (SD), or as number (percentage). Univariate comparisons of dichotomous data were performed with the use of the chi-square or Fisher exact test. Comparisons between groups were performed with the use of Mann-Whitney U test, to test group medians, and with the use of the T-test or the One-way ANOVA to test group means with SD. We calculated two-sided p values. A p-value <0.05 was considered to indicate statistical significance.

This study was reported following the STROBE guidelines.⁷

RESULTS

Eighteen patients, who underwent radical vulvectomy with complete inguinofemoral lymphadenectomy for advanced vulvar cancer during the study period, met the inclusion criteria and were included in the study. Seven (38.9%) women were treated with NPWT immediately after the surgery and were included in the NPWT group, and 11 (61.1%) in the control group. The mean age was about 71.3 ± 9.4 years in NPWT group and 72.1 ± 8.2 years in the control group (Table 1).

Table 2 shows the primary and the secondary outcomes. Women who received NPWT had significantly lower mean of length of stay in the hospital (14.2 ± 4.7 vs 17.1 ± 6.1 days, mean difference -6.90 days, 95% confidence interval -11.91 to -1.89), and significantly lower mean of length for wound healing (-31.90 days, 95% confidence interval -43.48 to -20.32). No significant differences were found in the rate of wound infection, wound edge necrosis, and wound dehiscence.

DISCUSSION

Main findings

In this single center retrospective cohort study, the use of NPWT in women who underwent radical vulvectomy with complete inguinofemoral lymphadenectomy for advanced vulvar cancer was associated with lower length of stay in the hospital and lower length for wound healing.

The small sample size and the retrospective study design are the major shortcomings of the study. Moreover, since the decision to NPWT was at attending discretion, the better outcome in the NPWT group could be underweighted due to selection bias.

Implication

Findings from our study suggest the use of NPWT in women who underwent radical vulvectomy with complete inguinofemoral lymphadenectomy for advanced vulvar cancer. This therapy may significantly reduce the length of stay in the hospital and the length for wound healing. Moreover, in future larger well-designed studies, also the decrease in wound infection, necrosis and dehiscence might be found significantly associated with the use of NPWT . No randomized controlled trials have been performed so far. The largest study on the use of NPWT for wound dehiscence in women with gynecologic malignancies was a retrospective study including only 27 women [8]. In this study, the use of NPWT resulted in 96% reduction in the size of the wound defect [8].

With specific regard to vulvar surgery, Dainty et al. reported seven cases of split thickness skin grafts for vulvovaginal reconstruction treated with fibrin glue, NPWT, and petroleum-impregnated gauze as an interface layer [9]. NPWT improved the quantity of granulation tissue, decreased force on the grafts, and simplified wound care [9]. NPWT may be used in patients who have had a total

pelvic exenteration or a combination of colostomy and urostomy. In order to reduce the risk of wound contamination, also short-term solutions may be suggested, such as anti- bowel motility agents, Foley catheters, parenteral nutrition, dressing changes timed simultaneously with bowel movements and/or a waterproof dressing underneath the negative pressure dressing adhesive sheet [10].

Wound care in women with vulvar cancer is of paramount importance. After radical vulvectomy, many women also receive local radiotherapy, and in case of wound infection or dehiscence, therapy may be delayed and worsen the prognosis. Other closures at high-risk of morbidity in women with gynecologic cancers are inguinal closures. Indeed, up to 50% of inguino-femoral incisions shows secondary wound healing, lymphedema, incisional defects, and/or wound infection [11,12]. Negative pressure dressings have also shown decrease in wound volume and complications in inguinal region with rapid wound preparation, faster healing and improved outcomes [11].

Conclusion

In summary, NPWT in patients who underwent radical vulvectomy with complete inguinofemoral lymphadenectomy for advanced vulvar cancer is associated with lower length of stay in hospital compared to standard care. Large and well-designed randomized trials with cost effectiveness analyses are needed to confirm these findings.

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DECLARATION OF INTEREST STATEMENT: The authors report no conflict of interest.

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LEGEND FOR TABLES

Table 1. Characteristics of the included women

	NPWT group	Control group	p-value
	N = 7	N = 11	
Age, years	71.3±9.4	72.1±8.2	0.85
BMI	26.3±8.7	25.0 ±7.2	0.74
FIGO stage IB	4 (57.1%)	6 (54.5%)	0.91
FIGO stage II	3 (42.9%)	5 (45.5%)	0.94

Data are presented as number (percentage) or as mean ± standard deviation

NPWT , negative pressure wound therapy; BMI, body mass index; FIGO, International Federation of Gynecology and Obstetrics

Table 2. Primary and secondary outcomes

	NPWT group N = 7	Control group N = 11	p- value	MD or RR (95% CI)
Hospital stay (days)	14.2±4.7	17.1±6.1	<0.01	-6.90 days (-11.91 to -1.89)
Wound infection	4 (57.1%)	8 (72.7%)	0.50	0.50 (0.07 to 3.70)
Wound edge necrosis	3 (42.9%)	6 (54.5%)	0.63	0.63 (0.09 to 4.22)
Wound dehiscence	2 (28.6%)	4 (36.4%)	0.73	0.70 (0.09 to 5.43)
Time to wound healing (days)	31.5±11.1	63.4±13.8	<0.01	-31.90 days (-43.48 to -20.32)

Data are presented as number (percentage) or as mean ± standard deviation. Boldface data, statistically significant

NPWT , negative pressure wound therapy; MD, mean difference; RR, relative risk; CI, confidence interval.

LEGEND FOR FIGURES

Figure 1. Negative pressure wound therapy system applied on vulva and inguinal region

