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Original Article

Role of Vaccum Dressings in Open Wounds of Pilonidal Sinus

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ABSTRACT

Pilonidal sinus is an acute suppurative condition occurring beneath the sacrococcygeal area presenting as an abscess acutely while as intermittent discharge in its chronic form. **Objective:** To determine the role of NPWT in the management of pilonidal sinus in a tertiary care hospital in Karachi, Pakistan over 6 months. **Methods:** 50 patients were divided into two groups; control and NPWT. It was an open-label randomized trial. The patients in the control group were being managed by wet dressing compared to the NPWT group where VAC therapy was used for wound healing. Both groups were followed for 14 days. Healing was measured by VAS score, wound size, and number of complications. **Results:** Wound size post-operatively was measured in both groups and was 36.33 squared centimeters in the control group with 30. 97 squared centimeters in the intervention group showed no statistical significance. On the 14th day of the trial, the wound size was compared again and in the control group, the size was found to be 24.4 cm^2 and 14.9 cm^2 in the intervention group. However, no statistical significance was shown. On the visual analog scale for pain after 14 days, both groups demonstrated a steep decline falling to nearly 1.5 from 9 on the first postoperative day however showing no significant difference across the two groups. **Conclusions:** There was no significant difference between the two methods and similar time was required in both groups before resuming daily life activities.

INTRODUCTION

Pilonidal sinus is an acute suppurative condition occurring beneath the sacrococcygeal area presenting as an abscess acutely while as intermittent discharge in its chronic form. It is twice as common in men as in women [1]. Pilonidal sinus can cause pain, and sepsis and diminish the quality of life of patients significantly by affecting their work schedule or daily routine [2]. Asymptomatic disease is managed conservatively while the acute form is managed by simple excision. The chronic form of this disease is usually managed by wide en-bloc excision followed by either primary midline closure or left to heal via secondary intention [3]. The appropriate mode of surgery is still debated and there are several articles concluding that primary closure may reduce the time taken to go back to normal routine but increases recurrence rates while there was 58% less recurrence when healing via secondary intention was adopted hence favoring healing via secondary intention [4-6]. To expedite the healing process through secondary intention and reduce the time required to go back to a normal lifestyle there have been a lot of proposed methods. Negative pressure wound therapy (NPWT) is used to enhance the healing process with a

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secondary intention [7]. VAC (Vacuum Assisted Closure) is the novel iteration of NPWT. It has four cardinal constituents; a filling substance usually foam placed in the wound, a non-adherent dressing that is partially permeable and is used as a conduit to transmit sub-atmosphere into the wound, a connecting tube, and a vacuum device. A negative pressure of 125 mm Hg is then set on the device to maintain a vacuum at the wound site. It augments healing by contracting the wound, inducing differentiation, and eradicating fluid thereby creating an anti-septic environment. Cases have been reported where NPWT was used for managing a pilonidal sinus and favor the use of this technique [8, 9]. The use of NPWT in preventing surgical site infections have also been indentified therefore it has become an indication in the prophylaxis of post operative infections in patients undergoing surgical resection for pilonidal sinuses [10]. Some cases however demonstrated no significant difference in wound healing times but showed improvement in mobility during treatment and reduction in pain [11]. All these studies warranted a further evaluation of the use of NPWT in pilonidal sinuses in the form of longer case series or randomized controlled trials. We aimed to find the role of Negative Pressure Wound Therapy in the management of pilonidal sinus at tertiary care hospital in Karachi, Pakistan over 6 months. The current study was a randomized controlled trial of NPWT against normal saline dressings in terms of patients' comfort, reduction in recurrence rates, and improved healing times.

METHODS

We conducted a randomized control trial. The sample size of the study was calculated using OpenEpi software. It included 50 patients, 25 of them were enlisted in the control group (no special intervention done), while the other 25 were included in the intervention group (Vacuum-assisted closure for closure of the wound). The p-value was set at <0.05 with a confidence interval of 95%. The randomization of this process was conducted with austere confidentiality using a software. All the patients admitted to Civil Hospital Karachi at surgical unit VI, with a complaint of the pilonidal sinus was thoroughly accessed for the inclusion criteria of this study, which can be given as follow: patients of both genders of age 18 to 50 years, wound depth of around 4-7cm, having an active inflammation, with or without recurrence and, patients who had previously undergone surgery for pilonidal sinus. The exclusion criteria of the study were patients suffering from a concomitant chronic illness (e.g. diabetes mellitus), patients taking immunosuppressants, noncompliance or inability to attend frequent follow-ups, and patients younger than 18 years. Moreover, patients who had pilonidal sinus less than 3 cm from the anus were also excluded, as it would hinder the placement of the NPWT device. All the patients assigned to the study were informed pre hand with an information prospectus of this trial, A consent form was signed by all the patients. Before initiating the study, approval from IRB (Institutional Review Board) was acquired. Patients were randomly assigned from the clinic to either NPWT or open wound care. The endpoint of the study was time-consuming in completion of wound healing (days taken for full thickness closure of skin), secondary endpoints included the following: wound size ratio at day 14 compared to that of wound size at postoperative day 0, Visual analog scale score to access the severity of pain at day 14, recurrence of the pilonidal sinus within 12 months after the closure of the wound. The standard surgical technique was exercised in all the patients, and spinal anesthesia (using 2% lignocaine) was given. Buttocks and pelvic area were shaved before the surgery and adhesive tape was applied for the separation of the buttocks. Patients were positioned in a prone jackknife position, a blunt needle was used as a probe, and methylene blue was injected in the natal cleft area for precise estimation of the borders of the cyst. An elliptical incision was given, followed by surgical diathermy for complete excision of the cyst. After complete excision, the diameter and height of the wound were measured and noted. The specimen was sent for histopathological assessment in a formalin-filled container. After hemostasis was achieved, a conventional porous silicone dressing was applied. An appropriate dose of paracetamol was prescribed alongside an additional NSAID to alleviate the pain. Based on software generated randomization list, if the patient falls under the trial group, a vacuum-assisted closure device will be applied directly by the treating surgeon or the wound care nurse. The wound site was covered with a sponge dressing, with duoderm (skin adhesive dressing) applied for the protection of the skin (to prevent damage while the placement of the NPWT device). NPWT device was stalled with adhesive dressing connected to a specialized vacuum pump. A negative pressure of 125 mm Hg was maintained for 24 hours a day. In the intervention group, sponge dressing was applied only once to minimize the pain (caused by the placement of the NPWT device). It was then removed on the third postoperative day. Patients were kept in the hospital for 14 days according to the hospital protocol. Patients were assessed daily and the progress report was maintained on a computer. The sponge was replaced on postoperative days 3, 7, and 10. NPWT was finished on day 14, and patients were discharged with the advice to maintain proper hygiene of the wound (rinse the wound thrice a day, until a superficial wound was achieved). After the surgical excision, the wound of patients who were assigned to the control group (via randomization list) was left open. A silicone wound

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dressing alongside a soaking bandage was applied. Patients were counseled to maintain proper hygiene and wash the wound thrice a day. No special interventions were done unless retention of purulent discharge or sloughy wound was noted. On a postoperative day, 14 patients were discharged from the hospital. After the disposal from the hospital, each patient was given a weekly scheduled follow-up sheet of outpatient department (OPD) days. Patients were asked to maintain that follow-up sheet and get their wounds examined every week till complete wound closure was achieved. Patients were then asked to show up in OPD after 6 months for a final assessment of the recurrence of the pilonidal sinus.

RESULTS

A total of 50 patients were included in this trial who met the inclusion criteria of this study. All included patients were fully informed and gave their consent for this study and then were randomized into two groups. The patient demographics are shown in Table 1. The mean age in the control group was 39.19 years compared to 38.31 years in the intervention group. The average weight of both groups is similar. Other characteristics are also compared in the figure below. Both groups had 1 diabetic patient. The control group had 2 hypertensive patients while the intervention group had 4. Both groups had 1 patient with diabetes and concomitant hypertension.

Table 1: Patient characteristics in both groups

Patient's Characteristic	Control (n=21)	Intervention (n=29)
Mean Age	39.19	38.31
Mean Weight (Kg)	72.71	71.00
ASA (Median)	2.00	1.00
Number of Sinus Tracts (Median)	1.00	1.00
Mean Duration of Symptoms (Days)	6.38	6.52
Smoking %	38.1% (n=8)	27.6% (n=8)
Co-morbidities %		
1) Diabetes	4.8 % (n=1)	3.4 % (n=1)
2) Hypertension	9.5 % (n=2)	13.8 % (n=4)
3) Hypertension and Diabetes	4.8 % (n=1)	3.4 % (n=1)

The number of dressings changed per group wasn't significantly different. Similar results were obtained when comparing the number of dressings changed due to pus with no significant difference. Wound size post-operatively was measured in both groups and was 36.33 squared centimeters in the control group with 30. 97 squared centimeters in the intervention group showed no statistical significance. On the 14th day of the trial, the wound size was compared again and in the control group, the size was found to be 24.4 cm^2 and 14.9 cm^2 in the intervention group. However, no statistical significance was shown. On the visual analog scale for pain after 14 days, both groups demonstrated a steep decline falling to nearly 1.5 from 9 on the first postoperative day however showing no significant difference across the two groups as shown in Table 2.

Table 2: Comparative analysis of mean in both groups

Correlations	Control (n=21)	Intervention (n=29)	p-value
The mean number of dressings changed due to bleeding	0.23±.538	0.31± 71	0.239
Mean number of dressings changed due to pus	0.76±1.54	0.72 ±1.36	0.189
Mean Wound size in cm^2 on T^0	36.33±12.19	30.96±19.51	0.590
Mean Wound size in cm^2 on T^{14}	24.42±9.85	14.93±9.14	0.564
Mean Pain visual analogue score on T^0	9.90±0.30	9.24±2.06	0.000**
Mean Pain visual analogue score on T^{14}	1.52±1.56	1.24±.68	0.645

**. Correlation is significant at the 0.01 level (2-tailed)

The wound site infection was treated in both groups on day 14, 4 from the control group and 6 from the intervention group. Neither pus nor bleeding was a complication in either group after 14 days postoperatively as shown in Table 3.

Table 3: Complications in both groups

Complications	Control (n=21)	Intervention (n=29)
Infection T^0	19.0% (n=4)	20.7% (n=6)
Infection T^{14}	0.0% (n=0)	0.0% (n=0)
Pus T^0	23.8 % (n=5)	24.1% (n=7)
Pus T^{14}	0.0% (n=0)	0.0% (n=0)
Bleeding T^0	19.0% (n=4)	13.8% (n=4)
Bleeding T^{14}	0.0% (n=0)	3.4% (n=1)

DISCUSSION

Pilonidal sinus is a fairly common disease with an incidence rate of 26 per 100,000 patients per year. Male to female ratio is 3-4:1 demonstrating a male predominance [12]. Our study is in line with this epidemiology as all of our participants are male. Its pathophysiology is largely unknown and is presumed to occur due to hook-shaped hairs piercing into the skin forming a cyst lined by vascular granular tissue [13]. The acute form usually presents with an abscess and is generally managed conservatively. For chronic diseases, there is a multitude of treatment options available to manage pilonidal sinuses ranging from phenol injections to advancement flaps [14]. Kober *et al.*, discusses in detail in their clinical review the current management options. Kober *et al.*, also concluded that surgical intervention is required for recurrent or chronic forms of the disease and excision followed by flab closure is commonly employed [15]. Al-Khamis *et al.*, urges to make off-midline closure the standard surgical option. However, primary closure is associated with high recurrence rates of up to 15-25%. Al-Khamis *et al.*, has reported significantly

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lower recurrence rates with secondary intention healing, reducing the rates by 35% [4]. These studies suggest open healing as the method of choice after surgery for pilonidal sinus. Negative pressure wound therapy (NPWT) assists in open wound healing. It aids in keeping the wound dry along with an approximation of the edges of the wound by applying sub-atmospheric pressures. In their meta-analysis, Yin *et al.*, discovered that NPWT was very effective in promoting the healing of split-thickness skin grafts [16]. Gao conducted a systematic review and concluded that NPWT is the best available option in cases of surgical site infections. However, the study demanded further trials for evaluation [17]. Some studies report no significant benefit of using NPWT against conventional dressings [18, 19], encouraging further studies and trials for evaluation. Our study, thus adds to the literature in determining the role of NPWT in wound healing. The results of this study show no statistically significant difference after the application of VAC therapy compared to usual dressing. This study however was done in a single center with a small sample size. The role of NPWT warrants further exploration and large-scale trials. A similar study done by Biter *et al.*, sets 2 weeks (14 days) as the observational period which is too short to report any clinical significance [20]. Our study affirms this concern. Due to the lack of trials in the literature, the optimum period for the observation was difficult to determine. Moreover, after two weeks patients usually did not return for the follow-ups making two weeks a suitable period to follow. The study done by Biter *et al.*, had similar outcomes as seen in our study. There was no significant difference observed in wound healing and visual analogue scale for pain. However, the wound size ratio was found significantly lower in the vaccum group in the study by Biter *et al.*, which was contradictory to the findings of our study which showed no significant difference. The time taken for complete wound healing in the study conducted by Biter *et al.*, showed that NPWT group took less days as compared to the control group, however, there was no statistically significant difference. The study also showed that there was no significant difference in the wound volume, infections and pus in both groups. These findings were consistent with the findings of our study [20]. Additionally, a study by Philip *et al.*, also reported the same findings [21]. There are several limitations in this study mainly the sample size which can be increased by including patients from various tertiary care centers, the study could not be blinded bilaterally and many patients weren't followed long enough to report recurrence. Furthermore, female patients weren't encountered, and few participants had co-morbid which leaves the healing process in these two segments of the population unexplored. However, this study can nevertheless play a vital role by providing further insights along with the studies currently available in the literature.

CONCLUSIONS

The 2 groups in the study; control and NPWT were compared on the basis of number of dressing changed, wound size, pain, infection, pus, bleeding. There was no significant difference between the two methods and similar time was required in both groups before resuming daily life activities.

Authors Contribution

Conceptualization: KF, FZ
Methodology: KF, MF, BJ, HS, SS
Formal analysis: KF
Writing-review and editing: KF, FZ, MF, UBS, SAS, MH

All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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