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General Surgery

VACUUM ASSISTED CLOSURE IN PILONIDAL ABSCESS - THE WAY FORWARD!

Dr. Srikanth K Aithal	HOD, Department of General Surgery, St Martha's Hospital, Bengaluru, Karnataka, India
Dr. Vijay R*	Post Graduate, Department of Surgery, St Martha's Hospital.*Corresponding Author
Dr. Karthik Patel	Post Graduate, Department of Surgery, St Martha's Hospital.

ABSTRACT Pilonidal sinus is a disease that arises in the hair follicles of the natal cleft of the sacrococcygeal area. Usual treatment of pilonidal disease consists of surgical excision. Much effort has been spent on developing new procedures to accelerate wound healing, among which negative-pressure wound therapy (nPWt) has been suggested. This Prospective, randomized controlled study aims to evaluate efficacy of VAC in pilonidal abscess with respect to time taken for healing, wound size reduction rate and time taken to resume daily activities. Out of 20 studied subjects most of them are males. Average age group was between 20-30 years. Complete wound healing after surgery was achieved at a median of 56 days in the nPWt group versus 84 days in the control patients (P=0.19). While comparing wound dimension at Day 1 of excision and after 2weeks of treatment, there was 51.66% wound reduction in vac group as compared to conventional group (p=0.02). The median time to resume full daily activities after surgery was 27 days in nPWt treated patients and 39 days in the control group (p= 0.92). The use of nPWt after surgical excision of pilonidal sinus disease is feasible. It resulted in a higher wound healing rate in the first 2 weeks after surgical excision. Also benefit of nPWt was seen with respect to time to complete wound healing and time to resume daily life activities.

KEYWORDS : Pilonidal disease, nPWt (negative Pressure Wedge therapy), vacuum, excision,

INTRODUCTION

In 1880, Hodge introduced the term 'Pilonidal sinus disease'.[1] Pilonidal sinus is a disease that most commonly arises in the hair follicles of the natal cleft of the sacrococcygeal area. Pilonidal sinus disease is a potentially morbid condition, Pathogenic feature of pilonidal sinus is the presence of midline pits. [2]. Histology shows foreign body giant cells with hair shafts and chronic granulation tissue lining sinus tracts.[3] incidence is 26 cases per 1,00,000 [4]

- Mean age at presentation 20 years
- 2-4 times more common in male

Factors responsible for poor healing are narrow groove, moist environment and higher bacterial burden near peri anal area.[5] Thus, fast and effective treatment is a considerable challenge.

Usual treatment of pilonidal disease consists of surgical excision which range widely from a simple excision with or without primary closure to complex flap reconstructions. As in our study we are primarily focusing on pilonidal abscess, and traditional treatment for which is I&D with healing by secondary intention. [6]

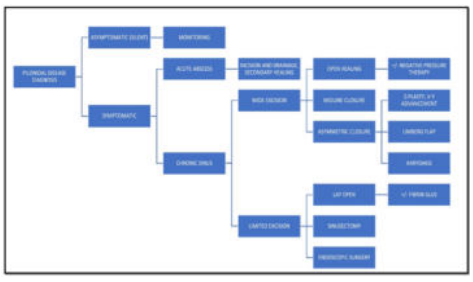


Fig 1 – Various modes of treatment for pilonidal disease

Open method is associated with significant morbidity in terms of soakage of cloths, frequent faecal contamination, difficulty in resuming to work and longer healing time. [6]

In search of alternative, much effort has been spent on developing new procedures to accelerate wound healing, among which negative-pressure wound therapy (nPWt) was developed two decades ago and consists of an open-cell foam dressing covered with an adhesive drape. The dressing is connected to a vacuum pump that creates a sub-atmospheric pressure of –50 to –125mm hg, which can be applied constantly or intermittently.

In literatures, various studies demonstrated use of vac dressing after excision of pilonidal abscess. Various advantages that are stated are[7]

Provides continuous drainage
Reduces leakage /soakage problem
Enhance granulation tissue formation and neo-vascularisation
Accelerates the wound healing process

We conducted a randomized Controlled trial to compare nPWt with standard open wound healing with regard to its efficacy and patient's comfort.

Aims and objectives:

To evaluate efficacy of vac in pilonidal abscess
To assess time taken for healing of wound when compared to conventional dressings
To assess wound size reduction rate
To assess time taken to resume daily activities

MATERIALS AND METHODS:

All patients requiring surgical treatment for a pilonidal abscess at our hospital between Jan 2021 to April 2022 were evaluated for inclusion in the current trial.

Exclusion criteria for participation were –
a. age younger than 16 years,
b. previous attempt at surgical excision of pilonidal disease,
c. inability to undergo frequent follow-up.
d. patients in whom the pilonidal abscess was situated less than 3 cm from the anus, because the nPWt device could not be placed into position locally.

Patients were requested to sign the informed consent form before random assignment, and were given an information prospect of the study. Randomization took place 1 day before the scheduled operation to facilitate the presence of a nPWt device in the operating room when required. The randomization process was conducted by the principal investigator of the study by using a computer-generated randomization list without any restrictions such as block size.

Study protocol

Before the start of the study, the local medical ethics committee had approved the study protocol. Patients were allotted the treatment based on computer generated randomisation at the outpatient clinic to undergo nPWt (device was applied directly after surgical excision) for 14 days, or to undergo standard open wound care. The primary end point of the study was time to complete wound healing, defined as the number of days until full skin closure was achieved. Secondary end points were the wound size ratio at postoperative day 14 [wound size at

postoperative day 14 (t1) divided by wound size at postoperative day 0 (t0)], ie, wound healing rate after 14 days, the visual analog scale score at postoperative day 14, time to resume daily activities such as work or school (patient' s self-report) and recurrence of the pilonidal sinus within 6 months after closure of the wound.

Surgery

The same surgical technique was applied in all patients. Complete surgical excision was performed under spinal anaesthesia with the patient in the prone jack knife position. The fistula was probed by using a blunt needle. Methylene blue was injected to define the exact borders of the cyst. An elliptical incision of the skin was made around the pilonidal sinus. Surgical diathermy was used for further complete excision of the cyst, if necessary, up to the level of the coccyx. After excision of the pilonidal sinus and removal of the tape used for patient positioning, the length, width, and height of the wound (all in centimetres) were measured in the operating room and documented. When haemostasis was obtained, dressing was left in the wound in all patients. In the postoperative phase, all patients were advised to take paracetamol on a regular daily basis (1000mg 4 times a day) and an additional nonsteroidal anti-inflammatory drug when needed.

Negative-pressure wound therapy

If the patient was randomly assigned to nPWt, the vacuum-assisted closure device was placed directly by an experienced surgeon in the operating room after surgical excision. First, a sponge was positioned in the wound on top of the surrounding skin. A topical skin adhesive was applied to the borders to prevent skin damage. The nPWt device (consisting of an open-pore foam covered by an adhesive semipermeable dressing) was applied and connected to a special medical vacuum. A negative pressure of 125mm hg was adjusted to the wound 24 hours a day. During follow-up, the sponge was replaced at postoperative days 5 and 10 at the outpatient Clinic. At day 14, nPWt was finished, and regular wound care was started. Patients were advised to rinse the wound 3 times daily until a superficial wound was achieved; hereafter, the rinsing frequency was reduced.

Standard open wound healing in the control group, the wound was left open after surgical excision. Wound dressing was applied with an absorbent bandage on top. Patients were advised to rinse the wound 3 times daily during the first 2weeks after excision. No special dressings were applied.

Follow-up

Follow-up consisted of a predetermined schedule for all patients at the outpatient clinic. Inspection was done by a surgeon together with his assistant. Each patient returned to the hospital at postoperative days 3, 7, 10, and 14 for wound inspection. Wound size, complications (such as infection [defined as pain and redness of the wound], abscess [defined as retention of pus in the wound], and bleeding), and pain score (measured by the visual analog scale score) were documented. After 2 weeks, all patients visited the outpatient clinic on a weekly basis for inspection and wound measurement until the wound was closed completely. Six months after wound closure, there was final check for the recurrence of pilonidal sinus disease.

Statistical evaluation

Before the start of this study, no sample size calculation had been performed. The available literature on using nPWt in patients who have pilonidal sinus is scarce, making a valid calculation impossible. Data were prospectively collected and stored in a database. Data analysis was performed in spss version 17.0 (spss, chicago, il). Statistical analysis appropriate for nonparametric data was used. Two-sided p values of <0.05 were considered significant.

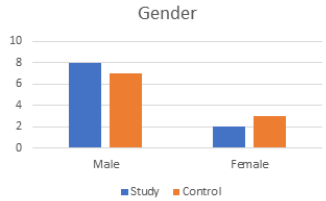
RESULTS:

Total of 24 patients with pilonidal abscess requiring surgical excision were evaluated for inclusion. A total of 20 patients signed the informed consent form and were randomly assigned for treatment. Patient characteristics were comparable in both groups (table 1).

Table 1: Basic demographic data of the patients

	VAC (n=10)	Open (n=10)
Mean Age (years)	23.3 years	27.6 years
Gender - M/F	8/2	7/3

Graph 1 - Basic demographic data of the patients



All 20 patients were included in the current data analysis according to the intention to treat principal outcome of both treatment groups is shown in below tables.

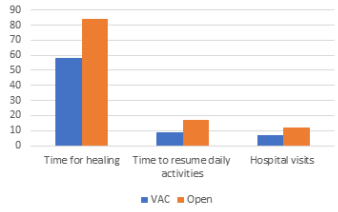
Complete wound healing after surgery was achieved at a median of 56 days in the nPWt group versus 84 days in the control patients (p = 0.19).

The median time to resume full daily activities after surgery was 27 days in nPWt treated patients and 39 days in the control group (p = 0.92).

Patients with Vac dressings needed less hospital visits (7.9) compared to control group who needed more visits (12).

Table 2: Table comparing time taken for healing, to resume daily activities and number of hospital visits

	VAC	Open	P value
Mean time taken for healing	56 days	84 days	0.19
Time to resume daily activities	27 days	39 days	0.92
Total no. hospital visits	7.9	12	0.08

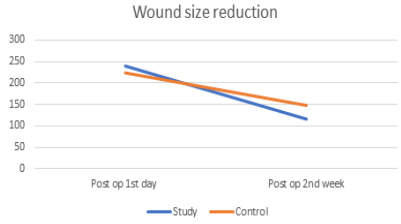


Graph 2: Table comparing time taken for healing, to resume daily activities and number of hospital visits

While comparing wound dimension at Day 1 of excision and after 2weeks of treatment, there was 51.66% wound reduction in vac group as compared to conventional group (p = 0.02), which means a higher wound healing rate during the first 2 weeks after surgical excision.

Table 3: Table showing rate of wound size reduction

	VAC	Open	P value
Average wound dimensions	240cm3	224cm3	
Wound size At end of 2nd week	116cm3	148cm3	0.02
Wound size reduction at 2nd week	51.66%	33.92%	

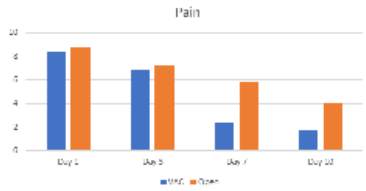


Graph 3: showing rate of wound size reduction

There was no difference in wound infection rate and disease recurrence between both groups. Pain on day one and day three after the procedure was similar in both study groups (no statistically significant differences were found). On day 7 and 10 a significant reduction of pain was found in the Vac group

Table 4: Table showing comparison between average pain scores

AVERAGE PAIN VAS SCALE	VAC	OPEN
DAY 1	8.4	8.8
DAY 3	6.8	7.2
DAY 7	2.4	5.8
DAY 10	1.7	4.1

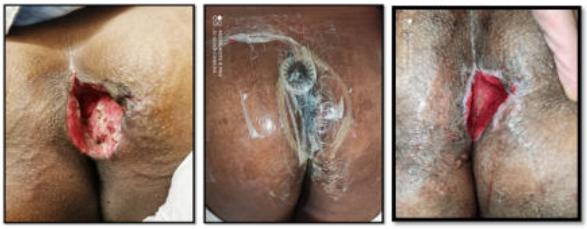


Graph 4: showing comparison between average pain scores

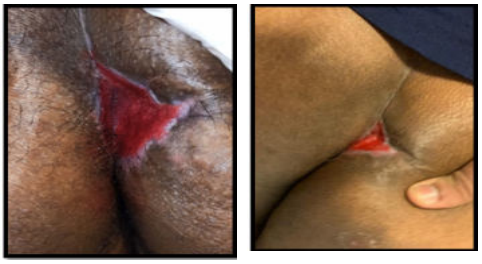
During the first 2 weeks after surgery, 1 patient from the nPWt group came to the emergency department because of a malfunctioning nPWt device that needed to be reconnected properly.

In the control group, frequent wound leakage was the most commonly reported concern (6/10 patients); furthermore, many patients experienced the frequent change of wound dressings as difficult, painful, and burdensome in the first 2weeks.

IMAGE GALLERY
CASES MANAGED WITH VAC
CASE I - [FIG 1]

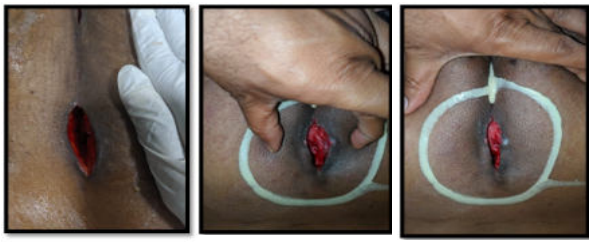


a. POST OP DAY 1 b.VACCUM DRESSING c. 1ST WEEK

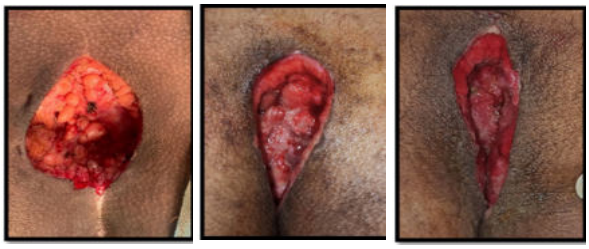


d. 2ND WEEK e. 6TH WEEK

CASE II [FIG 2]



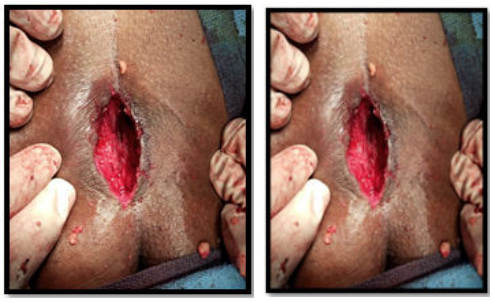
a. POST EXCISION b. POST-OP WEEK 2 c. POST-OP WEEK 4



a. POST-OP b. POST-OP WEEK 1 c. POST-OP WEEK 2

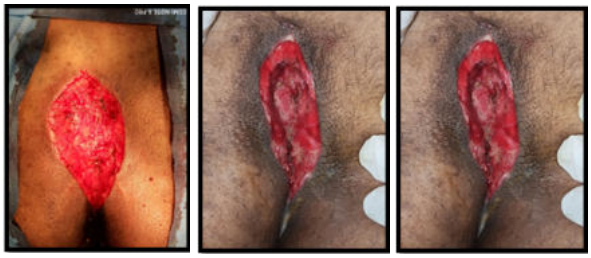
REGULAR CONVENTIONAL DRESSINGS – CONTROL GROUP

CONTROL 1 [FIG 4]



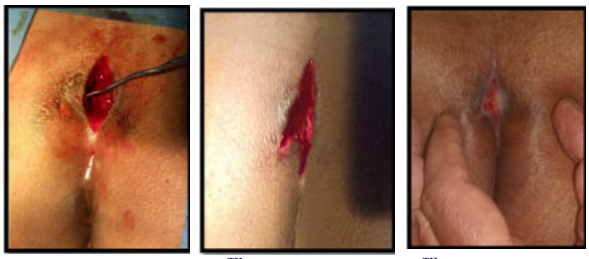
a. POST OP b. 4TH WEEK

CONTROL 2 [FIG 5]



a. POST OP b. 1ST WEEK c. 4TH WEEK

CONTROL 3 [FIG 6]



a. INTRA OP b. 4TH WEEK c. 10TH WEEK

DISCUSSION

Ideal treatment for pilonidal disease is controversial.[8] Disease stage and size, number and location, complexion and hair type, previous treatment attempt are confounders. Pilonidal sinus disease is known for recurrence, 91% occurs within the first post operative year [9]

In the present randomized controlled study, we compared nPWt with standard open wound care after surgical excision of pilonidal abscess, it appeared feasible to apply nPWt in all patients. The primary end point of this study was time to complete wound healing after surgery. However, results showed difference between the 2 groups in terms of time to complete wound healing, with wound healing rate was significantly higher in the nPWt group: after 14 days, wound volume was reduced with 51.6% after nPWt versus 33.92% in the control group. Nevertheless, this did not result in a shorter time to resume daily activities in the nPWt group.

In general, multiple studies have been conducted to determine the effect of nPWt in wound management in general. A systematic review by Ubbink et al [10], showed that nPWt did not result in faster wound healing in comparison with control patients. They concluded that there is little evidence to support the use of nPWt in wounds. In contrast, Suissa et al [11]. conducted a meta-analysis including 10 randomized controlled trials, which demonstrated a faster healing time in chronic wounds treated with nPWt in comparison control patients. Gregor et al [12]. Concluded in their review that nPWt may improve wound healing, although the body of evidence available is insufficient to clearly prove an additional benefit of nPWt. The drawback of these large meta-analyses is that predominantly heterogeneous groups of patients are included with different types of wounds.

The current study involves a surgical wound in the natal cleft of the sacrococcygeal area, which was not studied in the above stated studies. Thus far, no randomized controlled trial has been conducted in patients with pilonidal abscess to investigate the effectiveness of nPWt after surgery.

Five case series (each including 1– 5 patients) have been published, all suggesting that nPWt may be an emerging treatment option for pilonidal disease management (8–12) these case series have been summarized (n = 15 patients): the duration of nPWt ranged from 4 to 9 weeks (mean, 6weeks), and the time to complete wound closure varied between 9 and 22weeks. The time to complete wound closure in our patient group (median,56 days) was comparable to those reported in the published case series (varying from 8 to 22weeks) compared with the available case series, it is questionable whether the applied 2weeks of nPWt in our study was long enough.

A period of 2 weeks may have been too short to obtain a difference in time to complete wound healing (primary end point in this study). However, a 2-week interval was chosen to minimize patients' concerns and potential difficulties in daily life. There is also some evidence that the required angiogenesis to promote granulation tissue is optimal in the first 2 weeks of nPWt.

Moreover, by applying nPWt to all patients in this study group for 2 weeks, a homogenous cohort of patients with similar duration of therapy was obtained. Few patients treated with nPWt reported bad odour, pain, noise, skin irritation, air leakage, and practical reasons as important considerable disadvantages of the treatment. These concerns have been described in previous nPWt related studies and may result in a decreased quality of life. In the control group, wound leakage and the daily change of wound dressings were common concerns; this experience was difficult and burdensome. Therefore, it can be stated that both treatments have disadvantages.

Drawbacks of our study are that the study could not be blinded to both patients and doctors, no quality-of-life evaluation has been taken into account, and the number of patients is small, causing a potential statistical type 2 error. Nevertheless, it is the first randomized study on this topic. Further research can focus on patient preference and may identify those subgroups of patients that do benefit from nPWt in the postoperative treatment of pilonidal abscess. NPWt may be a good postoperative treatment in specific cases in which a fast wound healing rate is required in the first 2 weeks, or in those patients who are not able to perform intensive wound care on a daily basis. Also, it might be interesting to investigate the role of nPWt specifically in complex non-healing pilonidal wounds or recurrent disease, which are often difficult to manage. Research strongly supports the role of nPWt to prevent surgical site infections across high-risk patient-groups.

CONCLUSION

The use of nPWt after surgical excision of pilonidal sinus disease is feasible.it resulted in a higher wound healing rate in the first 2 weeks after surgical excision. With benefit of nPWt was seen with respect to time to complete wound healing and time to resume daily life activities. More research should be conducted before nPWt can be implemented as a standard treatment in specific patient groups with pilonidal abscess.

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