

# A comparative study between the closed tie-over and open vacuum suction drainage procedures in patients with sacrococcygeal pilonidal sinus disease

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## Background

Multiple surgical techniques have been adopted for the management of patients with pilonidal disease. A great debate still exists among surgeons regarding the best option. We describe our experience in comparing the tie-over and open excision with vacuum suction drainage for the management of such a disease.

## Patients and methods

This retrospective study reviewed the data of 65 patients diagnosed with pilonidal disease, who were allocated into two groups according to the performed procedure. The first group included 35 patients who underwent the tie-over approach, and the second one included 30 patients who underwent open vacuum drainage.

## Results

The demographic and preoperative clinical patient criteria were statistically comparable between the two groups. The tie-over approach showed a significant prolongation of the operative time (75.29 vs. 50.57 min in the vacuum group). Hospital stays and pain scores showed no significant difference between the study groups. Time to painless walking had median values of 6 and 8 days, whereas the same values were 7 and 9 days for painless toilet seat in the tie-over approach and the vacuum group, respectively. Return to daily activities occurred after 3 and 4 weeks, whereas complete wound healing was noticed in 2 and 5 weeks in the tie-over approach and the vacuum group, respectively. Recurrence was noted in 5.71 and 3.33% of patients in the tie-over approach and the vacuum group, respectively.

## Conclusion

The tie-over approach was associated with better postoperative outcomes, including faster wound healing and better recovery profile, with comparable recurrence rates, compared with the open vacuum suction approach.

## Keywords:

open vacuum drainage, pilonidal disease, tie-over

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## Introduction

Sacrococcygeal pilonidal disease (PND) is one of the most common surgical entities commonly encountered in the daily general surgical practice [1,2]. The term 'pilonidal' is extracted from the two Latin words pilus and nidus, which mean hair and nest, respectively [3].

This problem affects about 26 per 100 000 individuals, and it occurs in men two to four times more than in women [4,5]. Three main factors share a role in its pathogenesis, including the presence of hair, skin vulnerability, and the presence of a force directing the hair into the skin, as described by Karydakakis [6].

The proper management of such a condition entails complete eradication of the entire sinus tracts, healing of the overlying skin, as well as prevention of postoperative recurrence [7]. Multiple surgical

options are available, and they range from simple excision with or without primary closure to complex flap reconstruction [8]. The choice of the optimum procedure depends on disease criteria and operator experience [9].

There is still a great debate among surgeons regarding the optimum surgical strategy for PND [10,11]. Although wound closure is often associated with a better recovery rate compared with the open approach [12,13], it carries an increased risk for postoperative recurrence [12]. Therefore, numerous efforts have been made to enhance the wound

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healing process in the open approaches to enhance patient outcomes [7,14].

The application of negative pressure wound therapy, including vacuum drainage, is believed to drain the exudate arising from the open wound, decrease bacterial colonization, diminish wound edema, enhance circulation and oxygenation to the wound edges, and improve wound healing [15,16]. This technique has been successfully applied to open and closed wounds [3,16].

The closed method for PND management also carries a potential risk for deep space formation deep into the closed skin. This problem could be prevented in two ways: the application of a closed suction drain or the tie-over procedure. The latter entails the application of a pack over the closed wound, which helps to push the tissue layers against each other, leading to a decrease in the dead space and seroma formation [17,18].

After intensive research in the current literature, there is a clear paucity of studies comparing the tie-over with the open excision with vacuum drainage approaches in PND management, which was a fair motive for us to conduct the current investigation.

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## Patients and methods

This retrospective study was conducted at Mansoura University Hospitals (General Surgery Department) after gaining ethical approval from the Institutional Review Board (IRB) of our medical school.

We recruited and reviewed data of patients who underwent either excision of PNS and closed tie-over (group 1) or open excision with vacuum drainage (group 2) from patients' medical records over the study period who met the inclusion and exclusion criteria and compared the results among both groups. Technically, both approaches were performed according to the 'standard procedure.'

The choice of the surgical procedures in our study was stated according to the American Society of Colon and Rectal Surgeons' (ASCRS) Clinical Practice Guidelines for the Management of Pilonidal Disease, 2019, which states that Patients who require surgery for chronic PND may undergo excision and primary repair (with consideration for off-midline closure), excision with healing by secondary intention, or excision with marsupialization based on surgeon and patient preference. Drain use should be individualized.

Grade of recommendation was as follows: strong recommendation was based on moderate-quality evidence, 1B [19]. This was done after explaining the proposed advantages and disadvantages of each technique to patients in terms of healing and recurrence rates. The patients were classified according to surgical methods used.

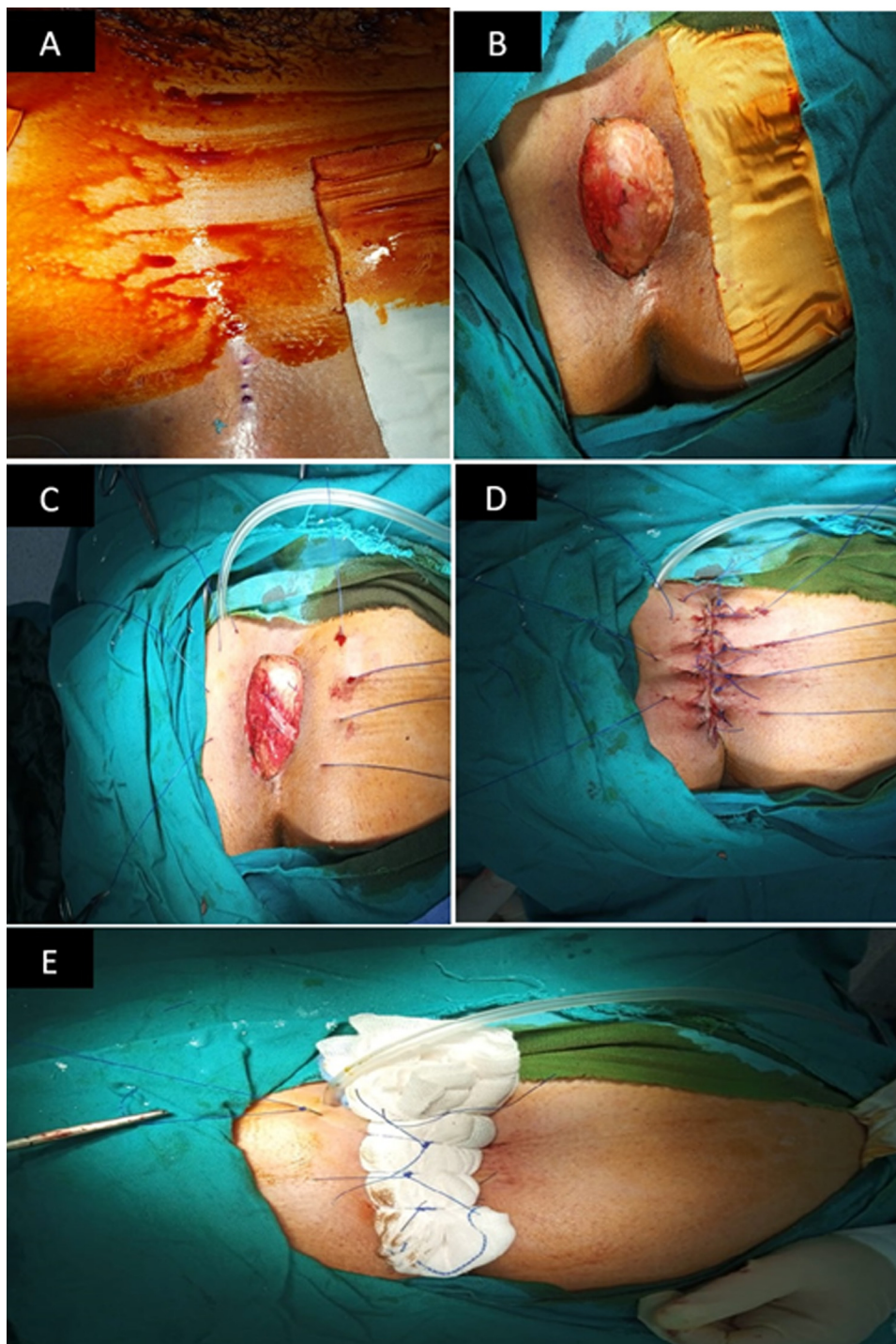
The data of 65 patients who were diagnosed with sacrococcygeal PND and were managed by either closed tie-over or open vacuum drainage during the period between January 2019 and December 2021 were reviewed. Patients diagnosed with recurrent PND who underwent other operations rather than the previously mentioned ones, presented with acute PND, or who were lost at follow-up were excluded from this study.

We reviewed the preoperative data of the selected patients in terms of history taking (focusing on symptoms and their duration), clinical examination (focusing on the location of pits and its Gunner stage [20]), and routine preoperative laboratory workup.

Patients were admitted to the surgical ward the day before the procedure. The patients were transferred to the operative theater. The sinus tract was injected with methylene blue dye for easy identification during surgery. The type of operation was entirely dependent on the operator's choice. All patients were performed under spinal anesthesia, and the procedure was done when the patient was in the prone position.

The sinus tracts were excised through a longitudinal elliptical incision 2 cm lateral to the midline. Excision of the sinus tracts was done down to the underlying sacral fascia. If any residual tissue was detected (identified by the blue dye remnants), it was removed as well. A total of 35 cases (the first group) were managed by the closed tie-over method. Three to five pretaken sutures (polypropylene 1 thread) were applied, followed by wound closure over a closed suction drain. After that, the pretaken sutures were tied over a pack that was removed on the fifth postoperative day (Fig. 1). The wound was left open in the other group (30 patients), and a vacuum device (RENASYS◇ EZ MAX, Smith & Nephew plc, Hertfordshire, UK) was applied under negative pressure of 125 mmHg adjusted to the wound 24 h a day to remove the discharge and accelerate wound healing (Fig. 2). This device was applied for 14 days after the operation. The operative time was recorded in both study groups.

Figure 1

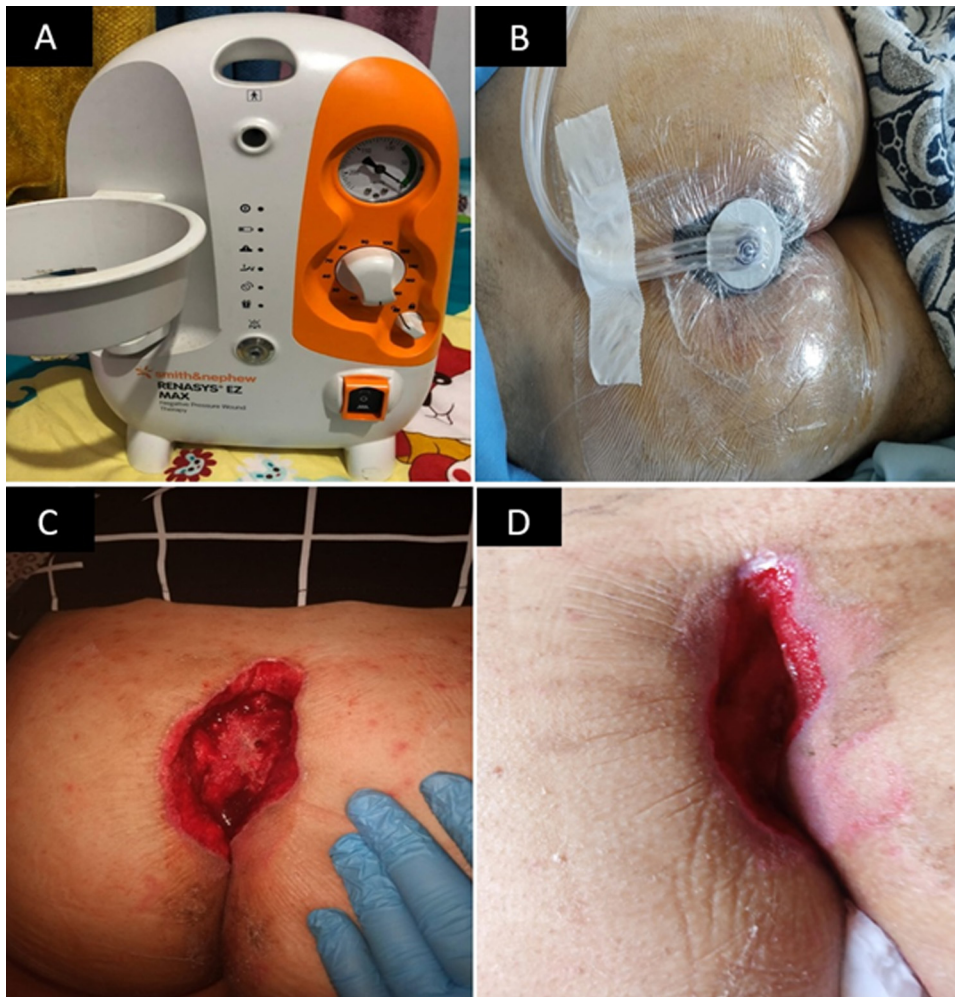


(a) A patient with PNS after positioning in the operating table (prone position) under spinal anesthesia and injection of methylene blue dye for delineation of the track. (b) After complete excision of the pilonidal sinus. (c) Polypropylene 1/0 sutures passing through the two edges of the wound (involving the presacral fascia) to close the dead space and decrease tension and wound dehiscence. (d) Wound closure with 2/0 polypropylene sutures with the stay tension sutures for further tie over. (e) The tie-over technique where the stay tension sutures were tied over a towel.

We reviewed postoperative data from the patient files, and data regarding pain on the first postoperative day measured via the visual analog scale [21] were collected. Other collected data included early complications like bleeding, infection, and urine retention.

Follow-up data were reviewed for 6 months after operation (3rd, 7th, and 14th days after operation, then weekly for 2 months, and then monthly for the remaining 4 weeks). Stitches in the tie-over group were removed after 10–14 days. The following parameters

Figure 2



(a) The vacuum (NPWT) device (RENASYS EZ MAX, Smith & Nephew) used in our study. (b) The VAC device applied on the wound after PNS excision. (c) Wound 2 days after the excision of PNS with VAC therapy with clean wound margins and granulation. (d) Wound after 1 week of VAC dressing; the wound became narrower with better healing. NPWT, negative pressure wound therapy.

were also collected from patients file: time to return to normal daily activities, time to pain-free walking, time to a pain-free toilet seat, time for complete wound healing (Fig. 3), time to complete wound healing, and finally, 6-month recurrence rate.

#### Statistical analysis

Statistical Package for the Social Sciences (version 27 for Windows; IBM SPSS Inc., Chicago, Illinois, USA) was used for data tabulation and analysis. Quantitative data were tested for normality using the Shapiro–Wilk test and then expressed as mean±SD or median (minimum–maximum). To compare two independent groups of parametric quantitative data, the independent samples *t* test was used, and to compare two independent groups of nonparametric quantitative data, the independent samples *t* test. Qualitative data were expressed as numbers and relative percentages. To compare two independent groups of qualitative data,  $\chi^2$  (Fisher's exact test or

Monte-Carlo test) was used as appropriate. A *P* value of 0.05 or less was considered to be significant.

#### Results

Patients in the tie-over and vacuum groups had mean ages of 28.83 and 28.97 years, respectively. Men represented 71.43 and 76.67% of participants in the tie-over and vacuum groups, respectively, whereas the remaining cases were women. Mean BMI was 30.13 and 29.73 kg/m<sup>2</sup> in the tie-over and vacuum groups, respectively.

Perianal discharge was the most common presentation in the tie-over and vacuum groups (94.29 and 93.33%, respectively), followed by pruritus and perianal pain, whereas bleeding was reported by only one patient in each group. The mean duration of the previous manifestations was 11.23 and 12.73 months in the tie-over and vacuum groups, respectively. Regarding

**Table 1 Demographic and clinical characteristics of the two study groups**

	Tie-over group (N=35)	Open vacuum drainage (N=30)	P value
Age (years)	28.83±6.52	28.97±6.32	0.932
Sex			
Male	25 (71.43)	23 (76.67)	0.632
Female	10 (28.57)	7 (23.33)	
BMI (kg/m <sup>2</sup> )	30.13±2.97	29.73±2.31	0.551
Clinical presentation			
Discharge	33 (94.29)	28 (93.33)	0.873
Pruritus	19 (54.29)	14 (46.67)	0.540
Perianal pain	18 (51.43)	14 (46.67)	0.702
Bleeding	1 (2.86)	1 (3.33)	0.912
Duration of symptoms (months)	11.23±3.43	12.73±2.86	0.162
Gunner stage			
1	9 (25.71)	7 (23.33)	
2	16 (45.71)	14 (46.67)	0.981
3	7 (20)	7 (23.33)	
4	3 (8.57)	2 (6.67)	

**Table 2 Operative time and postoperative complications in the two study groups**

	Tie-over group (N=35)	Open vacuum drainage (N=30)	P value
Operative time (min)	75.29±7.74	50.57±6.06	<0.001*
Complications			
Bleeding	0	0	–
Urine retention	2 (5.71)	2 (6.67)	0.873
Wound infection	2 (5.71)	1 (3.33)	0.648

\* = Statistically significant.

Gunner staging of our cases, stage 2 was present in 45.71 and 46.67% of cases, whereas stage 1 was noted in 25.71 and 23.33% of cases in the tie-over and vacuum groups, respectively. The remaining patients had either grade 3 or 4. All of the previous demographic and clinical variables were statistically comparable between the two groups ( $P>0.05$ ), as shown in Table 1.

The tie-over approach showed a significant prolongation of the operative time, which had a mean value of 75.29 min compared with 50.57 min in the vacuum group ( $P<0.001$ ). No patients developed postoperative bleeding in this study. However, urine retention was encountered in 5.71 and 6.67% of patients, whereas wound infection occurred in 5.71 and 3.33% of patients in the tie-over and vacuum groups, respectively (Table 2).

The hospitalization period ranged between 1 and 2 days in both study groups, whereas first-day visual analog scale had median values of 4 and 5 in the tie-over and vacuum groups, respectively. Both variables expressed no significant difference between the study groups.

**Table 3 Postoperative recovery profile in the two study groups**

	Tie-over group (N=35)	Open vacuum drainage (N=30)	P value
Hospital stays (day)	2 (1–2)	1 (1–2)	0.586
VAS	4 (3–6)	5 (3–6)	0.949
Time to return to daily activities (weeks)	3 (2–3)	4 (3–5)	<0.001*
Time to painless walking (day)	6 (4–8)	8 (6–9)	<0.001*
Time to painless toilet seat (day)	7 (5–9)	9 (7–11)	<0.001*
Time for complete wound healing (weeks)	2 (2–3)	5 (4–6)	<0.001*

VAS, visual analog scale. \* = Statistically significant.

Postoperative recovery parameters, including time to return to routine daily activities, time to painless walking, time to a painless toilet seat, as well as the time for complete wound healing, showed a significant decrease in the tie-over group ( $P<0.001$ ), as illustrated in Table 3. Time to painless walking had median values of 6 and 8 days, whereas the same values were 7 and 9 days for time to painless toilet seat in the tie-over and vacuum groups, respectively. Return to daily activities

**Table 4 Postoperative recurrence in the two study groups**

	Tie-over group (N=35)	Open vacuum drainage (N=30)	P value
Recurrence	2 (5.71)	1 (3.33)	0.648

occurred after 3 weeks in the tie-over group compared with 4 weeks in the vacuum patients. Finally, complete wound healing was noticed in 2 and 5 weeks in the tie-over and vacuum groups, respectively.

At 6-month follow-up, recurrence was noted in 5.71 and 3.33% of patients in the tie-over and vacuum groups, respectively, which was statistically comparable between the two groups (Table 4).

## Discussion

The ideal surgery for PND should have the following criteria: early return to daily activities, affordable financial cost, reduction in the follow-up visits required for dressing, accepted complication rates, and lower risk of recurrence [22].

Excision of the sinus tracts with leaving the wound open has multiple disadvantages, including the increased time required for wound healing, the need for frequent dressing, and increased postoperative pain [23]. Therefore, we added the vacuum drainage as an adjuvant to the lay open technique in the current study to overcome the previous drawbacks.

We compared the outcomes of the previous combination with the tie-over approach in the current investigation. We did not encounter any previous study in the existing literature handling the same comparison and that is considered an advantageous point in favor of our study. Moreover, the reader should notice almost no significant difference between the two study groups regarding all of the preoperative parameters. This should negate any bias skewing our findings in favor of one group rather than the other, despite the retrospective nature of our study.

Our results showed the increased operative time in the tie-over group compared with the vacuum one, with a statistically significant difference. It is reasonable to expend more time on wound closure and pretaken sutures in the tie-over group rather than leaving it open without closure.

We also noted a comparable postoperative pain between the two groups, although it was thought

that pain intensity is increased with open wounds. The decreased need for dressing in the vacuum group could explain that finding, as frequent dressing is accompanied by macrotrauma and microtrauma, which in turn leads to an increase in inflammatory mediators in the injured region, leading to increased pain [24,25].

Starting with open excision with vacuum suction drainage, its postoperative recovery outcomes were far inferior to the tie-over approach. Although open excision with vacuum drainage greatly improves PND outcomes compared with the open approach, it cannot be applied in all patients, especially when the wound is so close to the anal verge hindering its application [7]. Other drawbacks include financial cost, air leakage, bad odor, and hindering patient mobility. All of these problems could decrease patient satisfaction as well as quality of life [7,15,26].

The time to complete wound healing ranged between 4 and 6 weeks in our study. Multiple studies have reported that the time of complete wound healing ranged between 4 and 8 weeks when using the vacuum device [15,27–29], which is in accordance with our findings. However, other studies reported longer periods to complete wound healing, which ranged between 9 and 22 weeks [16,30]. This could be explained by different wound criteria and the duration of vacuum application between different studies.

One of the main limitations of our investigation is the lack of a lay-open group, which could have elucidated if the vacuum application was significantly beneficial in open wounds or not.

A previous systematic review conducted by Ubbink *et al.* [31] noted that open vacuum drainage did not lead to faster wound healing compared with controls, based on the data of the included 13 trials. Biter and colleagues reported that the application of vacuum drainage for the open PND wounds did not result in a significant acceleration of wound healing or improvement of other postoperative outcomes. Time to complete wound healing had median values of 84 and 93 days in the vacuum and control groups, respectively ( $P=0.44$ ). Nonetheless, the rate of wound healing within 2 weeks after surgery was higher in association with vacuum application (70 vs. only 43% in controls) [7]. The previous authors applied the vacuum device for only 2 weeks, rather than being dependent on the patient response like us, and that could explain their findings.

In contrast to the previous reports, a previous meta-analysis has confirmed the efficacy of vacuum application in fastening the healing process of open PND wounds when compared with open excision alone [32]. Bendewald *et al.* [30] also reported similar findings proving the efficacy of vacuum drainage in patients with PND. The previous heterogeneity regarding the efficacy of vacuum drainage could be explained by the different patient and wound criteria in different studies.

When it comes to the tie-over approach, it was suggested that the application of a pack over the closed wound and compressing it with multiple suture lines should decrease the dead space, decrease the need for routine drainage needed for such operations, and alleviate some tension over the wound, allowing earlier postoperative mobilization [22].

Although we did apply a drain in the tie-over group in the current study, the beneficial advantages were more evident regarding postoperative recovery when compared with the vacuum approach. This was manifested by the decreased time needed for wound healing, daily activities, painless walking, and painless toilet seat. This denoted that wound closure is still associated with a better post-operative recovery, even when the open approach is accompanied by adjuvant vacuum suction drainage.

Our findings showed comparable infection rates between the two groups, which were detected in 5.71 and 3.33% of patients in the tie-over and vacuum groups, respectively. Hannan *et al.* [15] reported a 3.3% infection rate after vacuum-assisted closure, whereas Sewefy *et al.* [22] reported a 1.3% infection rate for the tie-over approach. The previous two studies confirmed our findings regarding the low infection rates associated with either of the tested procedures. Contrarily, Hølmekbakk and Nesbakken [33] noted the increased infection rates with the tie-over procedure (43%). The application of a drainage system with the tie-over approach in our study could explain our low infection rates.

In our study, 6-month recurrence rates were 5.71 and 3.33% in the tie-over and vacuum groups, respectively, which was statistically comparable between the two groups. In the retrospective investigation conducted by Hannan *et al.* [15], recurrence was encountered in only one (1.6%) patient, and that was detected 19 months after open vacuum suction drainage. Sewefy *et al.* [22] reported that no patients developed recurrence

following the tie-over procedure (0%) within a 6-month follow-up period. Another study reported a 1.3% postoperative infection rate in the tie-over group [18]. All of the previous studies agree with our findings regarding the short-term recurrence rates after both approaches.

The current investigation has some limitations. Initially, it was retrospective in nature. In addition, it included a small sample of patients with PND who were recruited from a single surgical institution. Our study also lacked intermediate-term and long-term follow-up of the selected participants. Some selection biases were present owing to the retrospective nature of the study. All of the previous drawbacks should enhance surgeons to conduct similar research in the near future to reach a conclusive result for better patient outcomes.

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## Conclusion

The tie-over approach was associated with better postoperative outcomes, including faster wound healing and better recovery profile, with comparable recurrence rates, compared with the open excision with vacuum drainage approach. However, these findings should not be generalized till performing more large-volume studies with long-term follow-up.

## Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patients have given their consent for their images and other clinical information to be reported in the journal. The patient understands that his name and initials will not be published and due efforts will be made to conceal her identity, but anonymity cannot be guaranteed.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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