Al-Azhar Med. J. *Vol. 49(3), July, 2020, 1303-1312*
DOI : 10.12816/amj.2020.107126
https://amj.journals.ekb.eg/article_107126.html

COMPARATIVE STUDY BETWEEN VACUUM ASSISTED OPEN EXCISIONS VERSUS OPEN ALONE IN TREATMENT OF COMPLICATED PILONIDAL SINUS

By

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ABSTRACT

Background: Pilonidal disease is a type of skin infection which typically occurs as a cyst between the cheeks of the buttocks and often at the upper end. Sacrococcygeal pilonidal sinus is a common disorder among young adults, observed most commonly in people aged 15-30 years with a 3:1 male-to-female ratio.

Objective: To evaluate the role of vacuum therapy in pilonidal sinus disease compared with standard open wound care after surgical excision.

Patients and Methods: This was a prospective study conducted on 50 patients who were candidates for surgical excision of pilonidal sinus at Al-Azhar University Hospitals during the period from January 2019 to December 2019. Patients were classified into two equal groups: Group A were subjected to the conventional open surgical method without suturing of the wound, and Group 2were subjected to closed surgical excision with putting a vaccum system.

Results: Our results revealed a significant elongation in the operative time in vacuum group than in open ordinary method. In our study, the infection of the wound was more common in group A "ordinary open method" than the vacuum group "group B". Also, the recurrence rate after three months of follow up of cases was more common in group A than in group B. The time needed for complete healing in group B was shorter than in group A. Our study showed a significant decrease in frequency of dressing, and a significant patient satisfaction as well as early regain of normal daily activity in group B than in group A.

Conclusion: The use of vacuum assisted closure (VAC) therapy in cases of pilonidal disease has its advantageous effect in decreasing complications and accelerating healing.

Keywords: Pilonidal Sinus; VAC; NPWT.

INTRODUCTION

Pilonidal disease is an inflammatory and infectious soft tissue disorder of the sacrococcygeal intergluteal region. Wide complete excision of the abnormal tissue remains the dominant treatment, although controversy exists with respect to the preferred extent of excision, techniques and preferences for attempted primary closure, and management of open wounds following excision *(Sasse et al., 2013)*. Symptoms may include pain, swelling, and redness. There may also be drainage of fluid, but rarely a fever *(Khanna and Rombeau, 2011)*. Some people with a pilonidal cyst are asymptomatic *(Lim and*

Shabbir, 2019). If there is infection, treatment is generally by incision and drainage just off the midline. Shaving the area may prevent recurrence. More extensive surgery may be required if the disease recurs. Antibiotics are usually not needed. Without treatment the condition may remain long term *(Mubashir, 2018).*

A significant fraction of pilonidal disease results in an open wound after wide excision, and different strategies have evolved over time to facilitate healing of complex open pilonidal wounds. Most commonly, the open wound is packed with gauze on a daily or twice daily basis over a long period of time. The wound gradually heals in this manner by secondary intention, and the process can often take 6 months. Case reports have described a time course of up to 2 years for healing of open pilonidal wounds *(Bianchi et al., 2018).* Additional strategies have included flap surgery, delayed primary closure and the use of vacuum-assisted wound healing devices. Each of these approaches involves a level of patient discomfort, cumbersomeness, and a long period of time to complete healing *(Tas et al., 2017).*

Negative pressure wound therapy (NPWT) is one of the treatment approaches to increase healthy granulation tissue for complex wounds *(Ozkan et al., 2016).* It is also known that NPWT is an effective therapy decreasing bacterial contamination in wounds. There are few reports about its successful use in the management of pilonidal sinus disease and recurrent form in addition to surgical treatment *(Doll et al., 2016).*

The aim of this study was to evaluate the role of vacuum therapy in pilonidal sinus disease compared with standard open wound care after surgical excision.

PATIENTS AND METHODS

A prospective outcome analysis was done for 50 patients who were candidates for surgical excision of pilonidal sinus at Al-Azhar University Hospitals during the period from January 2019 to December 2019. Patients with pilonidal sinus: primary and recurrent. Inclusion criteria Primary or recurrent pilonidal sinus: infected or not infected. Exclusion criteria: Pilonidal sinus associated with peri-anal fistula.

Patients were classified into two randomized equal groups: Group I: Patients were subjected to the conventional open surgical method without suturing of the wound, and **Group II:** Patients were subjected to closed surgical excision with putting a vacuum system. Informed consents were taken from all patients of the study after informing them about the surgical procedure and its nature, duration, and possible complications.

All patients of the study were subjected to:

I. Preoperative Assessment:

a. Clinical assessment: Complete history taking. Medical history: focusing on the presence of other co-morbidities which may affect the process of wound healing. Present history: Onset, course, and durations of the present condition, previous surgeries and its complications which may or may not result in such condition. Clinical examination.

b. Investigations: Routine investigations for preoperative preparation. Specific investigations for recurrent cases that may include MRI, fistulogram or sinogram.

II. Surgical procedure:

a. Anesthesia: All patients received a general or local spinal anesthesia.

b. Position: Patients were positioned in left lateral or the prone position.

c. Surgical technique involved delineation of the sinus tracts with blue ink instillation through the primary sinuses. Complete surgical incision of the pilonidal sinus complex (the combination of primary sinuses, associated infected cavity, tracts, and/or secondary sinuses), then excising outside the blue ink-stained tissue with diathermy. Long-acting local anesthetic may be infiltrated.

III. Postsurgical Care: Group 1: Change the dressing daily using Iruxol ointment and silver nitrate ointment. **Group 2:** The wound cavity was filled with black foam dressing and an air-tight adhesive dressing was applied and connected to a unit providing continuous negative pressure of 125 mmHg to avoid skin irritation.

NPWT machine used: We used 3 devices. The machine was formed of 2 main components (i) Suction machine: It was low flow low suction machine with adjustable pressure and barometer to adjust the pressure needed for the dressing. (ii) Electrical timer: It was connected to the power supply of the suction machine to adjust the switch on and off of the VAC. The machine had been adjusted to be switched on for 5 minutes and switched off for 3 minutes. Continuous suction machine without using of the timer was used in case of dressings sealed with difficulty due to presence of site of leakage or large wounds with heavy exudate.

The dressing: (i) The sponge: Sponge selection was based on many factors, e.g. appropriate bore size, sponge intensity, and sponge thickness. So, 2 types were selected: the 1st type with thickness of 4 cm which we used for deep wounds and wounds with heavy exudate, while the 2nd type with thickness of 2 cm was used for all other wounds. (ii) The incifilm. (iii) The connecting tube: Ryle can be used as suction tube either within the sponge or over the sponge, and then connected to the suction machine.

Dressing application: (i) Cutting the foam dressing to dimensions that allowed the foam to be placed gently into the wound without overlapping onto intact skin. Cutting the foam was done away from the wound to prevent small pieces to fall into or be left in the wound upon dressing removal. (ii) Cutting the sheet or the incifilm to cover the foam dressing, and an additional 3-5 cm border of intact with the surrounding skin. Sometimes, we cut the sheet into multiple small pieces for easier handling, if a leak source was identified, patch with additional piece to ensure complete sealing. We used excess sheet to seal difficult areas, if needed. Patients of the study were followed up every 2 weeks for 3 months.

Statistical analysis:

Results of the present study were statistically analyzed using SPSS 25 (IBM, USA). Data were represented as mean + standard deviation (SD) or number and percentage. Numerical data

were compared using independent t-test while categorical data were compared using Fisher exact test or Chi-square test as appropriate. ROC curve was used to evaluate the performance of different tests differentiate between certain groups. The level of significance was taken at P value < 0.050.

RESULTS

The age of group A patients ranged between 16-38 years with a mean age of 26.84 ± 5.4 years, while the age of group B patients ranged between 21-44 years with a mean age of 32.44 ± 6.8 years and the statistical analysis revealed a non-significant difference between both groups of the study (P = 0.074).Twenty-two patients in group A were males (22/25, 88%), and 3 of them were females (3/25, 12%) with a male to female ratio of 7.3:1, while in group B 23 patients (23/25, 92%) were males, and (2/25, 8%) were females with a male to female ratio of 11.5:1 and the statistical analysis revealed a male predominance in both groups (P = 0.01 and 0.01 respectively) with a non-significant difference between both groups regarding sex (P = 0.869 and 0.753 respectively **(Table 1)**.

Table(1): Age and Sex distribution in cases of the studied groups

Age	**Group A**		**Group B**		**P**
Range Mean±S.D	16-38 26.84±5.4		21-44 32.44±6.8		0.074
Sex	**Male**		**Female**		**P**
	No.	**%**	**No.**	**%**	
Group A Group B	22 23	88% 92%	3 2	12% 8%	0.01
P	**0.869**		**0.753**		

The operative time in group A ranged between 20-40 min with a mean time of 29.4±5.7 min while in group B patients it ranged between 30-50 min with a mean of 40.28±6.03 min and the statistical analysis revealed a significant increase in the operative time of group B than in group A of the study (P = 0.001) **(Table 2)**.

Table (2): Operative time in cases of the studied groups

Operative time	Group A (N=25)	Group B (N=25)	P
Range Mean±S.D	20-40 29.4±5.7	30-50 40.28±6.03	0.001

Three cases (3/25, 15%) of cases of group A had recurrence of the pilonidal disease after the surgical interference, while in group B patients only one case (1/25, 4%) had recurrence of pilonidal disease after surgical interference, and the statistical analysis revealed that there was a not significant increase in the percentage of recurrence in group A than in group B (P>0.05) **(Table 3)**.

Table (3): Post-operative recurrence in cases of the studied groups

Postoperative Recurrence	Yes		No		P
	No.	%	No.	%	
Group A	3	15%	22	88%	0.001
Group B	1	4%	24	96%	
P	0.031		0.683		

The time needed for complete healing in group A patients ranged between 7-10 weeks with a mean period of 8.55±1.02 weeks, while in group B patients it ranged between 5-6 weeks with a mean period of 5.28±0.92 weeks and the statistical analysis revealed a significant reduction in the period needed for complete healing in group B than in group A (P = 0.001) **(Table 4)**.

Table (4): Time for complete healing in cases of the studied groups

Time for complete healing	Group A	Group B	P
Range	7-10	5-6	0.001
Mean±S.D	8.55±1.02	5.28±0.92	

Most of cases (19/25, 76%) of group A passed without infection, while only 6 cases (6/25, 24%) had post-operative infection, and in group B 21 cases (21/25, 84%) passed without infection, while only 4 cases (4/25, 16%) has post-operative infection, and the statistical analysis revealed that there was a not significant increase in the percentage of post-operative infection in group A than in group B (P > 0.05) **(Table 5)**.

Table (5): Distribution of post-operative infection in cases of the studied groups

Postoperative infection rate	Yes		No		P
	No.	%	No.	%	
Group A	6	24%	19	76%	0.001
Group B	4	16%	21	84%	
P	0.021		0.683		

In group A, the frequency of dressing ranged between 29-38 times with a mean of 35.1±3.3 times, while in group B the frequency of dressing ranged between 15-18 times with a mean of 16.5±1.7 times, and the statistical analysis revealed a significant reduction in number of dressing times in group B than in group A (P = 0.001) **(Table 6)**.

Table (6): Frequency of dressing in cases of the studied groups

Frequency of dressing	Group A	Group B	P
Range	29-38	15-18	0.001
Mean±S.D	35.1±3.3	16.5±1.7	

DISCUSSION

In our study, there was no difference between both groups regarding age and gender, but there was a male predominance in each group. *Banasiewicz et al. (2013)* found that there was no difference between both groups regarding gender which was in agreement with our results, but all patients in both groups were males which disagreed with our results as the Egyptian males are almost hairy, while females are mostly house-wives.

Our results revealed a significant elongation in the operative time in vacuum group than in open ordinary method. *Banasiewicz et al. (2013)* found that there was no difference between both groups regarding operative time which disagree with our results. This was because, in our group, the institution of the vacuum assisted closure (VAC) set took some time which increased the operative time in group B.

In our study, the infection of the wound was more common in group A "ordinary open method" than the vacuum group "group B". Also, the recurrence rate after three months follow up of cases was more common in group A than in group B. *Chmielecki et al. (2019)* found that the use of NWPT postoperatively in cases of pilonidal disease decrease the complications rates than standard open surgical method which was in agreement with what we found in our study. *Bianchi et al. (2018)* found that the use of NPWT in pilonidal disease significantly decrease postoperatively complications as seroma and infections than the standard open surgical method which run in line with our results. *Strugala and Martin (2017)* found that the use of VAC therapy in pilonidal disease decrease the infective complications post-operatively than the standard open surgical method which runs in line with our results. *López et al. (2020)* found that open surgical procedure for pilonidal disease significantly complicated by infection of surgical site, and a recurrence rate of about 10% which was in agreement with our study.

In our study, the time needed for complete healing in group B was shorter than in group A. *Banasiewicz et al. (2013)* found that the postoperative time needed for complete healing was shorter in VAC therapy which run in lines with our results. *Biter et al. (2014)* found that there was no difference between VAC group and standard open method regarding the time for complete healing which disagrees with our results but they found significant reduction in the wound size in the first two postoperative weeks which run in line with our results. *Danne et al. (2017)* concluded that the use of VAC- or NPWT-therapy is improving the healing process especially in the first two postoperative weeks and reduced recurrence rates are reported comparing the method to standard laying open procedures which run in lines with our study.

Our study revealed that there was a significant decrease in frequency of dressing, a significant patient satisfaction as well as early regain of normal daily activity in group B than in group A. *Banasiewicz et al. (2013)* found that the use of VAC dressing leads to speed the granulation process in the wound and reducing the inflammation-related edema, results in resolution of pain, leading to

improved functional comfort of patients and obviously facilitates restoration of complete activity which run in lines with our results. *Hussain et al. (2018)* found that patients who are given a portable NPWT device need to be visited up to every 48 hours by trained medical staff. This is mainly for dressing changes, but also to check that their device usage is appropriate that was in agreement with our results.

CONCLUSION

The use of VAC therapy in cases of pilonidal disease has its advantageous effect in decreasing complications and accelerating healing.

Conflict of interest: The authors declare no conflict of interest.

Funding sources: The authors have no funding to report.

Acknowledgement: The authors are grateful for the patients without whom this study would not have been done.

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دراسة مقارنة بين الاستئصال المفتوح بمساعدة الفراغ (الڤاك) والاستئصال المفتوح فقط فى علاج الناسور العصعصى المعقد

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خلفية البحث: يعد الناسور العصعصى نوعا من إلتهابات الجلد التى تحدث غالباً بين فلقتى المقعدة من الناحية العليا، ويحدث غالباً فى صغار البالغين مابين 15-30 عاماً. ويعالج الجرح الجراحى الناتج عن العلاج الجراحى إما بالالتآم الأولى أو الثانوى أو الإصلاح عن طريق تحويلات الجلد.

الهدف من البحث: تقييم دور الضغط السلبى "الشفط" في علاج الناسور العصعصى مقارنة مع الطريقة التقليدية في علاج الناسور العصعصى بعد الإستئصال الجراحى.

المرضي وطرق البحث: تمت هذه الدراسة على خمسين من المرضى الذين يعانون من الناسور العصعصى في مستشفيات جامعة الأزهر في الفترة مابين يناير 2019م إلى ديسمبر 2019م. تم تقسيم المرضى إلى مجموعتين الأولى تم لها استئصال الناسور العصعصى بالطريقة التقليدية مع الغيارات التقليدية بعد الجراحة حتى التآم الجرح، بينما المجموعة الثانية تم لها استئصال الناسور جراحياً مع وضع جهاز لشفط الإفرازات من مكان الجراحة حتى يتم تكوين النسيج النامى وبعدها يتم للمرضى الغيارات التقليدية.

نتائج البحث: أظهر البحث عدم وجود فارق إحصائى بين المجموعتين بمقارنة العمر والجنس، بينما وجد الذكور أكثر إصابة في المجموعتين. كما أظهر البحث زيادة فى مدة العملية الجراحية في المجموعة الثانية، و فى معدل الإلتهابات الجراحية بعد العملية، وكذلك زيادة معدل الإرتجاع الجراحى فى المجموعة الأولى عنها في المجموعة الثانية. كذلك أظهر

البحث نقص في المدة المطلوبة لإكتمال إلتآم الجرح بعد الجراحة مع تقليل معدل الغيارات الجراحية وزيادة في تقبل المرضى للطريقة العلاجية، إضافة إلى سرعة عودة المرضى للنشاط العادى بعد الجراحة في المجموعة الثانية عنها في المجموعة الأولى.

الإستنتاج: إستخدام الضغط السلبى "الشفط" بعد الجراحة في حالات الناسور العصعصى يحمل الفائدة فى تقليل المضاعفات وتسريع الإلتآم للجرح الجراحى، لهذا فإننا نوصى باستخدام هذه الطريقة كطريقة مميزة فى العلاج الجراحى لهذه الحالات لتقليل المضاعفات والإسراع فى إلتآم الجرح الجراحى.