

## PORTABLE VAC THERAPY IMPROVE THE RESULTS OF THE TREATMENT OF THE PILONIDAL SINUS – RANDOMIZED PROSPECTIVE STUDY

TOMASZ BANASIEWICZ, ADAM BOBKIEWICZ, MACIEJ BOREJSZA-WYSOCKI,  
MACIEJ BICZYSKO, ANDRZEJ RATAJCZAK, STANISŁAW MALINGER, MICHAŁ DREWS

Department of General Surgery, Oncological Gastroenterology, and Plastic Surgery,  
Medical University in Poznań  
Kierownik: prof. dr hab. *M. Drews*

Multiple therapeutic approaches of the treatment of pilonidal sinuses have been described in the literature, but there are still controversies and lack of standardization. Vacuum Assisted Closure (VAC) therapy has potential beneficial effect on the wound healing after the sinus resection.

**The aim of the study** was to analyze the results of VAC therapy in the treatment of pilonidal sinuses.

**Material and methods.** After randomization in the control group (9 men) the simple excision of the pilonidal cyst was performed with the standard wound dressing. In the VAC group (10 men) the same surgical procedure was performed, but after the excision the VAC dressing with mobile VAC Freedom device was used. Both groups were treated in an outpatient setting under local anesthesia. The wound size, time of surgery, time of wound healing time of recovery and pain after the surgery (VAS score) were compared.

**Results.** In VAC treated group the wound size and time of surgery were similar to control group. Time of wound healing, recovery and the pain after surgery in days 4-7 were reduced in comparison to the standard treated group.

**Conclusions.** VAC therapy can be easily used in an outpatient setting, mobile device is highly accepted, operation of the equipment is simple. VAC therapy significantly decreases the time of wound healing and absenteeism from work as well as the postoperative late pain.

**Key words:** pilonidal sinuses, vacuum assisted therapy, VAC

Pilonidal sinus (also referred to as a pilonidal cyst, pilonidal abscess or sacrococcygeal fistula) is a chronic inflammatory skin and subcutaneous tissue condition on the natal cleft of the buttocks, in the sacrococcygeal region (1). It is most common in young subjects, aging 20-30 years, in particular in men with dark complexion and highly developed body hair, in particular in the natal cleft. Surgical techniques used in its treatment are highly variable, from simple excision of the pilonidal sinus with its primary closure or leaving the wound to heal (2), various types of excision with a Limberg transposition flap (3, 4), fasciocutaneous V-Y advancement flap

(5) or an excision with Z-plasty (6). The pilonidal sinus under local anesthesia and leaving the wound for granulation to occur is a technique that is used and accepted in an outpatient treatment, however is accompanied by prolonged pain and limitation of activity after the procedure. Excision of the pilonidal sinus under the local anesthesia is one of commonly used and accepted methods of surgical treatment (7). One of the surgical procedures used in an outpatient practice is excision of the pilonidal sinus and leaving the wound for granulation to occur (8); this method has comparable efficacy to methods involving primary wound suturing.

Literature reports sporadic cases of using Vacuum Assisted Closure therapy in the treatment of the pilonidal sinus (9), however typically these are case reports of observational nature (10). The authors browsed literature reviews and metaanalyses, but did not find any prospective, randomized study using Vacuum Assisted Closure therapy.

Use of Vacuum Assisted Closure therapy for the treatment of chronic wounds facilitated the granulation and healing process and reduces septic complications in the wound (11). Miniaturization of equipment for such therapy, with preservation of all its benefits and abilities, allows for their use in an outpatient setting (12). Growing offer of such equipment with their further miniaturization and reduction of costs should result in their widespread use in outpatient settings.

## MATERIAL AND METHODS

The study was conducted in 2012. The study was approved by Bioethics Committee at K. Marcinkowski University of Medical Sciences in Poznań (approval no. 182/12).

### The study group

Patients with the pilonidal sinus, treated at the Outpatient Department of Proctology and Surgery, Department of General Surgery, Surgery of Gastrointestinal Oncology and Plastic Surgery, K. Marcinkowski University of Medical Sciences in Poznań, were eligible to participate in the study. The pilonidal sinus in patients qualified for the surgical procedure was asymptomatic or produced only minimal symptoms at the time of the procedure; patients with an active inflammation (abscess) did not undergo surgical treatment. The study subjects were randomly assigned to group 1 with local excision of the pilonidal sinus and standard dressing or to group 2 with local excision of the pilonidal sinus and VAC dressing, using a portable equipment VAC FREEDOM (VAC Freedom System; Kinetic Concepts Incorporated, San Antonio, TX). The first group was composed of 9 men (average age 23.3 years), the second group was composed of 10 men (average age 24.4 years).

### Procedure description

In both study groups patients before the procedure took one oral dose of an antibiotic 1.5-2 hours before the procedure. The procedure was performed in supine patients, the buttocks were separated and stabilized with an adhesive tape to the operating table. The precoccygeal area was shaved with a large margin and disinfected using iodine solution. Subsequently one of the orifices of the cyst was anesthetized locally using 2% lignocaine. Following administration of methylene blue, a canal and another orifice/s of the pilonidal sinus were located in the natal cleft or in this area. The extent of excision was marked and local anesthesia with 2% lignocaine was continued, however the total volume of 15 ml 2% lignocaine was not exceeded. Subsequently tissues affected by inflammation were excised along with the fistula canal, maintaining 1-2 cm tissue margins around the orifices affected by inflammation and 0.5-1 cm margin around the canal. Careful hemostasis was done using bipolar coagulation. The wound was washed with Octanisept solution. Then it was covered with a conventional absorbing dressing that was secured to the buttock skin with an adhesive tape in the group 1. KCl Vacuum Assisted Closure dressing was placed in the group 2. The sponge was cut to the size of the wound and then placed on the wound. If the wound margin was close to the sponge margin, it was covered with a small amount of stoma paste (Stomahesive) from the side of the rectum to improve leak proof properties of the dressing. Subsequently a foil was applied and close attention was paid to its anatomical adjustment (a hole for the anus, round inferior margin). A support for the suction drain was fixed to such foil and was connected to VAC Freedom with a disposable 300 ml container. The equipment was set to 3-8 minutes of suction (pressure range 100-130 mm Hg), 1-3 minutes of suction free interval. Parameters of operation were adjusted individually in the above mentioned ranges, depending on the size of the wound, bleeding, distance from the anus. After approximately 45-90 minutes of observation the patients were discharged home (assessment of tightness of the dressing, assessment of bleeding). The patients were informed of possible use of analgesics (Ketonal 2 x 100 mg orally) and of the date of a follow-up visit on the next day.

The dressing was changed during the follow-up visit in the group 1. In the group 2, the dressing was changed only if the foil detached and the dressing lost its tightness (1 case). Dates of subsequent visits were scheduled individually, depending on the assessment of wound healing/nature and amount of the discharge in the VAC Freedom container. The patients attended follow-up visits until their wounds were healed to the degree that made possible restoration of normal activity.

Analyzed parameters

Before the procedure, the nature of the pilonidal sinus was assessed (primary/recurrent) and duration of complaints before the procedure.

During the procedure, size of the excised lesion as well as the duration of the procedure was assessed. Duration of the procedure was counted since the start of the first incision until the placement of the dressing (conventional in the group 1 and Vacuum Assisted Closure dressing in the group 2).

After the procedure the following parameters were assessed: number of days the patient was under care of the Outpatient Department (time from excision to the last follow-up visit), number of days from the excision to restoration of daily activity (education, work), average pain on VAS scale on day 1 after the procedure, average pain on VAS scale on day 3 after the procedure, average pain on VAS scale on day 4 after the procedure, average pain on VAS scale on day 7 after the procedure, total number of visits at the Outpatient Department since the excision until the completion of treatment.

RESULTS

Groups 1 and 2 were homogeneous with regard to sex (males). No significant differences were found with regard to the nature of the pilonidal sinus (presence of recurrent cysts), duration of complaints before the procedure, size of the wound (maximum longitudinal and transverse diameter) and average duration of the procedure. Detailed information on the analyzed parameters in both study groups are provided in tab. 1.

Assessment of postoperative parameters revealed that duration of treatment, i.e. time when a patient was under care of the Outpatient Department, was significantly longer in the group 1 and was on average 30.3 days, while duration of treatment for patients in the group 2 (VAC therapy) was 11.8 days. Furthermore, the number of visits at the Outpatient Department was also significantly higher in patients receiving conventional therapy (on average 8.5) versus patients treated with VAC therapy (on average 4.9). Restoration to daily activity was significantly faster in the group 2 (VAC therapy) and was on average 7.3 days versus on average 15.9 days in the group 1 (conventional dressing). Pain on day one and day three after the procedure was similar in both study groups (no statistically significant differences were found). On day 4 and 7 a significant reduction of pain was found in the group 2 and the difference versus the group 1 was statistically significant. Detailed data on the assessed parameters in both study groups can be found in tab. 2.

DISCUSSION

It is difficult to compare various treatment methods of the pilonidal sinus due to high

Table 1. Clinical information on the study groups and performer procedures

Assessed feature	Excision and dressing	Excision and dressing VAC	Statistical significance
Age (years)	23,3 ± 4,4	24,4 ± 4,7	ns
Group size (including recurrent cysts)	9 (2)	10 (2)	ns
Average duration of complaints before the procedure (months)	9 ± 6,8	8,2 ± 7,6	0,593988
Average size of the wound (cm, maximum longitudinal diameter)	6,61 ± 4,3	6,55 ± 3,9	0,897574
Average size of the wound (cm, maximum transverse diameter)	4,1 ± 1,2	3,9 ± 0,9	0,890350
Average duration of the procedure (minutes)	13,1 ± 7,2	16,4 ± 8,9	0,382573

Table 2. Comparison of treatment outcomes depending on the method of wound dressing

Assessed feature	Excision and dressing	Excision and dressing VAC	Statistical significance
Time of being under care of the Outpatient Department (time from the excision to the last follow-up visit)	30,3 ± 8,3	11,8 ± 4,7	0,000013
Time from the excision to restoration of normal activity	15,9 ± 6,5	7,3 ± 3,6	0,002073
Average pain on VAS scale (day 1)	1,2 ± 0,7	1,4 ± 0,9	0,662283
Average pain on VAS scale (day 3)	2,1 ± 0,6	1,5 ± 0,8	0,098165
Average pain on VAS scale (day 4)	2,3 ± 0,7	1,1 ± 0,7	0,004747
Average pain on VAS scale (day 7)	2 ± 0,7	0,9 ± 0,7	0,000143
Total number of visits at the Outpatient Department between the excision and completion of the treatment	8,5 ± 2,2	4,9 ± 0,7	0,000875

variability of the pilonidal sinuses with regard to their size, location, number and location of orifices, complexion and hair type in a patient, previous treatment by an abscess incision or attempts to excise the cyst, co-occurrence of other diseases and multiple other factors. Attempts have been undertaken to classify the cysts depending on their size and other clinical parameters (13), however such scales are not commonly used in the routine clinical practice.

Furthermore, assessment of treatment results and comparison of effectiveness of various therapeutic methods is problematic due to lack of clear, objective criteria. Assessment of the pilonidal sinus before the surgical treatment used in this study and assessment of treatment results were based on simple, evaluable parameters, such as size of the wound following excision of the cyst, duration of the wound healing, number of days until restoration of normal activity or assessment of intensity of pain. Similar methods have been adopted in other publications analyzing effects of treatment of the pilonidal sinuses (7, 13).

Results obtained in this study indicate that the two study groups were identical with regard to sex distribution and similar with regard to age, duration of complaints, recurrent cyst rate. Extent of the procedure, expressed as size of the wound in the longitudinal and transverse diameter, was also similar in both groups. The procedure duration was slightly longer in the VAC therapy group, however this difference did not reach statistical significance. Main differences were found for the duration of wound healing: duration of being under care of the Outpatient Department was twofold shorter in patients from the VAC therapy group versus the conventional therapy group. The difference in time to restoration of normal activity was similarly large. This time was twofold higher in patients receiving conventional therapy. Duration of the wound healing after excision of the pilonidal sinus and time to restoration of normal activity in patients receiving conventional dressing were similar to that reported by other authors (13), however these parameters were markedly lower in the group of patients from the VAC therapy group.



Fig. 1. Wound two days after the excision of the pilonidal sinus in a patient treated with the VAC therapy. Clean wound margins, no bleeding, granulation



Fig. 2. The VAC dressing on the wound after the excision of the pilonidal sinus, a suction drain directed laterally

When assessing postprocedural pain, one must take into consideration that the intensity of pain was relatively mild in both study groups. It was similar in both study groups during the first 3 days after the procedure. Starting from day four after the procedure, these complaints were significantly reduced in patients treated with VAC therapy, but did not change significantly in patients treated with conventional dressings, similarly as on day seven. This finding may suggest that immediately after the procedure pain is related to the excision itself, while type of the dressing has negligible effect on its intensity. Subsequently, the VAC dressing, by speeding 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. It is commonly accepted that the VAC therapy not only beneficially affects the wound healing process and shortens the duration of treatment (14), but also has beneficial effect on the quality of life of patients, in particular with poorly healing, chronic wounds (15). In the group of patients treated with the VAC therapy, patients accepted the VAC therapy, considered it only as a minor burden and inconvenience. Obviously portability of the device, its small size and mass, the fact that it was very simple to operate (periodic battery charging) contributed to this effect. A container attached to the device in all cases was sufficient to collect the wound discharge without the need for its replacement. This device had all options of an advanced Vacuum Assisted Closure system, such as adjustable intensity and duration of vacuum and possibility of intermittent therapy. Similar devices have also been successfully used in the treatment of large traumatic wounds in combat settings (16).

The Vacuum Assisted Closure system, as any other method, also has its limitations. It seems that in the treatment of the pilonidal sinus, it should be used by persons experienced with this type of dressings and their proper application. The main practical problem lies in specific anatomic conditions of the operated

region. Proper functioning of the VAC dressing is determined by adequate, tight application of a self-adhesive foil that is necessary to form vacuum in this area. The natal cleft of the buttocks is a region where application of this foil is rather difficult. First, it should be adequately shaped so that it does not restrict the patient's movements. Furthermore, adequately large area of skin should be shaved before the procedure so that the foil is not placed on the hairy skin; otherwise the patient will experience pronounced pain and discomfort both with movements and with the dressing replacement. The skin should be completely dry and well strained by an assistant during the foil application. A stoma paste can be used in the region of the natal cleft of the buttocks, to improve the tightness of the dressing in this key region. It is also important to maintain adequate distance between the foil and the anus and inform the patient that care needs to be taken with any hygienic maneuvers in the anal region, so that the foil is not detached.

However, it needs to be emphasized that a small leakage of the dressing that was found in some patients during the follow-up visit, did not have a negative effect on the treatment outcome. One of the main advantages of the VAC dressing, stressed by the patients, is lack of discharge in the buttock and perineal region. Conventional dressings were characterized by accumulation of discharge, unpleasant moisture, leaching through the clothes or irritating the skin around the wound. The VAC dressing, draining the discharge in a leak proof system, provided the patients with greater comfort. Similar findings were reported by other authors who used the VAC therapy in the treatment of the pilonidal sinus, in adults (17) as well as in children (18).

We believe that the VAC therapy using portable devices is an effective form of treatment of the pilonidal sinus and accepted by patients that can be used in an outpatient setting. It reduces the wound healing time and facilitates restoration of complete activity and more rapid resolution of pain. It can be of particular value for professionally active patients.

## REFERENCES

1. Goodall P: The aetiology and treatment of pilonidal sinus. A review of 163 patients. *Br J Surg* 1961; 49: 212-18.
2. Gencosmanoglu R, Inceoglu R: Modified lay-open (incision, curettage, partial lateral wall excision and marsupialization) versus total excision with primary closure in the treatment of chronic sacrococcygeal pilonidal sinus: a prospective, randomized clinical trial with a complete two-year follow-up. *Int J Colorectal Dis* 2005; 2: 415-22.
3. Eryilmaz R, Sahin M, Alimoglu O, Dasiran F: Surgical treatment of sacrococcygeal pilonidal sinus with the Limberg transposition flap. *Surgery* 2003; 134: 745-49.
4. Cihan A, Ucan BH, Comert M et al.: Superiority of asymmetric modified Limberg flap for surgical treatment of pilonidal disease. *Dis Colon Rectum* 2006; 49: 244-49.
5. Schoeller T, Wechselberger G, Otto A, Papp C: Definite surgical treatment of complicated recurrent pilonidal disease with a modified fasciocutaneous V-Y advancement flap. *Surgery* 1997; 121: 258-63.
6. Lamke LO, Larsson J, Nylen B: Treatment of pilonidal sinus by radical excision and reconstruction by rotation flap surgery of Z-plasty technique. *Scand J Plast Reconstr Surg* 1979; 13: 351-53.
7. Maghsoudi H, Nezami N, Ghamari AA: Ambulatory treatment of chronic pilonidal sinuses with lateral incision and primary suture. *Can J Surg* 2011; 54(2): 78-82.
8. McCallum IJ, King PM, Bruce J: Healing by primary closure versus open healing after surgery for pilonidal sinus: systematic review and meta-analysis. *BMJ* 2008 19; 336(7649): 868-71. Epub 2008 Apr 7.
9. Bendewald FP, Cima RR, Metcalf DR, Hassan I: Using negative pressure wound therapy following surgery for complex pilonidal disease: a case series. *Ostomy Wound Manage.* 2007; 53(5): 40-46.
10. Lynch JB, Laing AJ, Regan PJ: Vacuum-assisted closure therapy: a new treatment option for recurrent pilonidal sinus disease. Report of three cases. *Dis Colon Rectum* 2004; 47(6): 929-32. Epub 2004 May 4.
11. Banasiewicz T, Borejsza-Wysocki M, Meissner W et al.: Vacuum-assisted closure therapy in patients with large postoperative wounds complicated by multiple fistulas. *Wideochir Inne Tech Malo Inwazyjne* 2011; 6(3): 155-63.
12. Fraccalvieri M, Sarno A, Gasperini S et al.: Can 'single use negative pressure wound therapy' be an alternative method to manage keloid scarring? A preliminary report of a clinical and ultrasound/colour-power-doppler study. *Int Wound J* 2012. doi: 10.1111/j.1742-481X.2012.00988.x.
13. Awad MMS, Amr Abd Elbaset, Samir Ebraheem et al.: A scoring system as a method to evaluate pilonidal sinus disease to make an easy decision for its management. *Indian J Plast Surg* 2009; 42(1): 43-48.
14. Chiummariello S, Guarro G, Pica A, Alfano C: Evaluation of negative pressure vacuum-assisted system in acute and chronic wounds closure: our experience. *G Chir* 2012; 33(10): 358-62.
15. Karatepe O, Eken I, Acet E et al.: Vacuum assisted closure improves the quality of life in patients with diabetic foot. *Acta Chir Belg* 2011; 111(5): 298-302.
16. Fang R, Dorlac WC, Flaherty SF et al.: Feasibility of negative pressure wound therapy during intercontinental aeromedical evacuation of combat casualties. *J Trauma* 2010 Jul; 69 Suppl 1:S140-5. doi: 10.1097/TA.0b013e3181e452a2.
17. Moreau I, Ripoche S: Pilonidal sinus and Vac Therapy. *Soins* 2008; (728): 27-30.
18. Bütter A, Emran M, Al-Jazaeri A, Ouimet A: Vacuum-assisted closure for wound management in the pediatric population. *J Pediatr Surg* 2006; 41(5): 940-42.

Received: 28.03.2013 r.

Adress correspondence: 60-355 Poznań, ul. Przybyszewskiego 49

e-mail: tbanasiewicz@op.pl