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ORIGINAL ARTICLE

Effectiveness of a drain in surgical treatment of sacrococcygeal pilonidal disease. Results of a randomized and controlled clinical trial on 803 consecutive patients

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Abstract
Purpose The aim of this study was to evaluate the influence of cavity drainage in the surgical treatment of sacrococcygeal pilonidal sinuses.
Methods The study was prospectively carried out in 803 patients randomized into two groups of respectively 401 and 402 patients. In the first group, primary excision and closure were associated with drainage of the wound; in the second group, the wound was not drained. We have analyzed time off work, time to walk without pain, time to sitting on the toilet without pain, recurrences, and wound infections. We have also evaluated the satisfaction rate and esthetic results.
Results On comparing time off work, time to walk without pain, and time to sitting on toilet without pain postoperatively, there were no significant differences between the two groups. A significant difference between the two groups with regard to wound infection rates ($p=0.5$) and recurrence rates ($p=0.6$) was not observed. In order to prevent prolonged inpatient stay and social intolerance, this study suggests that the post-operative period is tolerated by a few when a drain was used. The visual analog scale (VAS) in the drained group was 3.2±0.9, and VAS in the non-drained group was 3.5±0.9 with a significant statistical difference ($p=0.0001$). As regards the cosmetic appearance of the scar after surgery, we achieved a high satisfaction rate among patients in either group with 82.9% good cosmetic results.
Conclusions The use of a drain, in our experience, appears to be useless in achieving a quick healing of the sacral wound; in addition, it has a low satisfaction rate.

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Introduction

Sacrococcygeal pilonidal disease is a common and well-recognized entity. In 1833, Herbert Mayo described a hair-containing sinus, but not until 1880 did Hodge suggest the term "pilonidal" [1] (Latin: pilus=hair and nidus=nest) to indicate a disease consisting of a hair-containing sinus in the sacrococcygeal area [2]. Pilonidal disease is a chronic intermittent disorder of the sacrococcygeal region that most commonly arises in the hair follicles of the natal cleft, affecting predominantly young adults of working age [3]. Many factors were implicated in the etiology such as large buttocks with a deep natal cleft, family history, prolonged sitting, traveling or driving, excessive body hair, folliculitis at another site, obesity, and poor local hygiene [4]. Evidence suggests that one or more of the following are required for pilonidal sinus formation: tough semi-curved hairs, the deep natal cleft [5], the rolling effect of one buttock surface over the other [6], and the vulnerability of the skin to the insertion of hair at the depth of the natal cleft aided by the stretching forces that occurs during sitting [5–7].

Pilonidal sinus is still a troublesome disease entity because of the high morbidity of most treatment options [8]. Although many surgical methods have been proposed, no clear consensus as to optimal treatment has been reported so far in the literature. Despite controversy about the best surgical technique for the treatment of pilonidal sinus, an ideal operation should be simple, without the need of prolonged hospital stay, with a minimal patient inconvenience, with a low recurrence rate, and with minimal pain and wound care to decrease time off work [9–15].

We have analyzed the clinical outcome of all patients treated with excision and primary closure of a sacral wound for sacrococcygeal pilonidal sinus, in order to evaluate the effectiveness of wound drainage.

Patients and methods

Patients with primary and recurrent diseases were included in the study, except for those who were recurrent after a previous flap surgery. If signs of inflammation in the surrounding tissues were detected, antibiotic treatment was given, and the excision was undertaken 2 or 3 weeks later when the inflammatory process was controlled.

Before surgery, the patients were randomized into two groups according to the admission protocol number. In the first group, primary excision and closure were associated with drainage of the wound; in the second group, the wound was not drained. Informed consent was obtained from all patients. Important changes to the methods after trial commencement were not made.

The surgeries were performed under local anesthesia with 30 to 60 ml of mepivacaine (Carbosen, 20 mg/ml; Galenica Senese). Supplementary intravenous sedation, 1% propofol (Propofol Kabi, 10 mg/ml; Fresenius Kabi), was given if required.

The patient was placed in the prone position with the hips slightly flexed. The buttocks were retracted with adhesive tape. The sacral area was shaved and disinfected with povidone–iodine. The sinuses were injected with a few milliliters of methylene blue in order to stain all of the sinuses and their branches. A significant reduction in the recurrence rate can be achieved with a single careful injection of the dye into the sinus at the start of the operation [16]. We have performed a limited excision including all the marked tissues. An elliptical excision was marked around the sinuses with its long axis midline oriented. The skin incision was deepened down to the presacral fascia with diathermy, but the fascia was not included in the excision. Hemostasis was carefully achieved with electrocauterization. If the patient was in the drained group, a closed suction drain Jackson Pratt type (Becthon Divisione Medica Srl) was put in place before the wound was closed and extended through the contralateral flap skin. In the non-drained group, sutures are meticulously applied to close the bottom of the operative cavity and to ensure the absence of a dead space between the bottom of the cavity and the subcutaneous layer. A series of strong resorbable deep sutures (Polyglactin 910) were passed at intervals of 1 in. and at about halfway between the skin and the presacral fascia. Each deep suture was passed through the midline of the presacral fascia (Fig. 1). Post-operative management included pressure dressings. Oral intake was allowed 2 h postoperatively, and patients were encouraged to walk after 8 h. Closed suction drains were removed when the 24-h suction output was less than 10 ml but not earlier than 2 days after surgery. Instructions on discharge included avoidance of prolonged sitting and riding bicycles or scooters until 6 weeks postoperatively to prevent wound disruption and improve local hygiene, and regular removal of hairs by shaving or depilatory cream were given to patients. The patients were examined during follow-up with a standard physical examination after 1 week, 1 month, and every 3 months thereafter for 1 year, and we have excluded the patients lost during the follow-up.

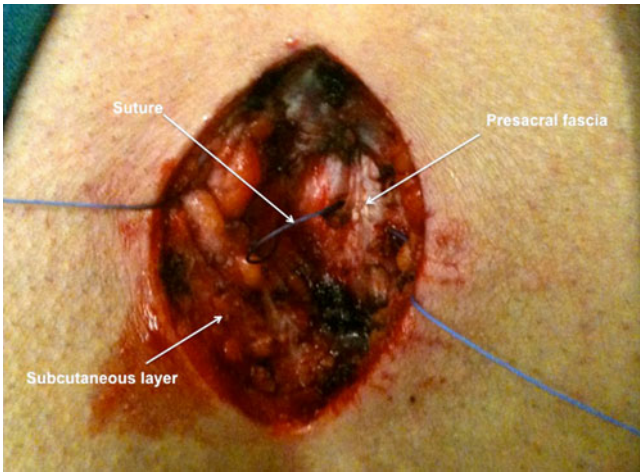

Fig. 1 Suture technique. The suture is passed through the subcutaneous layer and the presacral fascia to ensure the absence of a dead space between the bottom of the cavity and subcutaneous layer

In this study, we analyzed hospital stay, time off work, time to walk without pain, time to sitting on the toilet without pain, recurrences, and wound infections. Wound infection was defined as redness and/or edema of the skin and/or discharge.

Patients were asked to complete a 5-cm long Visual Analog Scale (VAS) for their health status 1 month after surgery, which ranged from 0 for "very bad" to 5 cm for "very good." The scale was constructed with numeration, thus allowing patients to mark a point along the scale that best represented their health status at that time.

In this study, the esthetic satisfaction rate of the patients were assessed after a period of 6 months by questioning the patient to give a grade for his operation as regards the scar and the shape of the buttocks on a scale of good, fair, or bad.

Statistical analysis was performed with SPSS. The Yates-corrected chi-square test was used as a means of evaluating differences in categorical variables, and the Mann–Whitney *U* test was used for continuous variables. Statistical significance was accepted when the p value was less than 0.05.

Results

The study was carried out in 803 consecutive patients who underwent surgery for sacrococcygeal pilonidal sinus at our institution between January 1998 and December 2009 and had at least 1 year of follow-up (average follow-up of 1.3 years); 51 patients were excluded because we have lost them at follow-up.

Wounds were drained in 401 patients, whereas in 402 patients, wounds were not drained. There were no significant demographic and clinical differences between the two groups (Table 1).

Excision procedures for sacrococcygeal pilonidal disease can be performed under local anesthesia with acceptable results, without requiring regional or general anesthesia. No complication from the anesthetics was observed.

The median surgical time was of 28.7±3.6 min in both groups, whereas a significant difference was found between the two groups in terms of hospital stay. In fact, the patients receiving wound drainage reported a more protracted hospital stay of 2–3 days, whereas the patients receiving no wound drainage were monitored for a short time (4–6 h) before returning home. Only 17 patients (4.2%) of the non-drained group required a prolonged hospital stay of 24 h for pain. The median time before drainage removal was 2.5± 0.4 days.

On comparing time off work, time to walk without pain, and time to sitting on the toilet without pain postoperatively, there were no significant differences between the two groups (Table 2).

A significant difference between the drained group and the non-drained group with regard to wound infection rates (p=0.5) and recurrence rates (p=0.6) was not observed. The infection and disruption of sacral wounds was observed on immediate follow-up (until 1 month after surgery) in 39 patients (9.7%) of the drained group and in 44 patients (10.9%) of the non-drained group. Thirty eight (9.4%) patients in the drained group and 43 (10.6%) patients in the non-drained group developed recurrences (Fig. 2). No further problems or symptoms were registered in either group.

In order to prevent prolonged inpatient stay and social intolerance, this study suggests that the post-operative period is tolerated by a few when a drain was used. VAS in the drained group was 3.2±0.9, and VAS in the non-drained group was 3.5±0.9 with significant statistical differences (p=0.0001). In fact, 207 patients (51.4%) in the non-drained group referred that this period was good or very good (VAS 4–5) versus only 160 patients (31.4%) of the drained group (Fig. 3). No patient referred that this period was very bad (VAS 1).

After all, as regards the cosmetic appearance of the scar after surgery, in this study, we achieved a high satisfaction rate among our patients in either group with 82.9% (666 patients) with good cosmetic results and only 11% (89 patients) with bad cosmetic results.

Table 1 Study design

	Drained group	Non-drained group	Statistical significance
Sex			
Men	271 (67.5%)	254 (63.1%)	p=0,17
Women	130 (32.4%)	148 (36.8%)	
Mean age	26	24	p=0,80
Risk factor			
Obesity	37 (9.2%)	44 (10.9%)	p=0,40
Smoking	95 (23.6%)	81 (20.1%)	p=0,24
Sinus complexity			
Presence of lateral tracks	93 (23.1%)	102 (25.3%)	p=0,44
Recurrent disease	43 (10.7%)	51 (12.6%)	p=0.65

Discussion

Despite surgical therapy dating from more than a century ago, optimal management remains controversial, and recent reports have suggested different surgical approaches [17, 18]. There is a general agreement, however, that pilonidal disease with acute abscess formation should be treated by incision and drainage. For chronic and recurrent sinuses, analyzed in our study, various techniques have been reported, and no one method is universally acceptable. Allen-Mersh did an extensive review in 1990 of over 90 papers dealing with the treatment of pilonidal sinus [2, 11]. He concluded that "virtually without exception these studies are flawed because of one or more defects in study design…" [2, 11]. The choice of a particular surgical approach is dependent on the surgeon's familiarity with the procedure and perceived results in terms of low recurrence of the sinus and of quick healing of the resulting cavity or surgical wound.

From the profusion of studies, it is apparent that various methods are being tried, and not one method is universally acceptable [2]. Although many surgical and nonsurgical treatment methods have been described, the ideal treatment method has not yet been established. Complete excision of the sinus is widely practiced, but it remains controversial what to do with the wound after excision [10, 19].

Surgical methods can be broadly categorized as wounds left to heal by open healing or by primary closure, which is further subdivided into midline and off-midline closure techniques where the wound is placed outside the midline [3, 7].

Table 2 Results

	Drained group	Non-drained group	Statistical significance
Time off work (days)	21.3±9.1	21.5±9.0	p=0.6
Time to walk (days)	10.3±4.4	9.8±3.8	p=0.2
Time to sitting on the toilet without pain (days)	11.5±4	12.1±4.5	p=0.1

Compared with open packing and marsupialization, excision and primary closure is known to provide faster healing and faster return to work. Most of the patients return to work in 3 to 4 weeks. [8, 20, 21]. However, a high complication rate has been reported because of tissue tension [8, 22], although some surgeons have reported good results after primary closure [8, 23, 24]. The main problems with the primary closure technique appear to be high recurrence rate and high infection rate [8, 25–27]. Gluteal pulling forces on the wound and its particular location with a closed and humid environment promote infectious complications [15, 28, 29]. In fact, surgical site infection is not unexpected and ranges from 6% to 14% [30–33].

The problems related to a continuing natal cleft after pilonidal sinus surgery have prompted surgeons to discover techniques to eliminate the gluteal furrow. Bascom hypothesized that infection starts in the hair follicles, which have open orifices that initiate the development of infection and sinus. He recommended excision of the midline pits with lateral open drainage of any associated abscess [8, 34]. Karydakis used an asymmetric excision and primary closure to prevent hair penetration into the natal cleft [8, 35, 36]. With this technique, the natal cleft is flattened, and the incisional line and scar are transferred laterally from the midline. To eliminate natal cleft and wound tension, various plastic reconstructive techniques such as Z-plasty, W-plasty, V-Y plasty, and various flap techniques have been used [8, 37]. However, adipo-fasciocutaneous flap, classic Limberg flap, and modified Limberg flap techniques are the most recently favored techniques [8]. The aim of most flaps is to use asymmetrical, oblique, elliptical, or lateral incisions in an attempt to keep scars out of the natal cleft [7, 38], leaving deformed buttocks and visible ugly scars. This denotes the cosmetic superiority of the midline scars and the importance of the buttocks as a major component of the concept of beauty in most cultures [7, 39]. One of the most dramatic developments in health care in the past 10 years has been increasing consensus about the importance of subjective accounts of health in monitoring medical outcomes [10, 40]. Few outcome measures currently available for routine use satisfy the criteria of validity, reliability, and sensitivity to the changes in health status. Two measures that deserve careful consideration are the short form 36 (SF-36) health survey questionnaire [10, 41] and the VAS [10, 42].

The cosmetic aspect and esthetic outcome of pilonidal sinus surgery, which are major goals for most patients, were rarely studied in the literature. One study by Holmebakk and Nesbakken [39] showed poor results after rhomboido-plasty technique due to the conspicuous scar the patient was left with. In this study, not only were women concerned about the cosmetic outcome, but young men were also aware of their look [39]. In another study, 20% of the patients were not pleased with the cosmetic appearance of the scar after rhomboid flap for recurrent pilonidal disease [43]; meanwhile, El-Shaer [7] showed a high satisfaction rate with 78.5% good cosmetic results with midline closure. It is obvious that maintaining a midline scar that is thin, strong, non-tender, and pliable is the most esthetically pleasing. In our study, we achieved a high satisfaction rate among our patients with 82.9% good cosmetic results and only 11% bad cosmetic results.

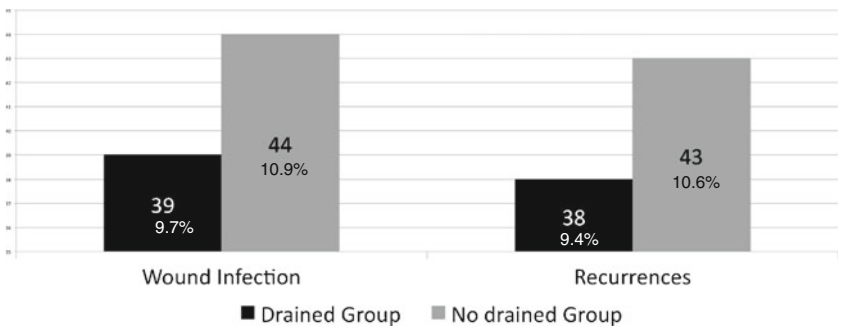

Fig. 2 Recurrences and wound infections

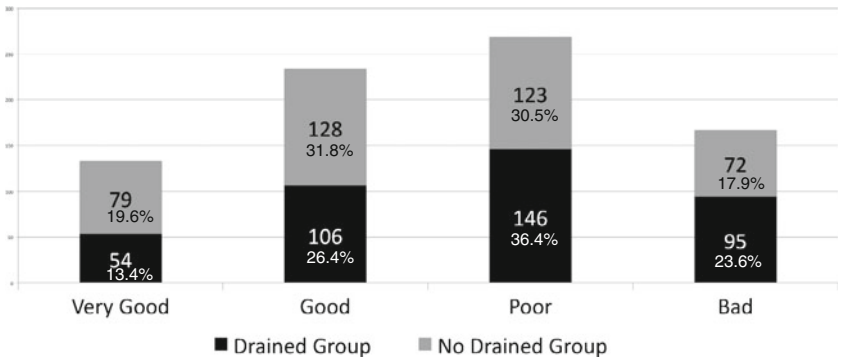

Fig. 3 Satisfaction rate

Limited excision of a pilonidal sinus that is our standard technique represents one of the best therapeutic options. The result of this method is comparable with the more aggressive frequently used excisional method, and it has the advantage of having a shorter convalescence and better patient satisfaction [44]. By this viewpoint, more limited excision—however respectful of desirable radicality—reduces the size of the residual cavity and makes its closure less troublesome [45].

The need for drainage has been questioned in several surgical procedures, including thyroid surgery, orthopedic surgery, colonic surgery, cholecystectomy, and elective hepatic resection. Most surgeons traditionally use drains following surgery in the hope that this will obliterate the dead space and evacuate any collected blood and serum [46–51]. However, some studies have suggested that the placement of drains after routine surgery may induce rather than prevent fluid collection, has no effect on complications, leads to extra scarring, and prolongs the hospital stay. Currently, it is recognized that drains cannot substitute for adequate hemostasis and might not prevent hematoma or seroma and their related complications. Furthermore, some studies in other fields have shown that drains may increase the rate of surgical wound infections, contribute to the discomfort of the patient, prolong the hospital stay, and thereby increase the cost and compromise the cosmetic result.

Closed suction drains are preferred to other types of drainage because they are considered to remove body fluid or liquid from surgical wounds without increasing infection rate. However, other authors say that the placement of drains predisposed the area to infection and prolongs the hospital stay, even with closed drains [47, 52–54].

In this context, only few clinical trials have been performed to ascertain definitively whether the use of drains has a value after flap procedures in the treatment of pilonidal sinus [9, 18, 45, 46, 55, 56]. Erdem et al. and Colak et al. [46, 53] achieved the best results without drainage while Gurer et al., Tocchi et al., Triatapepe et al. and Akinci et al. [9, 45, 55, 56] achieved the best results with drainage. It is so clear that a definitive conclusion cannot be drawn from the current literature.

The theory in favor of drainage says that, even if extremely thorough hemostasis is achieved, the excision of the pilonidal sinus inevitably may lead to the collection of some blood or serum at the bottom of the operative cavity. Therefore, the scrupulous drainage and the antiseptic/saline flushing of the operative cavity ensure that the dead space remains clear and favor the normal healing process and the final scar formation around the suture [56]. Then, early or late breakdown after primary closure should be related to the formation of an infected hematoma in the wound cavity [57].

On the other hand, our theory says that the use of drainage prevents the complete closure of the bottom of the operative cavity. In fact, a dead space remains around the suction drainage, and this space is the cause of the collection of some blood and serum.

This trial shows that the drains failed to prevent complications. Drainage is useless to achieve the best results in performing pilonidal sinus surgery. In fact there is not a statistical difference between the drained and non-drained groups regarding surgical site infections and recurrences (p=0.5 and p=0.6). Moreover, our results regarding the incidence of complications are in accordance with The Cochrane Collaboration of 2010 [58]. Furthermore, the satisfaction rate of the non-drained group is statistically (p=0.0001) better than that of the drained group.

Conclusion

In conclusion, as clearly shown in our series, the application of the suction drain after excision and primary closure of sacrococcygeal pilonidal sinus was not recommended. On the basis of our findings, the use of the drain appears to be useless in achieving a quick healing of the sacral wound; in addition, it has a low satisfaction rate.

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