

Original Article

Safety and/or effectiveness of methylene blue-guided pilonidal sinus surgery

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Received March 11, 2014; Accepted April 10, 2014; Epub April 15, 2014; Published April 30, 2014

Abstract: The effectiveness of methylene blue-guided sacrococcygeal pilonidal sinus disease (SPSD) surgery for the prevention of incomplete excision was evaluated. Method: It was a prospective randomized clinical trial that included 33 patients diagnosed with SPSPD. Before the excision, methylene blue was injected into the opening of each sinus. At the first excision, all areas that were stained with methylene blue were resected along with the opening of the sinus (Group 1). At the discretion of the surgeon, all areas with granulation tissue were macroscopically re-excised as a single specimen (Group 2). Specimens were evaluated based on five microscopic assessment parameters. Results: All microscopic assessment parameters for SPSPD were positive in both the groups. No significant differences were observed between the groups in terms of the positivity of all parameters, except hair shaft (parameter 4) positivity ($p > 0.05$). Intensities of positivity in Group 1 for all parameters were higher to a statistically significantly degree compared with those of Group 2 ($p < 0.05$). Discussion: The application of methylene blue for guidance in SPSPD surgery may cause inadequate excision of the diseased area. In clinical practice, this condition may manifest itself by recurrence and poor wound healing.

Keywords: Pilonidal, sinus, methylene, blue

Introduction

Pilonidal sinus, first described by Hodges in 1880 [1], generally occurs in the sacrococcygeal region and in a limited area around it; however, some rare cases are reported in literature when it has occurred outside the sacrococcygeal area [2]. Sacrococcygeal pilonidal sinus disease (SPSPD) is a chronic inflammation and infection of the sacrococcygeal region. This condition, commonly observed among young adults after puberty, presents with an abscess, and a painful sinus region associated with seropurulent discharge in the presacral region [3]. Although its etiology is not precisely known, risk factors include increase in the amount of hair in the region, male gender, obesity, prolonged sitting, family history, trauma, irritation of the coccyx, and inattention to personal hygiene [4]. The incidence of SPSPD is reported to be 0.26%-7% [5, 6].

Methylene blue (MB) is a water-soluble thiazine dye, which can be intravenously, topically, and/or

intraluminally applied. MB is generally used for the visualization of tumor tissue during head, neck, and parathyroid surgery; for detection of a sentinel lymph node; testing for the stability of gastrointestinal anastomosis; scanning fistulae and sinuses in the bladder; and in intestinal, anal, and pilonidal sinus surgery [7, 8].

Various treatment modalities for SPSPD include primary repair, healing by secondary intention, and repair with flaps. There are reports of a wide range of recurrence rates for all these procedures [1, 9, 10]. Because inadequate excision is an important cause of SPSPD recurrence [11], several surgeons apply MB through the outer mouth of the pilonidal sinus in order to stain the tissues before operating. The blue color provides a reliable guide [12-17], assisting surgeons in identifying the exact extent of tissue to be excised. However, when applied through the outer mouth of the sinus, MB may be inadequately distributed because of the presence of hair or other foreign bodies, acute

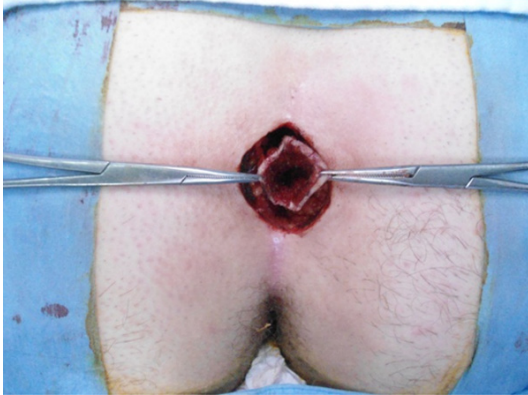


Figure 1. Pericystic tissue excision.

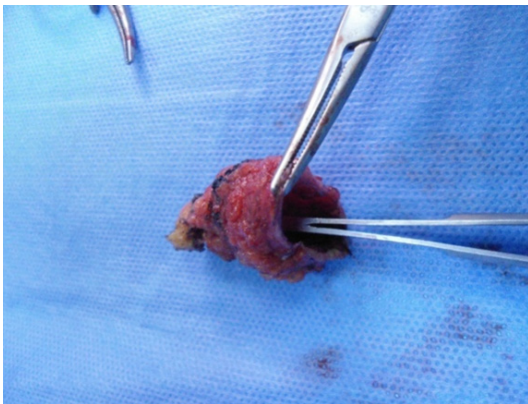


Figure 2. Pericystic excision material.

inflammation, etc. This study investigated the efficiency of the application of MB in SPSP surgery for the prevention of inadequate excision.

Methods

The study was designed at the Department of General Surgery of Bezmialem Vakif University Faculty of Medicine as a prospective, randomized, clinical trial. The methodology was approved by the local ethics committee of Istanbul University Faculty of Medicine, and registered under clinical trials.

68 patients diagnosed with SPSP who had been admitted to the Bezmialem Vakif University Faculty of Medicine Department of General Surgery outpatient clinic between November 2012 and March 2013 were included in this study. After a power analysis, 33 patients (28 men, 5 women; male/female ratio: 5.6;

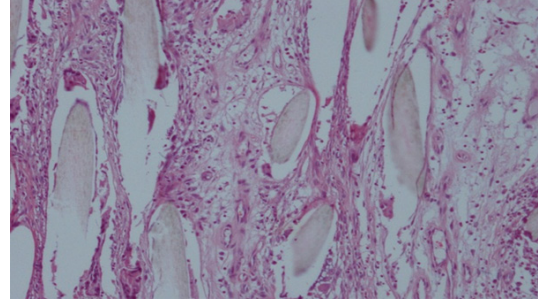


Figure 3. The presence of an abundance of hair shafts and inflammatory cell infiltration within the sinus in Group 1.

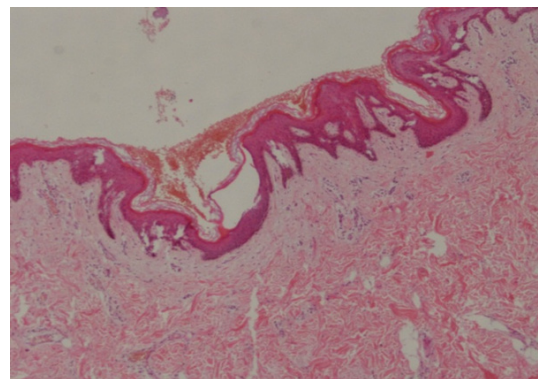


Figure 4. Enlarged hair follicle structures and the presence of abundant keratin material in Group 2.

mean age: 27 years; age range: 19-36 years) were accepted to the study with a 95% confidence interval and 80% power. Exclusion criteria were patients younger than 16 years of age, recurrent disease, acute inflammation, and the presence of abscess.

After receiving spinal anesthesia, patients were placed in a jackknife position; the operation site was shaved and disinfected with povidone iodine (Baticon®, Adeka Co, Istanbul, Turkey). The area around the surgical site was then covered with sterile sheets; 22-gauge sterile injector containing a minimum of 4 ml MB (Methylene Blue, USP®, Akorn, IL, USA) was inserted in the opening of each sinus into the sacrococcygeal region. Before the insertion, the injector needle was broken from the middle to avoid tearing the sharp end in the tract. After ensuring that the needle was correctly positioned, MB was injected with enough pressure to cause it to leak out of the tract. All stained areas were excised as a

Table 1. Microscopic assessment parameters for SPSP

Parameter 1	Presence of an enlarged hair follicles
Parameter 2	Presence of dispersed keratin lamella within the follicle
Parameter 3	Presence of inflammatory cell infiltration
Parameter 4	Presence of hair shafts in the sections
Parameter 5	Presence of fibrosis

Table 2. Distribution of the positivity of microscopic assessment parameters

	Group 1	Group 2	p value
Parameter 1	32	31	1
Parameter 2	33	29	0.114
Parameter 3	33	30	0.238
Parameter 4	29	5	< 0.001
Parameter 5	32	32	1

Table 3. Distribution of the positivity intensities of microscopic assessment parameters

	Mean		Median		Standard Deviation	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Parameter 1	1.97	1.30	2.00	1.00	0.810	0.637
Parameter 2	1.97	1.15	2.00	1.00	0.770	0.677
Parameter 3	2.61	1.03	3.00	1.00	0.609	0.529
Parameter 4	2.36	0.15	3.00	0.00	1.055	0.364
Parameter 5	2.06	1.12	2.00	1.00	0.747	0.485

single piece by a circular incision involving the opening of the pilonidal sinus without leaving any stained tissue behind. Specimens, thus obtained, were classified as Group 1. At the discretion of the surgeon, all areas with granulation tissue macroscopically visible, were re-excised as a single specimen and named Group2 (**Figures 1** and **2**). The choice of repair technique (primary, flap, etc.) was based on the preference of the surgeon.

Specimens were histopathologically examined in 10% formaldehyde via labeled containers. In the pathology laboratory, the specimens were dipped in paraffin after dehydration, and 5-mm sections were prepared. All histopathological examinations were performed under 100 × magnification of a light microscope (**Figures 3** and **4**). A pathologist who was blinded for the study protocol assessed the specimens based on pilonidal sinus microscopic assessment criteria [18] (**Table 1**).

Statistical analysis

Statistical evaluation of data was performed by the statistical package for the Social Sciences® for Windows® (version 21, SPSS, Chicago, IL, USA) program. Data were presented as mean ± standard deviation (mean ± SD). The comparisons of the groups were performed by Wilcoxon test. The results were assessed at the significance level of $p < 0.05$.

Results

All the microscopic assessment parameters for SPSP were positive in both groups (**Table 2**). No statistically significant differences were observed between the two groups in terms of positivity of all parameters. Only parameter 4 (positivity for hair shaft) was significantly different between the two groups ($p < 0.001$). However, when the positivity intensities of microscopic assessment parameters for SPSP were evaluated, the results obtained from Group 1 compared with those from Group 2 for all parameters were higher to a statistically significant degree (**Table 3**, $p < 0.05$).

Discussion

Inadequate excision is considered an important cause of high SPSP recurrence rates and poor wound healing after SPSP surgery [19, 20]. There are articles in literature, mainly curettage studies, advocate that removal of the sinus tract is unnecessary; otherwise, the generally accepted view is to remove all granulation tissue [21]. Inexperienced surgeons may excise only blue areas stained by MB, whereas experienced surgeons may insist on excising inflamed areas macroscopically visible even if such tissue is not stained by MB. Only excising blue-stained areas (particularly in complicated cases) may cause a false sense of confidence even for experienced surgeons.

Literature review has disclosed that the clinical studies discussing surgical techniques for

SPSD are mostly of operations performed with the guidance of MB [12-17]; other than Doll et al. [22], these studies did not examine the reliability of MB to help with adequate excision. Doll et al studied 247 patients who had been operated upon for acute and chronic SPSP. Of 197 operations guided by MB, 23.3% were for acute SPSP and 73.3% for chronic SPSP. After a mean of 14.9 years, these patients were followed by a telephonic survey and asked whether it had recurred, and if so, whether it had necessitated a repeat surgery. It was observed that a recurrence had occurred in 16.2% (n = 32) out of the 197 cases (with MB guidance). Of the 50 patients operated upon without MB guidance, 30% had recurrence, a statistically significant difference (p = 0.018). However, comparing only the patients who underwent the operation for a diagnosis of chronic SPSP, the recurrence rates were 19% in the patients operated on with MB guidance and 24% among those without MB (p = 0.35). In acute SPSP, the 20-year recurrence rate of patients whose first operation was guided by methylene blue was 19%, and was 43% among those who were operated without methylene blue (p = 0.078) [22]. Considering that several SPSP surgical studies were performed on patients diagnosed with chronic SPSP, like in the present study, the results of Doll et al. highlight the finding that operations guided by MB do not decrease recurrence rates to a statistically significant degree.

However, recurrence is not the only issue encountered in SPSP surgery. Surgical site infections are also important complications. The rate of surgical site infections is 8%-26% after SPSP surgery [23, 24]. Ersoy et al enrolled 100 patients in their study to compare the Karydakos and Limberg flap techniques. They reported surgical site infection rates as 26% for Karydakos and 8%, for Limberg flap respectively [23]. Surgical site infection is also the most common cause of recurrence of SPSP. A study by Saylam et al addressed the causes of delayed wound healing in 374 patients who underwent SPSP surgery. They determined that the most important factors leading to recurrence were wound infection, obesity, female gender, abscess drainage, and wound dehiscence [18].

The study by Kapan et al showed that the most important factors contributing to recurrence after Limberg flap operations were inadequate

excision and poor personal hygiene, followed by surgical site infections and postoperative complications [19]. A study by Guyuron et al revealed that after excision and grafting techniques, inadequate excision was a more common etiologic factor than inadequate technical practice, in the development of postoperative complications such as recurrence and surgical site infections [20].

According to literature, inadequate excision is the most important etiologic factor in the development of both SPSP recurrence and wound complications. To prevent these issues, the most frequent approach in surgical practice has been MB-guided surgery [12-17]. However, in this study, the positivity of all microscopic assessment parameters for SPSP in all Group 2 patients showed that MB-guided SPSP surgery does not prevent inadequate excision. If MB guidance were a reliable technique to provide adequate excision, microscopic assessment parameters for SPSP of Group 2 compared with those of Group 1 would be lower to a statistically significant degree. No statistically significant differences were observed between any parameter except hair shaft positivity (parameter 4). It is clear that hair shafts are often located in pilonidal sinus tracts and these tracts constituted the center of the excisional specimens in Group 1. For the same reason, the intensities of positivity of all parameters in Group 1 were statistically higher compared with those in Group 2.

The application of methylene blue for guidance in SPSP surgery may cause inadequate excision of the diseased area. In clinical practice, this condition may later manifest as sinus recurrence or poor wound healing.

Disclosure of conflict of interest

None.

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