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Methylene Blue Provides an Efficient Resection for the Treatment of Pilonidal Sinus Disease

Metilen Mavisi, Pilonidal Sinüs Hastalığının Tedavisinde Etkili Rezeksiyon Sağlar

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Amaç: Metilen Mavisi (MM) Sacrokoksigeal Pilonidal Sinüs Hastalığı (SPSH) için yaygın olarak kullanılan bir boyadır.
 Bu randomize prospektif çalışmanın amacı, Karydakis flep prosedüründe sakrokoksigeal (SPSH) için (MM) yararlarını ve etkinliğini saptamaktır.
 Hastalar ve Yöntem: Ocak 2016 ile Nisan 2017 tarihleri arasında SPSH Karydakis flep prosedürü uygulanan olan toplam

100 hasta randomize olarak, iki eşit gruba ayrıldılar. Hastaların yaş, cinsiyet, VKİ, hastalık süresi, delik sayısı ve eksize edilen numune yüksekliği, genişliği, alanı, çevresi, derinlik, hacim ölçüleri, postoperatif komplikasyonlar ve hastanede yatış süresi kaydedildi.

Bulgular: Her iki grupta da hastaların özellikleri benzerdi. MM kullanılan grupta eksize edilen örneklerin derinliği dışındaki tüm parametreler istatistiksel olarak anlamlı bulundu (p<0.01).

Sonuç: Sonuçlarımız MM kullanımının Karydakis flep prosedüründe açık bir fayda sağladığını gösterdi.

Anahtar kelimeler: Sakrokoksigeal pilonidal sinüs hastalığı, Metilen mavisi, Karydakis flebi, boyut.

Abstract

Aim: The Methylene Blue (MB) is commonly used dye for Sacrococcygeal Pilonidal Sinus Disease (SPSD). The aim of this randomized prospective trial was to determine the benefits and effectiveness of (MB) for (SPSD) by comparing the results of Karydakis flap procedure.

Patients and Methods: Between January 2016 and April 2017, a total of 100 patients with sacrococcygeal pilonidal sinus disease were randomly assigned to two equal groups which underwent Karydakis flap procedure with or without MB usage. Patients age, gender, BMI, duration of the disease and number of the orifices, excised specimen height, width, area, circumference, depth, volume,postoperative complications and duration of hospital stay were recorded.

Results: Characteristics of the patients were similar in both groups. In the MB used group all the parameters except the depth of the excised specimens found as statistically significant (p<0.01). **Conclusion:** Our results showed a clear benefit for surgical management by Karydakis flap procedure in patients with MB usage.

Keywords: Sacrococcygeal pilonidal sinus disease, Methylene blue, Karydakis flap, dimension.

INTRODUCTION

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Acute or chronic subcutaneous inflammation of the sacrococcygeal area was defined as Sacrococcygeal Pilonidal Sinus Disease (SPSD) (1). It was first descriped by Mayo in 1833 (2). SPSD commonly affects the young adults (3). For the treatment of SPSD many procedures including Karydakis flap (4), Limberg flap (5), marsupialisation (6), and Bascom procedure (7) have been performed but not a standard treatment established (8,9). Due to procedure performed, recurrence rates are changing (10). Total excision of fistula tracks has been reported by Doll et al (11). And he demonstrated that the prevalence of recurrence decreased from 30% to 16% after methylene blue (MB) usage (12). It also has been shown that methylene-blue staining (MBS) was applied significantly less often in emergency cases

(13). There are only few publications on the use of MB in SPSD (14).

In this prospective study we examined the effectiveness of the treat-ment of SPSD with MBS on the dimensions of excised pathological specimens.

PATIENTS AND METHODS

This study included 100 patients who underwent surgery for PSD of the sacrococcygeal region. We carried out this prospective study at the Aksaray University Aksaray Training and Research Hospital, Aksaray, Turkey from January 2016 to April 2017. The protocol was submitted to institutional review board and with institutional approval of the study.

Study Design

This was a prospective, controlled, randomized, single-center clinical trial including 2 groups of 50

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	MB (+) n: 50	MB (-) n: 50	p value
	(Mean ± SD)	(Mean ± SD)	•
Age (years)	25.14±7.91	26.07±8.13	0.721
Gender (M/F)	42/8	43/7	0.524
BMI (kg/mg ²)	28.85±4.52	29.81±3.09	0.819
Duration (month)	12.82±2.29	11.92±1.98	0.642
Number of orifices	2.37 ± 0.87	2.24 ± 0.98	0.436
Postoperative complications			
Wound infection	1	2	
Hematoma	0	1	
Dehiscence	0	0	
Hospital stay (day)	1.76±0.72	2.01±0.82	0.561

Table 1. Site of oral mucosal le	esions according to benign.	precancerous and malignan	t pathologies.

BMI: body mass index, MB: methylene blue

patients in each with pilonidal sinus disease comparing 2 groups of Karydakis flap procedure with or without MB usage. From January 2016 to April 2017, a total of 100 patients were included into this study. 100 patients with SPSD, older than age 18, were randomized to receive excision and Karydakis flap procedure with MB (group 1) or without MB (group 2) and statistically analyzed.

Patients with chronic non-recurrent disease were included in this study. Exclusion criteria of the study were the following: acute infection, recurrence of the disease ASA III and IV, body mass index >35, insulin-dependent diabetes, severe allergy toward local anesthetics or other medications, abuse of substances with central nervous system activity, drug addiction and alcoholism.

The written informed consent approved to participate in this surgical treatment was obtained from all patients preoperatively.

The data obtained were patient age, gender, body mass index, duration of symptoms of the disease and number of the orifices. Patient characteristics are shown in table 1.

Surgical Procedure

The procedures were undertaken with the understanding and appropriate informed consent of each patient before surgery. All patients were underwent Karydakis flap surgery by six different senior surgeons under spinal anesthesia.

The gluteal area, including the region surrounding the intergluteal sulcus, was shaved the day before surgery. Preoperatively, the patients were administered with 1g cefuroxim aksetil intravenously for prophylaxis. After positioning the patient in the prone position, the skin around the intergluteal sulcus was stretched using medical tape and the skin was cleaned using 10% povidone iodine.

In both groups Karydakis flap, the sinus tract was removed down to the sacrococcygeal fascia by an asymmetric semilateral elliptic incision as described in the Karydakis technique (14). The cranial and caudal tips of the incision were placed at opposite sides of the perianal opening. The ellipse was based only on the pits in the vicinity of the midline. The incision covered lateral secondary openings. In group 1 under the guidance of methylene blue, both sides of the elliptical incision were deepened into the

Table 2. Comparison of the height, width, area, circumference, depth and volume of excised specimens of groups with or without MB.

	MB (+) n: 50	MB (-) n: 50	p value
	(Mean±SD)	(Mean±SD)	
Height (mm)	3.96±2.06	5.6±1.71	0.0001
Width (mm)	1.71±0.78	2.8±1.6	0.0001
Area (mm ²)	5.66±5.85	13.26±12.03	0.0001
Circumference (mm)	8.77±0.85	13.12±4.78	0.0001
Depth (mm)	1.81±0.81	2.08±0.6	0.06
Volume (mm ³)	11.89±15.53	30.86±33.35	0.004
MB: methylene blue			

gluteal fascia. 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 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.

The flap was prepared as described by Karydakis (14). The flap was then sutured with polyglycolic acid sutures in 2 layers, and a suction drain was placed in the cavity for aspiration. Finally, the skin and circular perianal incision were sutured separately with using 3–0 polypropylene sutures. An oral free feeding regimen was initiated in the early postoperative period. The patients were advised to pay special attention to perineal hygiene following defecation. The aspiration drain was removed when the flow rate was below 50mL per day. Oral antibiotics were continued until the end of the first postoperative week.

Patients excised specimen height, width, area, circumference, depth, volume, postoperative complications, and duration of hospital stay were also evaluated.

Statistical Analysis

Data were expressed as mean \pm standard deviation (mean \pm SD). Statistical evaluation of data was performed by the statistical package program for the Social Sciences for Windows (version 21, SPSS, Chicago, IL, USA). The comparisons of the groups were tested for significance by student t-test. A p value of less than 0.01 was considered statistically significant.

RESULTS

The average ages of groups were 25.14 ± 7.91 (18-60) years and 26.07 ± 8.13 (17-54) years. Male gender was dominant in the study. The mean BMIs of the patients were similar in both groups; 28.85 ± 4.52 kg/m2 (24.1-42.7) to 29.81 ± 3.09 kg/m² (22.4-43.5), respectively. The mean duration of symptoms was 12.82 ± 2.29 (1-36) months in group 1 and 12.82 ± 2.29 (2-48) months in group 2. Number of orifices were similar in both groups; 2.37 ± 0.87 (1-4) to 2.24 ± 0.98 (1-5), respectively.

The average height of the excised specimen in

group 1 was 3.96 ± 2.06 (2.40-6.05) while 5.6 ± 1.71 (4.35-13.50) in group 2. The average width of the excised specimen in group 1 was 1.71 ± 0.78 (1.30-3.60) while 2.8 ± 1.6 (2.50-5.75) in group 2. Excised specimens calculated mean areas were 21.37 ± 19.85 (7.18-45.94) volume of the excised specimen was 21.37 ± 19.85 (7.18-45.94) mm3. All patients were operated under spinal anesthesia. We performed Karydakis flap to all patients. Wound infections developed in three patients (3%) one in MB used group, hematoma occurred in one patient (1%) without MB, and there was no wound dehiscence after the removal of sutures in all patients.

DISCUSSION

SPSD is not has a standard treatment until today and MB is on the fo-cus of some studies. It has been showed that a decrease occurs with the usage of MB in the recurrence risk o SPSD (15). With 14.9 years control follow ups, it has observed that recurrence reduced from 30% to 16% (12). A clinical practice noticed in some cases that the change of the excision extent was seen when the MB was used (14). This is probably the reason why some specimens presented as multiple parts. Thus, they also assumed that not only the antimicrobial effect but also the more radical excision extent may have contributed to the recurrence reduction (14) as also reported before (12). In our study, we determined that the volume of excised specimen was lesser in SPSD treated with MBS compared with those without MBS. The effect of MBS on the volume of excised SPSD specimens has been only once described previously (14). With contrast to previous study, it was demonstrated that the volume of excised specimens was decreased remarkably with MB usage in this study.

Excision without MBS may increase the recurrence risk of a SPSD. In a study it has been showed that ,a linear correlation between the size of the excision of a Pylonidal Sinus and the period of wound healing of the open granulation (16). It means that the secondary healing after a more radical excision would take longer time.

Many authors recommend the Karydakis procedure and the Limberg procedure (4,5). In the case of plastic coverage with a Limberg flap, Alptekin et al. showed that this was associated with a significant increase in the prevalence of surgical-site infections as a complication of larger excised volumes (17). This is interesting because Søndenaa et al. have shown in their study of 145 patients that an infection

after a surgical procedure increases the number of recurrences markedly (18). This may imply that the use of MB and, thus, larger excised volumes may lead to higher infection and recurrence rates. But, these studies did not explicitly refer to the usage or not usage of MB. It is not clear if the infection risk is increased with plastic surgical coverage because MB has antimicrobial effects (19). The local administration of an antimicrobial substance within the fistula system, contamination of the wound or the flap is minimised (14). In several studies has been showing the clinical assessment by the surgeon and according to ultrasound diverge considerably (20,21). Besides MB usage, the optimal size of an excision can be determined via ultrasonography, thereby aiding in the estimation of the extent of the SPSD fistulas. In addition to the visualisation of the fistulas with MB usage, its antimicrobial effect is beneficial. In large abscess forming SPSD in particular, microbes are identified in approximately 80% of some cases (22) Some several publications have discussed phenol injection into the fistulas (23,24). The inflammation within the fistula system causes scarring. It is assumed that the injection reaches into the entire fistulas.

There is only a few article in the recent literature on MBS (14). Further, be conducted to investigate the impact of MBS in the risk of recur-rence. Limitation of the study was about the usage of MB in mililiters. A predominant male gender may be the another limitation of the study. There is need to randomised controlled trials with larger amounts and enhanced parameters.

CONCLUSIONS

This study determined that the sinus tract, branches, and borders could be accurately identified by MB. This method can be employed while deciding upon a surgical intervention for pilonidal sinus patients.

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