Is gentamicin-impregnated collagen sponge to be recommended in pilonidal sinus patient treated with marsupialization?
A prospective randomized study

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BACKGROUND: *The ideal treatment method for pilonidal sinus has always been a matter of debate. Although primary closure or various flap applications offer shorter wound healing times, their infection rates are very high. Secondary recovery involves long recovery period. The aim of this study is to investigate the effects of gentamicin-impregnated collagen sponge on wound healing and infection in patients undergoing marsupialization.*
PATIENTS AND METHODS: *Fifty patients were included in the study. Twenty-five patients in control group (Group 1) underwent excision and marsupialization. Gentamicin-impregnated collagen sponge was used postoperatively in twenty-five patients in group 2. Three-dimensional wound measurements were made on the 0.7 and 15th days and recorded.*
RESULTS: *No significant difference was observed between the groups in terms of development of hemorrhage and infection. Excessive granulation was detected in five patients (two in group 1 and three in group 2). There was no significant difference between the groups with respect to this criterion. Full recovery times were 29.6 and 28.2 days respectively. No statistically significant difference was observed between the groups (p = 0.571). None of the patients developed recurrence at the end of the follow-up period of 6-30 months.*
CONCLUSION: *In accordance with the results obtained in this randomized and controlled study, no significant difference was observed between gentamicin-impregnated collagen sponge group and control group with respect to development of infection, hemorrhage and wound healing times. Therefore, we do not recommend the use of gentamicin-impregnated collagen sponge after marsupialization.*

KEY WORDS: Gentamicin-impregnated collagen sponge, Marsupialization, Pilonidal sinus

Introduction

Pilonidal sinus is a common disorder (Fig. 1). The disease is more common in men than women (2.2 times) and frequently occurs in adulthood. The incidence is 26/100.000 [1]. The condition was probably first described by Mayo in 1833 as a sinus containing hair [2]. In 1880, Hodges used the phrase "pilonidal sinus" to describe the condition in the sacrococcygeal region [3]. The pathogenesis of the disease has been the subject of debate for many years. In 19th century, most of the researchers argue that lesion is congenital origin on the basis of studies conducted on human embryos [4]. Today, congenital theory is not considered [5]. Acquisition hypothesis is more accepted [6] and Karydakis and Bascom are the pioneers of this acquisition theory [7,8].
The ideal method for the surgical treatment of pilonidal sinus is still subject of debate. Methods such as marsu-

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Fig. 1

Fig. 2

pialization or leaving open after local excision require long recovery periods with lower rates of development and recurrence of infection. Primary midline closure or various flap applications provide opportunity for shorter healing time and return to work. However, infection and recurrence rates are higher [4,9-14].

Although there are studies showing the efficacy of gentamicin-impregnated collagen sponge (GCS) on wound healing and infection [15-18], studies regarding the GCS as useless exist as well in the literature [19]. There are some studies reporting good results related using gentamicin-impregnated collagen sponge after pilonidal sinus surgery [20-22], but there are also reports proposed that it is useless [23].

In our prospective randomized controlled study, we investigated the effects of GCS on wound healing and infection in patients treated with the marsupialization.

Patients and Methods

After obtaining approval from Ankara Training and Research Hospital Ethics Committee, fifty patients undergoing surgery for pilonidal sinus at Ankara Training and Research Hospital, Department of General Surgery and Samsun 19 Mayıs University Faculty of Medicine, Department of General Surgery between January 2011 and December 2012 were included in the study. The patients were randomly divided into two groups and followed up prospectively. Patient's age, gender, duration of symptoms, recurrence, presence of obesity and smoking status were recorded. Those with diabetes were excluded. Patients with pilonidal abscess were operated after drainage and oral antibiotics treatment.

All patients were operated under spinal or general anesthesia in prone position. Methylene blue was used to demonstrate sinus tracts. All patients underwent wide

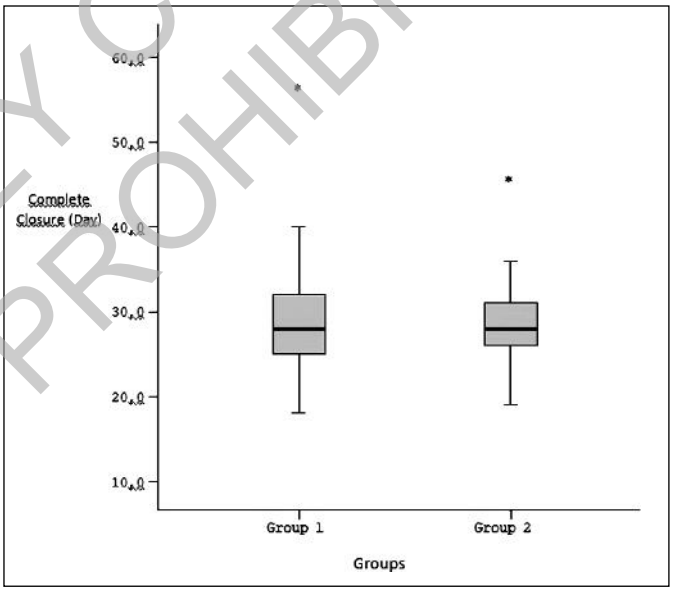
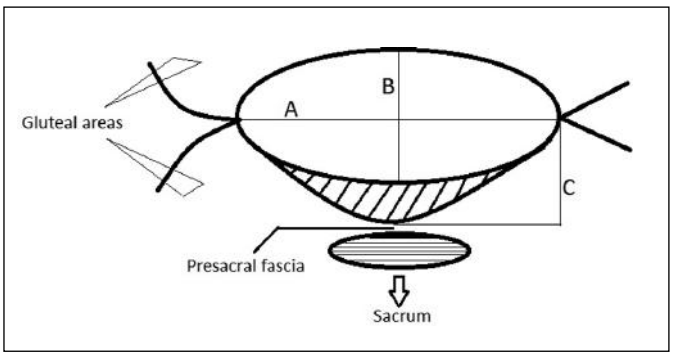


Fig. 1



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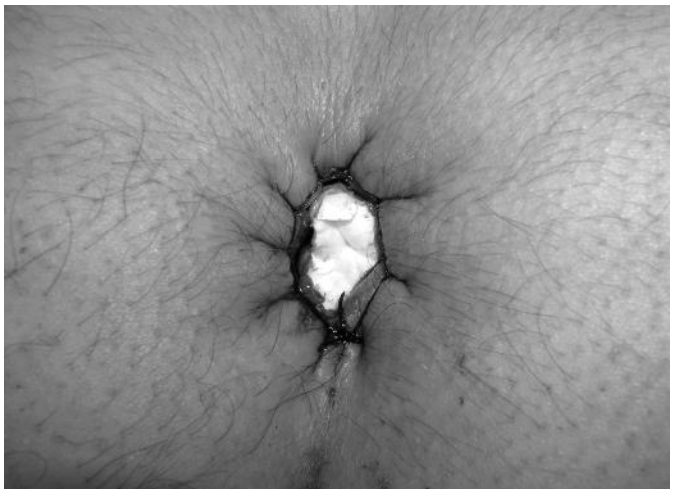

Fig. 3

excision including all tracts and extending down to presacral fascia (Fig. 2). Cautery was not used, unless necessary, not to leave necrotic tissue and hemorrhage control was achieved by suppressing with hot gauzes. The skin was closed with continuous sutures to the presacral fascia and then marsupialization of the wound was performed using 2/0 vicryl rapide sutures. Three-dimensional measurements (vertical axis, transverse axis and depth) of the wounds were made and recorded (Illustration 1). While the patients in group 1 received no additional post-operative treatment, gentamicin-impregnated collagen sponge (GCS) prepared in accordance with the size of the wound was used in patients in group 2 and the defect was covered (Fig. 3). The patients were discharged from the hospital on the 1-4th days. The patients did not receive topical or systemic antibiotics treatment. The patients were followed up weekly until they fully recovered and bimonthly to evaluate the recurrence. The sutures were removed on the 15th day control on average depending on the size of the wounds not earlier than the 10th day. However, vicryl rapide sutures were not removed and were allowed to dissolve on their own in patients with large wound in which expected healing time was greater than one month. Measurements of wound size were repeated on the 7th and 15th day and recorded. Finally, fully closing times were also recorded. In addition, all patients were monitored during the follow-up period in terms of short and long-term complications, postoperative infections and recurrence.

STATISTICAL ANALYSIS

Statistical analyses were made using one-way analysis of variance, chi-square test and Kruskal-Wallis analysis of variance based on the parameters. p value of <0.05 was considered statistically significant.

Results

Fifty patients were included in the study. Forty patients (80%) were male and ten patients (20%) were female. Mean age (years) and weight (kg) were 26.9 and 83.9 respectively. Duration of symptoms was 10 months. 7 of 50 patients (14%), were recurrent cases and 13 (26%) were smokers. All patients were evaluated in terms of these parameters and no statistically significant difference was observed between groups (Table I).

Localization and the number of sinus were evaluated preoperatively. Thirty-one patients (42%) had one whereas thirty-nine (58%) patients had multiple sinus tracts. Sinuses located in the midline in 43 patients (86%) and lateral in 2 patients (4%). Five patients (10%) showed midline and lateral placement. No statistically significant difference was observed between groups in terms of these criteria (Table II).

Three-dimensional measurements of wounds were made on 0, 7 and 15th days and differences between measurements were recorded. No statistically significant differences were observed between 7-0, 15-0 and 15-7 days in groups with respect to the measurements of width, height and depth. Similarly, complete closure of wounds

TABLE I - *Characteristics of the patients (SD: standard deviation, min: minimum, max: maximum, med: median)*

Parameters	Group 1 (n=25)		Group 2 (n=25)		p
	Mean±SD	Med (min;max)	Mean±SD	Med (min;max)	
Age (Years)	27.4 ± 6.05	27 (14;37)	26.4 ± 6.19	26 (18;44)	0.551
Average Weight	82.1± 14.8	82 (54;120)	85.6±13.8	84 (60;135)	0.346
Duration of Symptoms (Months)	10.6 ±9.1	9 (2;48)	9.5±7.75	6 (2;36)	0.187
	n	%	n	%	
Recurrence Cases	4	%16	3	%12	0.684
Smokers	6	%24	7	%28	0.747
Sex (Male/Female)	18:7	Male %72	22:3	Male %88	0.157

TABLE II - *Preoperative Findings*

	Group 1 (n=25)	Group 2 (n=25)	p
Sinuses			
Single	9 (%36)	12 (%48)	0.390
Multiple	16 (%64)	13 (%52)	
Localizations of sinuses			
Midline	22 (%88)	21 (%84)	0.684
Lateral	1 (%4)	1 (%4)	1
Midline+Lateral	2 (%8)	3 (%12)	0.637

TABLE III - *Postoperative evaluations (SD: standard deviation, min: minimum, max: maximum, med: median)*

Wound Sizes		Group 1 (n=25)	Group 2 (n=25)	p
Height (7-0 days)	Mean±SD	0.96±0.26	0.90±0.32	0.288
	Med(min;max)	0.93 (0.5;1.5)	0.8 (0.5;1.7)	
Height (15-0 days)	Mean±SD	1.83±0.54	1.7±0.54	0.446
	Med(min;max)	1.8 (1;3)	1.6 (1;2.8)	
Height (15-7 days)	Mean±SD	0.86±0.34	0.8±0.26	0.609
	Med(min;max)	0.84 (0.5;1.8)	0.9 (0.4;1.35)	
Width (7-0 days)	Mean±SD	0.68±0.29	0.67±0.38	0.564
	Med(min;max)	0.67 (0.2;1.3)	0.7 (0.2;2)	
Width (15-0 days)	Mean±SD	1.18±0.35	1.17±0.47	0.861
	Med(min;max)	1.2 (0.6;2)	1.2 (0.5;2.5)	
Width (15-7 days)	Mean±SD	0.50±0.16	0.50±0.17	0.968
	Med(min;max)	0.5 (0.2;0.9)	0.5 (0.3;0.95)	
Depth (7-0 days)	Mean±SD	0.37±0.11	0.38±0.13	0.754
	Med(min;max)	0.38 (0.1;0.6)	0.4 (0.1;0.6)	
Depth (15-0 days)	Mean±SD	0.69±0.2	0.73±0.24	0.564
	Med(min;max)	0.7 (0.3;1.1)	0.7 (0.3;1.1)	
Depth (15-7 days)	Mean±SD	0.32±0.12	0.35±0.15	0.634
	Med(min;max)	0.34 (0.15;0.6)	0.3 (0.2;0.7)	
Complete Closure (day)		Group 1 (n=25)	Group 2 (n=25)	p
Mean±SD		29.6±7.5	28.2±5.5	0.571
Med(min;max)		28 (18;55)	28 (19;44)	

TABLE VI - *Postoperative Findings*

Parameters	Group 1 (n=25)	Group 2 (n=25)	p
Hemorrhage	2 (%8)	0 (%0)	0.149
Overgranulation	2 (%8)	3 (%12)	0.637
Infection	0	0	–

did not differ significantly between groups (Table III). In post-operative period, 2 patients (4%) developed minimal hemorrhage that can be treated with compression dressings and 5 patients (10%) developed overgranulation. None of the patients developed infection requiring debridement and antibiotic treatment. No statistically significant difference was observed between groups with respect to these criteria (Table IV).

Discussion

Pilonidal sinus is a common disease. The pathogenesis of pilonidal sinus has been the subject of debate for many years. In the past years, although many researchers argued that the disease is congenital, today the disease is thought to be acquired [4-8]. Acquisition theory refers to the condition that hair follicles extend due to accumulation of keratin in intergluteal sulcus and subsequently become infected. This is a chronic, progressive and inflammatory process. According to the congenital theory, the disease may be caused by neural canal, but this condition is very rare [24].

Despite being a simple entity, no consensus has been achieved on surgical treatment since it was first defined in 19th century. Surgeon experience and choice as well as patient's characteristics, preferences and occupational status play an important role on the procedure to be selected [25]. Advantages or disadvantages of the techniques namely leaving the wound open, primary closure or different flap applications after excision have been reported in various publications. In their study comparing open and closed techniques, Füzün M. and colleagues reported that despite the fact that primary closure group have a trend towards a longer hospital stay, recovery and return to work times were significantly shorter than the other group. However, infection and recurrence rates were reported to be lower in those undergoing open techniques [26].

Recurrence is a common problem after surgery for pilonidal sinus. Recurrence rates may vary in different studies (up to 20- 40% regardless of surgical technique). Reasons for recurrence depend basically on two factors. First, inattentive wound care and inadequate hygiene condition. Hair follicles moving into scars by sweating and friction may lead to recurrent infections and recurrence of disease if adequate care is not paid on hygiene and hair removal in postoperative period. The other factor is the missed sinus tracts that have been overlooked and not fully excised related with inadequate surgery [27,28]. We believe that inadequate excision is the most important cause of relapse regardless of the technique used. Sinus tracts should be completely excised during the surgery to prevent relapse. For this purpose, a wide resection is appropriate. Not to leave diseased tissue is imperative to prevent recurrence. Leaving the surgical wounds open after resection is a standard technique applied in

Fig. 4

many clinics. However, recovery time may be too long if the wound left completely open after extensive resection. There are publications reporting that mean wound healing duration after an open technique was longer than two months, and even extends to 6 months [22,24]. Therefore, partial wound closure combined with marsupialization rather than leaving it fully open after resection seems reasonable.

Mean duration of wound closure after marsupialization was approximately 1 month, in other words, significantly shorter than that of wide excision [24]. There are publications indicating less complication development and lower pain levels after marsupialization in comparison to extensive excision and flap methods [29,30]. In their study comparing primary closure, wide resection and marsupialization, Spivak H. et al. reported lowest recurrence rates in the group treated with marsupialization [10]. According to these information, marsupialization can be considered as one of the methods that can be applied to the treatment of pilonidal sinus securely. It is evident that it is more advantageous than extensive resection. However, the surgeon faces with an open wound after marsupialization and the patient should be follow up to certain period of time for the closure of the wound. Shortening healing time would be beneficial in follow-up after surgery. In their study Aldemir M. et al. divided marsupialization-applied-patients into two groups and wounds of patients in one group were dressed using pomades containing collagenase and reported that wound closure time in this group was significantly shorter than that of other group [24].

Wound healing occurs mainly by epithelialization and wound contraction. For this process, complete fibrablast function and collagen productions are required [31]. Wound contraction is defined as the closure of open wounds by the migration of the tissues to the center. Collagen level increases at 10th postoperative hour and reaches its highest level after 5-7 days. Not only the construction but also the destruction of collagen is important for normal wound healing. This procedure is carried out by collagenase enzymes secreted by inflammatory cells, fibroblasts and epithelial tissue. Collagenase enables rapid removal of necrotic tissue from the wound bed. Collagen fibers attach necrotic tissues which are located base of the wound. These fibers are removed by callogenolysis through surrounding macrophages. Meanwhile, epidermal growth factors are stimulated and granulation is increased by epithelial cells and proliferation of fibroblasts [24, 32].

GCS (Gentafleece; Baxter, Deerfield, IL USA) is a product containing 2.8 mg / cm² collagen produced from horse tendon and 2 mg/cm² gentamycin sulphate (1.10 to 1.43 mg / cm² gentamicin) [33]. Products with similar contents available in the markets. As mentioned above, the effects of these products on wound healing and infection have been the subject of numerous studies [15-23]. For the first time in the literature, in our study GCS was used in patients treated with marsupialization in the surgical treatment of pilonidal sinus.

In our study, we used GCS in second group. In this group, defects were covered with GCS after surgery. The primary aim of the study was to investigate whether this product shortens the duration of wound healing. GCS covered the wound like a gel 48-72 hours after the application (Fig. 4) and resolved in 7-10 days as the literature [19]. This gel coverage of the wound via GCS was promising for accelerate wound healing. We also evaluated its effects on infection and bleeding control. However, our past experiences showed that hemorrhage and infection can be prevented through meticulous surgery and attentive care. None of our patients developed infection thanks to regular follow-up, care on dressing and hygiene. Two patients in group 1 developed minimal post-operative hemorrhage within 24 hours. These hemorrhages were treated with compressed dressings repeated a few times and did not require reoperation. A total of five patients (two in group 1 and three in group 2) had excessive granulation. However, this is minimal and not requiring additional intervention.

While evaluating the effects of GCS on wound healing (our primary goal), three-dimensional wound measurements were made on 0, 7 and 15th days and differences between these measurements were recorded. No statistically significant differences were observed between 7-0, 15-0 and 15-7 days in groups with respect to width, height and depth measurements. Complete wound closure times of groups were 29.6 and 28.2 days respectively with no statistically significant difference (Graph 1).

Most recurrences occur in the first 3 years after surgery for pilonidal sinus [21]. No recurrence occurred in follow-up period of 6-30 months in our study.

Marsupialization is a superior method when compared with wide resection, in terms of development of com-

plications and recurrence. Also, this method provides shorter healing times. We aimed to further shorten the duration of wound closure by using this product containing collagene. There are studies in the literature using GCS in different forms after surgery for pilonidal sinus [20-23]. However, none of these studies used GCS as a wound dressing in an open wound. We used GCS in this way after marsupialization but we did not find a significant difference between the groups with respect to these criteria. Although GCS reduce dressing and the need for debridement during the period of before its resolved in the wound, we do not support the use of GCS after marsupialization.

Riassunto

PREMESSA: Il metodo ideale per il trattamento delle fistole pilonidali è da sempre argomento di dibattito. Nonostante che la chiusura per primam, con utilizzo di vari tipi di lembo offra la possibilità di tempi più brevi per la guarigione, l'incidenza delle infezioni è molto elevata e il nuovo ricovero presenta lunghi tempi di degenza. Lo scopo di questo studio è una indagine sugli effetti dell'uso di spugne di collageno impregnate con gentamicina sulla guarigione della ferita e l'incidenza di infezioni nei pazienti trattati con la tecnica della marsupializzazione.

MATERIALE DI STUDIO: La casistica dello studio si basa su cinquanta pazienti, venticinque dei quali (gruppo 1) trattati con escissione e marsupializzazione, e in altri venticinque (gruppo 2) è stata usata potoperatoriamente una spugna di collagene impregnata con gentamicina.
Si è provveduto quindi a misure tridimensionali della ferita dopo l'intervento (giorno 0), e poi a 7 ed a 15 giorni.

RISULTATI: Non è stata osservata nessuna differenza significativa tra i due gruppi in termini di complicanze emorragiche e di infezioni. In cinque pazienti del gruppo 1 ed in tre del gruppo 2 è stato rilevato un eccesso di granulazione, con nessuna differenza significativa rispetto a questo parametro.
Il tempo per la completa guarigione è stato rispettivamente di 29,6 e di 28,2 giorni, con nessuna significativa differenza statistica tra i due gruppi (p = 0.571). Nessun paziente è andato incontro ad una recidiva entro la fine di un periodo di follow-up compreso tra i 6 ed i 30 mesi.

CONCLUSIONI: In considerazione dei risultati ottenuti con questo studio randomizzato e controllato non è stata rilevata alcuna differenza significativa tra il gruppo trattato con spugna di collagene impregnata con gentamicina ed il gruppo di controllo in termini di complicanze infettive o emorragiche, e nei tempi di guarigione. Pertanto non vi sono elementi per dover raccomandare l'uso di spugne di collagene impregnate con gentamicina dopo l'intervento di marsupializzazione.

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