



ORIGINAL ARTICLE

CLINICAL TRIAL COMPARING KARYDAKIS FALP PROCEDURE WITH MODIFIED LIMBERG FLAP IN THE TREATMENT OF RECURRENT OR COMPLEX SACROCOCCYGEAL PILONIDAL DISEASE

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Abstract

Aim: The Purpose of this study was to compare Karydakis procedure (KP) with the modified Limberg flap (MLF) in the treatment of recurrent and complex sacrococcygeal pilonidal disease.

Methods: Sixty patients were randomized into two groups: Group I (30 patients) the mean age was 29 ± 7.2 years (22 men) underwent excision and (KP) and Group II (30 patients) the mean age was 28 ± 6.6 years (21 men) that underwent (MLF). Follow up (months) was 23.2 ± 7.65 for group I and 21.6 ± 8.32 for group II.

Results: The operative time (minute) for group I was 49.8 ± 7.3 which was significantly less than that for group II 52.7 ± 5.3 . However, there was no significant difference between both groups as regard hospital stay, pain score, period off work, and healing period Postoperative follow-up showed that there was no significant difference between both groups as regard incidence of complications. Meanwhile recurrence occurs in only one case 3.33 in both groups

Conclusion: Karidakis procedure should be the preferred method in treatment of recurrent and complex sacrococcygeal pilonidal disease, and Modified Limberg flap is relatively major procedure and its results was comparable to Karidakis method.

Keywords: Natal cleft, Closed Excision, Complications.

INTRODUCTION

Pilonidal sinus disease (PSD) is a common disorder in man which occurs in the 3rd decade and lowers the quality of life. There are some predisposing factors for its occurrence. Some of these factors are hairy sacrococcygeal area, sitting on the firm ground for a long time, narrow and deep natal cleft and humid skin.^(1,2)

Infrequently, patients develop complex or recurrent pilonidal disease, complex pilonidal disease

characterized by chronic or recurrent abscesses and extensive, branching sinus tracts. Recurrent pilonidal disease are thought to be due to an unrecognized sinus at the time of initial excision; repeated infections of the scar, causing abscess; or an intergluteal cleft anatomy that promotes the accumulation of perspiration, friction, and the tendency for hair to grow into the scar. The midline scar is the most susceptible to the recurrence of pilonidal disease and poor wound healing.^(3,4)

Patients with recurrent pilonidal disease or complex unhealed pilonidal wounds present a challenge to the

surgeon. Tissue loss from previous attempts at excision further complicates the surgical management and limits options. Primary closure of these wounds is not a viable option given a dehiscence rate of up to 37%, and open management with healing by secondary intention is not suitable because of the length of time that would be required for healing.⁽⁵⁾ Reconstructive procedures are typically required in these cases. These procedures not only cover the wound but also, in theory, flatten the natal cleft, reducing hair accumulation, mechanical irritation, and risk of recurrence. Each offers relatively short healing time but requires an extensive operation under general anesthesia and lengthy hospitalization. Complications, including flap necrosis, wound dehiscence, and infection, are a considerable risk.^(6,7)

A wound that has failed initial therapy must be reexcised down to the sacrococcygeal fascia. The reexcision must include the unhealed wound, scar, and granulation tissue. A flap procedure is then performed to achieve primary wound closure. The techniques available include the cleft closure, advancement flap (Karydakis procedure), local advancement flaps (Limberg, modified Limberg flap or V-Y advancement flap), and rotational flap (gluteus maximus myocutaneous flap).⁽⁶⁻⁸⁾

The aim of this study is to compare Karydakis flap procedure with the modified Limberg flap in the treatment of recurrent and complex sacrococcygeal pilonidal disease.

PATIENTS AND METHODS

This study conducted in colorectal unit, surgery department at Alexandria university hospital during the period from February 2008 to March 2011 sixty patients who were treated for recurrent or complex pilonidal disease were eligible for the study.

Informed consent was obtained from all patients included in the study which was approved by the local ethics committee. All patients subjected to thorough history taking, clinical examination, and laboratory test. Randomization achieved through a computer-Generated schedule and the results sealed into envelopes. The envelopes were drawn and opened by a nurse in the operating room

The patients then randomized into two groups: group I 30 patients underwent Karydakis procedure (KP); group II 30 patients underwent Modified Limberg flap procedure (MLFP).

All patients operated on under general anesthesia. Patients were placed in prone Jack-knife position with two adhesive straps in each gluted region to pull them laterally to allow better visualization of the natal cleft, then shaving off the hairs around the sinus and cleaning the area with povidone Iodine. A prophylactic antibiotic in the form of a third generation cephalosporin administered 30 minutes before the operation and for 3

days after operation.

In group I (Karydakis procedure), begins by excising the wound, with the sinuses removed en bloc with an elliptical specimen of overlying skin. The incision made off midline. Once the wound excised, a full-thickness flap created on the opposite side of the semi lateral incision. This allows the opposite side to be mobilized to allow primary wound closure, thus avoiding a midline wound (Fig. 1). After placing deep approximating 0 polyglactin sutures (VicrylTM; Ethicon., New Jersey, USA), the skin was approximated with 2/0 polyglactin interrupted subcutaneous sutures (VicrylTM; Ethicon., New Jersey, USA) and the skin edges were closed with 2/0 polypropylene interrupted mattress sutures (Propilen; Dogsan, Trabzon, Turkey). The wound is closed over a closed suction drain (Fig. 2).

In group II (Modified Limberg flap), the lesion was excised with a rhomboid shaped incision with each side equal in length (Fig. 3) with lateralization of the inferior apex. The depth of the rhomboid excision extended to the gluteal fascia. The rhomboid flap then rotated from the gluteal fascia to the excised area without tension (Fig. 4). Subcutaneous tissue sutured with interrupted vicryl 2/0 (VicrylTM; Ethicon., New Jersey, USA) and the skin was sutured separately with interrupted proline 2/0 sutures (Propilen; Dogsan, Trabzon, Turkey) at the end of the procedure, a suction drain was inserted. Methylene blue not used to identify the tracks in either group. A single dose of antibiotic prophylaxis used immediately before incision.

Patients discharged when clinically free after the operation, Removal of the drain 4 – 5 days after operation all patients advised to visit outpatient clinic every week for one month and then every 3 months for at least 12 months during the follow-up period. Stitches were removed 14 days post-operative (Figure 5, 6). All patients recommended to walk freely but not to exercise until removal of stitches. All patients advised to shave the area well around the operative site at least monthly.

The duration of operation, postoperative pain, length of hospital stay, duration of incapacity for work, postoperative complications (infection, flap oedema, wound dehiscence), and postoperative recurrence were recorded. Duration of operation defined as the length of time between the first incision and placement of the last suture. To evaluate patient satisfaction with the treatment modality used, visual analogue scale (VAS) was used from 0 (no pain) to 10 (worst pain imaginable) on the first postoperative day. Duration of incapacity for work defined as the time from the date of surgery to the date on which the patient returned to normal activities including employment and leisure activities. Infection considered as leakage of purulent secretion through the surgical wound and not only peri-incisional hyperemia.

Statistical analysis: The statistical analysis of data done by using excel program and SPSS program statistical package for social science version 10. The description of

the data done in form of mean \pm SD for quantitative data, frequency & proportion for Qualitative data. The analysis of the data was done to test statistical significant difference between groups. For quantitative data student t-test was used to compare between two groups. Chi square test was used for qualitative data.

N.B: P is significant if $<$ or $=$ 0.05 at confidence interval 95%.

RESULTS

This study was conducted on 60 patients with recurrent or complex sacrococcygeal pilonidal disease 15 patients after lay open and curettage, 12 after Bascom's technique, and 33 with complex pilonidal disease that were randomly allocated by closed envelop technique into two groups. Group I (30 patients) the mean age was 29 ± 7.2 years (22 men, and 8 women) that underwent excision and Karydak's procedure (KP) and Group II (30 patients) the mean age was 28 ± 6.6 years (21 men, and 9 women) that underwent modified Limberg flap

procedure (MLFP). There was no significant difference between both groups regarding age, sex, type of previous surgery, preoperative symptoms, and period of follow up. Intermittent discharge and pain were the most common symptoms. Follow up (months) was 23.2 ± 7.65 for group I and 21.6 ± 8.32 for group II Table 1.

Operative data showed that the operative time (minute) for group I was 49.8 ± 7.3 that was significantly less than that for group II 52.7 ± 5.3 . However, there was no significant difference between both groups as regard hospital stay, pain score, period off work, and healing period Table 2.

Postoperative follow-up showed that there was no significant difference between both groups as regard incidence of complications with only two cases 6.67 % in group I and one case 3.33 % in group II with wound infection, and wound dehiscence. Parasthesia of the flap observed only with MLFP in 20 % of cases. Meanwhile recurrence occurs in only one case 3.33 in both groups Table 3.

Table 1. Patients demographic and pre-treatment symptoms.

	Group I (n=30)	Group II (n=30)	P Value
Males: Female	22:8	21:9	0.4230
Age (years)	29 ± 7.2	28 ± 6.6	0.2896
Previous surgery	14	13	0.3956
Lay open and curettage	8	7	0.3805
Bascom operation	6	6	0.5000
Complex sinus	16	17	0.6044
Follow up (months)	23.2 ± 7.65	21.6 ± 8.32	0.7500
Symptoms			
Discharge	30	30	0.5000
Pain	22	23	0.3805
Pruritus	16	17	0.3956
Bleeding	1	1	0.5000

NS – not significant.

Table 2. Outcome of surgery.

	Group I (n=30)	Group II (n=30)	*P value
Operation time (minute)	49.8 ± 7.3	52.7 ± 5.3	0.0444*
Hospitalization (days)	2.5 ± 1.3	2.4 ± 1.4	0.6118
Period off work (days)	16.7 ± 4.1	15.4 ± 3.2	0.9093
Pain VAS score	2.6 ± 1.7	2.3 ± 1.4	0.7692
Healing Period (days)	13.9 ± 3.1	14.6 ± 2.5	0.1718

VAS, visual analogue scale.

Table 3. Postoperative complications.

	Group I (n=30)	Group II (n=30)	*P value
Wound infection, n (percent)	2 (6.67)	1 (3.33)	0.7271
Flap oedema, n (percent)	3 (10)	2 (6.67)	0.6780
Wound dehiscence, n (percent)	2 (6.67)	1(3.33)	0.7271
Parasthesia, n (percent)	0 (0)	6 (20)	0.0049*
Recurrence , n (percent)	1 (3.33)	1(3.33)	0.5000

*student's unpaired t-test.

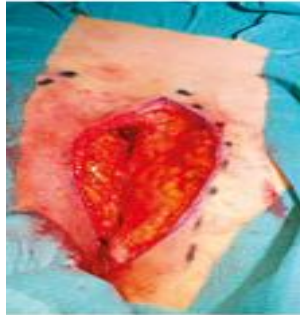


Fig 1. Elliptical skin incision which was made off midline with full-thickness flap is created on the opposite side of the semi lateral incision.



Fig 4. The rhomboid flap was then rotated from the gluteal fascia to the excised area without tension.



Fig 2. The wound was closed in multiple layers over a closed suction drain.

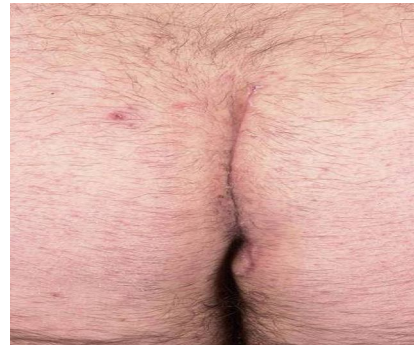


Fig 5. Stitches were removed after Karydakis flap procedure.

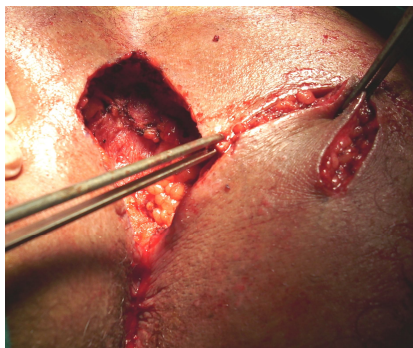


Fig 3. The lesion was excised with a rhomboid shaped incision with each side equal in length.



Fig 6. Stitches were removed after modified Limberg flap.

DISCUSSION

The goal for treatment of pilonidal disease is 2-fold. The first is excising and healing with a low rate of recurrence. The second is minimizing patient inconvenience and morbidity after the surgical procedure and avoiding hospitalization with loss of workdays. The method used to treat the patient should satisfy these goals.^(5,6)

Many conditions in surgery have a preferred operation for which supporting evidence may be thin (few if any randomized controlled trials (RCT)). Pilonidal sinus is one condition where there is no consensus as to the correct operation, yet there is actually sufficient level 1 evidence to make a choice.⁽⁹⁾

There have been many studies of various techniques with relatively small numbers along with varied follow up and outcomes. Allen-Mersh in 1990, in a careful survey of many studies, concluded that off-midline closure has the superiority over excision with primary closure and wide excision with second intention (open) healing, in terms of healing time and rate of recurrence.⁽¹⁰⁾ In 2002, Petersen et al. evaluated 74 publications, including 10 090 patients and showed lower recurrence rate with off-midline flap closure compared with midline closure.⁽¹¹⁾

In the last decade, 18 RCT have been published involving 1573 patients and these have now been analysed by McCallum et al. in Aberdeen in a Cochrane overview to provide evidence-based guidance for surgical treatment.⁽¹²⁾ The review concluded that off-midline closure is the best choice if the sinus is to be excised and sutured and is associated with short hospital stay and the lowest recurrence rate.

In the current study two flaps procedure Karydakias flap procedure and modified Limberg flap was compared in the treatment of recurrent and complex sacrococcygeal pilonidal disease. George karydakias described his procedure that lead to flattening of the cleft and off-midline closure with no part of the wound crossing the midline.⁽¹³⁾ The Limberg flap technique involves creation of a flap to achieve primary closure and to obliterate the deep natal cleft but lateralization of the inferior apex of the flap (modified Limberg flap technique) appears to provide a more efficient flattening of the natal cleft, including the most inferior part that is inclined to invert toward the anal region.⁽¹⁴⁾

In the current study, operative time for group KP was 49.8 ± 7.3 minute which was significantly less than that for MLFP 52.7 ± 5.3 minute similar results were achieved by Can et al,⁽¹⁵⁾ there was no significance difference between both groups as regard hospital stay, and time of work similar results were achieved by Ersoy et al,⁽¹⁶⁾ and Can et al.⁽¹⁵⁾ Visual Analogue Scale scores showed no significance difference between both groups similar results were achieved by Can et al,⁽¹⁵⁾ while Ersoy et al⁽¹⁶⁾ reported that there were significantly

higher values for need for analgesia in KP. Hospital stay for patients treated with MLFP was 2.4 ± 1.4 days, which was similar to 2 to 3 days as reported by Menten et al,⁽¹⁷⁾ and shorter than reported by Ebu Galala et al,⁽³⁾ and Katsoulis et al.⁽¹⁸⁾ 6 days and 4 days respectively. The mean hospital stay for patients treated with KP was 2.5 ± 1.3 days which was similar to the time period reported in many other series.^(19,20)

Postoperative follow-up showed that there was no significant difference between both groups as regard incidence of complications with only two cases 6.67 % in KP and one case 3.33 % in MLFP with wound infection, and wound dehiscence similar results were achieved by Can et al,⁽¹⁵⁾ while Ersoy et al⁽¹⁶⁾ reported that there were significantly higher wound infection rate in the Karydakias group than in the Limberg group (13/50 and 4/50 respectively). Menten et al. [18] have reported that wound dehiscence 1.7% and wound infection 6.5% occurred in 353 patients, for whom LFP was implemented. Karydakias⁽²¹⁾ reported 8.5% incidence of complications in his own large series of 6545 cases. Bessa et al.⁽²²⁾ reported wound infection in four (4.9%) patients out of 82 patients in whom KFP was used.

Parasthesia over the flap was reported with MLFP in 6 patients (20%) and never occur with KP in the current study. This may be due to interference with the nerve supply of the flap, especially large ones. This was also reported by Lodhi et al.⁽²³⁾ who used rhomboid flap in 30 patients, with 9 complaining of numbness over the flap and El-Khadrawy et al⁽²⁴⁾ Parasthesia was also reported in 11 patients (18.3%) in there study.

Recurrence showed no significant difference between both groups with only one case observed in both groups 3.33%, similar results were achieved by Can et al,⁽¹⁵⁾ and Ersoy et al.⁽¹⁶⁾ Karydakias⁽²¹⁾ reported recurrence rate below 1% upon healing of the wound. Anyanwu et al.⁽²⁵⁾ reported that there was no recurrence in 28 patients, who were followed up average for about three years with KP. Daphan et al.⁽²⁶⁾ reported recurrence in seven (4.8%) patients out of 147 LFP. Urhan et al.⁽²⁷⁾ reported recurrence in five (4.9%) patients out of 102 LFP. While Akca et al.⁽²⁸⁾ reported no recurrence with LFP after a median follow up of 28 (23–36) months.

In conclusion: Karidakias procedure should be the preferred method in treatment of recurrent and complex sacrococcygeal pilonidal disease, and Modified Limberg flap is relatively major procedure and its results was comparable to Karidakias method.

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Conflict of interest statement.

None declared.

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