

Original Research Article

Randomized Comparative Study of Four Lines of Treatment of Sacroccocygeal Pilonidal Sinus

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Abstract

Pilonidal sinus (PNS) is a blind epithelial tract. Various surgical and non-surgical modalities have been described for management of pilonidal disease. The aim of the study is to compare different techniques of management of sacroccocygeal PNS.

A prospective randomized comparative study was carried out in a tertiary General Teaching Hospital. 192 Patients with PNS were randomly distributed for the definitive surgical procedure in to four groups:(1) Excision and healing by secondary intention (EHSI),(2) Excision and Primary Closure (EPC), (3)Karydakakis Technique (KT) and (4)Limberg Flap (LF) techniques. Patients were seen regularly on postoperative days 5, 10, and 14 and then follow-up every 3 months for 24 months. Primary outcomes were post-operative complication, recurrence rate , while secondary outcomes were type of anesthesia, ASA, complain, BMI, duration of operation, removal of drain ,removal of stitching and pain free time. The overall mean age of all patients with PNS was (24.05±5.93) years old and (54.5%) of patients were aged between 20-30 years. (70.6%) of patients were males. There were no significant Comparison of Type of PNS treated groups with ASA, Complain and BMI. (60.0%) of all recurrence were among EPC type of operation. (50.0%) of seroma were for each of LF and KT.(67.7%) of partial dehiscence were by LF. There were significant Comparison of Type of PNS treated groups with pain free time, removal of stitching, removal of drain and duration of operation.

KT and LF were better than EPC and EHSI in the treatment of PNS disease because healing time is short, morbidity is low, low rate of recurrence because it flattens the natal cleft. KT showed lower rate of partial dehiscence when compared with LF procedure. KT is a promising procedure for the treatment of sacroccocygeal PNS.

Key words: Pilonidal Sinus, Karydakakis Technique, Limberg Technique, Recurrence rate.

دراسة مقارنة عشوائية من أربعة خطوط لعلاج جيب كيس الشعر العجزي العصصي

الخلاصة

جيب كيس الشعر هو قناة ظهارية عمياء. لقد وصفت مختلف الطرائق الجراحية وغير الجراحية لعلاجها. الهدف من الدراسة هو المقارنة بين عدة طرق لعلاج جيب الشعر العجزي العصصي.

أجريت دراسة مقارنة مستقبليّة عشوائية في المستشفى التعليمي العام الجامعي. وزع ١٩٢ مريض يعانون من جيب كيس الشعر عشوائياً لإجراء العمليات الجراحية في أربع مجموعات هي: (١) الاستئصال والشفاء ثانوي (٢) الاستئصال وغلقها ابتدائياً (٣) تقنية كاريدياكسو (٤) تقنية لمبرك. تمت متابعة المرضى بانتظام في أيام ما بعد الجراحة ٥ و ١٠ و ١٤ و ثم متابعة كل ٣ أشهر لمدة ٢٤ شهراً. وكان البحث عن النتائج الأولية وهي مضاعفات ما بعد الجراحة ، معدل الرجوع، في حين كانت النتائج الثانوية (نوع التخدير، تصنيف المريض حسب الجمعية الأمريكية لأطباء التخدير، شكوى المريض عند المراجعة، مؤشر كتلة الجسم ، مدة العملية ، وإزالة أنبوب التصريف، إزالة خيط العملية ومدة انتهاء الألم).

كان متوسط أعمارهم المرضى الشامل لجميع الذين يعانون من جيب كيس الشعر (24.05 ± 0.93) سنة و (54.5%) من المرضى كانت تتراوح أعمارهم ما بين 20-30 سنة. (70.6%) من المرضى من الذكور. لم تكن هناك مقارنة كبيرة بين مجموعات جيب كيس الشعر مع تصنيف المريض حسب الجمعية الأمريكية لأطباء التخدير، شكوى المريض ومؤشر كتلة الجسم. وكانت (60.0%) من كل رجوع الناسور في المجموعة التي عولجت بطريقة الاستئصال وغلقه ابتدائياً. (50.0%) من التورم المصلي كانت لكل من تقنية لمبركو تقنية كاريدياكس. (67.6%) من كل الانفلاق الجزئي كانت من قبل تقنية لمبرك. كانت هناك مقارنة كبيرة بين المجموعات لعلاج جيب كيس الشعر مع مدة انتهاء الألم، إزالة خيط العملية، إزالة أنبوب التصريف ومدة العملية.

كانت تقنية كاريدياكس و لمبرك أفضل من الاستئصال الناسور والشفاء ثانوياً أو الاستئصال وغلقها ابتدائياً في علاج جيب كيس الشعر لأن وقت الشفاء قصير، نسبة الاعتلال منخفضة، انخفاض معدل تكرار الناسور لأنه يسطح شق المولدي. أظهرت تقنية كاريدياكس انخفاض معدل الانفلاق الجزئي بالمقارنة مع إجراء تقنية لمبرك. تقنية كاريدياكس هو إجراء واعد لعلاج جيب كيس الشعر العجزي العصصي.

الكلمات المفتاحية: جيب الشعر العجزي، تقنية كاريدياكس، تقنية لمبرك، نسبة الرجوع.

Introduction

Sacrococcygeal Pilonidal sinus (PNS) is a blind epithelial tract situated in the skin of the natal cleft, a short distance behind the anus and generally containing hair. It is a commonly encountered condition in adult, and it causes significant morbidity[1]. It can result in an abscess, draining sinus tracts, and moderate debility for some. It probably results from hair penetration beneath the skin, for reasons that are not totally clear [2]. The accepted explanation for the pathogenesis of PNS was suggested by Karydakos[3] who attributed the happening of PNS to three main factors: the invader (loose hair), the force (causing insertion) and the skin vulnerability (depth of the natal cleft). PNS might occur in different parts of the body such as umbilical[4], finger pulp, axilla[5], nipple areola but it is often formed in sacrococcygeal area [6] in young men. Various surgical and non-surgical modalities have been described for management of pilonidal disease from a simple phenol injection to a complex flap mobilization, but an ideal treatment has not been determined because of substantial complications and high rate of recurrence [7]. Several surgical techniques are being performed in the treatment of pilonidal sinus disease; however there is no single agreed technique that could be used in all patients [8]. These different techniques vary from simple drainage[9], excision of the sinus tract followed by either primary closure or healing by secondary

intention[10], fibrin glue and phenol injection [11], V-Y advancement flap[12], Limberg flap, Karydakos flap techniques[13] and Bascom procedure[14]. Surgeon's experience and disease condition may affect the option and the most appropriate treatment which should offer the least recurrence and postoperative complication rate with the highest patient satisfaction[6].

The aim of our study was to evaluate and compare between Excision and healing by secondary intention (EHSI), Excision and Primary Closure (EPC), Karydakos Technique (KT) and Limberg Flap (LF) techniques for the treatment of patients with sacrococcygeal PNS as regard duration of operation, time of healing, hospital stay, complications and recurrence rate.

Materials and Methods

Study design/Study Location

This hospital-based prospective randomized comparative study was carried out in a tertiary General Teaching Hospital.

Study population

All patients with diagnosed PNS in wards and outpatients general surgery clinic in Babylon Teaching Hospital between December 2009 and January 2014 were included in this study.

Inclusion criteria:

Patients with primary non recurrent and uncomplicated pilonidal sinus were included in the study.

Exclusion criteria:

Patients not willing to give informed consent. Patient with chronic medical conditions, such as diabetes mellitus, immunosuppressant and renal failure were excluded from the study. Patients loss to follow up were also excluded.

Randomization is done by choosing the type of surgery by the patient. The patient select one of the lines of treatment (LF, KT, EPC or EHSI) which were written on a paper in a closed envelope.

Instruments and procedure

All patients received a single intravenous dose of ceftriaxone at the time of induction of anesthesia and at 12 hr postoperatively for 48 hr and then shifted to oral forms amoxicillin and clavulanic acid 1 g every 12 h, plus metronidazole 500 mg three times per day for 7 days.

Open method(EHSI and EPC):

All patients were operated in the operating room. After anesthesia, the patient was placed in the prone position with the buttocks strapped apart using wide adhesive tape. Then probing and injection of methylene blue. An elliptical incision parallel to the midline is made. The sinuses are excised with the surrounding skin and subcutaneous fat to the level of sacrococcygeal fascia and then proper hemostasis is induced with diathermy, and any side tracks are unroofed using a fistula probe. In EHSI The resulting opened wound is packed with gauze while in EPC the wound is closed by 2/0 nylon.

LimbergFlap procedure:

All patients were operated on in the operating room. After anesthesia, the patient was placed in the prone, jack-knife position, with the buttocks strapped apart using wide adhesive tape. The excision was carried down to the fascia overlying the sacrum. A Limberg flap was prepared from the right or left gluteal region. A suction drain was placed through a separate incision that was located 2 cm lateral from the initial incision and maintained in place until the drainage decreased to less than 20 ml/day

KarydakisTechnique procedure:

Operations were performed with the patient in the prone position with the buttocks strapped apart. Probing of the sinus is carried out, followed by injection of methylene blue. A Karydakis flap was created after elliptical asymmetrical biconcave excision. A suction drain was placed through a separate incision that was located 2 cm lateral from the initial incision in all patients and were maintained in place until the drainage decreased to less than 20 ml/day.

Postoperative follow up:

Patients were seen regularly on postoperative days 5, 10, and 14 for wound inspection and removal of sutures and continued to be seen until complete healing was achieved. Drain was removed when collecting fluid less than 20 ml/day. Any wound complications were recorded. Consider sitting in toilet without pain is the pain free time and recorded. Patients were advised to shave intergluteal cleft and adjacent buttocks and keep the operative area clean and dry at all times. Patients were informed to follow-up every 3 months for 24 months by contact them by phone and to be seen at any time of suspected recurrence.

Primary outcomes were post-operative complication, recurrence rate, while secondary outcomes were type of anesthesia, ASA, complain, BMI, duration of operation, removal of drain, removal of stitching and pain free time.

This study had been authorized by Babylon health directorate/Babylon general teaching hospital as well as this study has been acknowledged by College of Medicine University of Babylon. Consent form has been obtained from all patients who agreed to participate in this study.

Statistical Analysis

Statistical analysis was carried out using SPSS version 20. Categorical variables were presented as frequencies and percentages. Continuous variables were presented as means with their 95% confidence interval (CI). The Pearson's chi-square test (χ^2) test was used to determine

the associations between categorical variables. A p -value of ≤ 0.05 was considered as statistically significant.

Results

Distribution of Patients with PNS by Age and Sex

The overall mean age of all patients with PNS was (24.05 ± 5.93) years old and (54.5%) of patients were aged between 20-30 years (Figure 1).

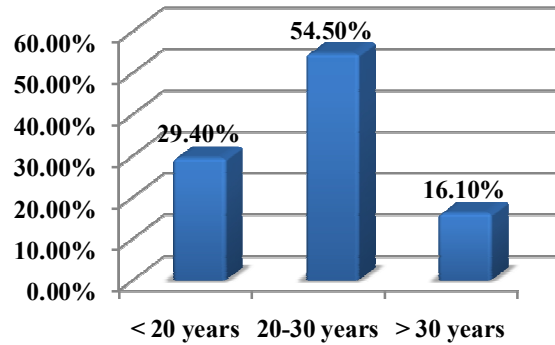


Figure 1: Distribution of patients with PNS by age groups

Figure 2 shows the distribution of patients with PNS by sex. (70.6%) of patients were males.

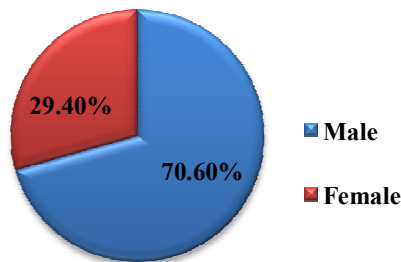


Figure 2: Distribution of patients with PNS by sex

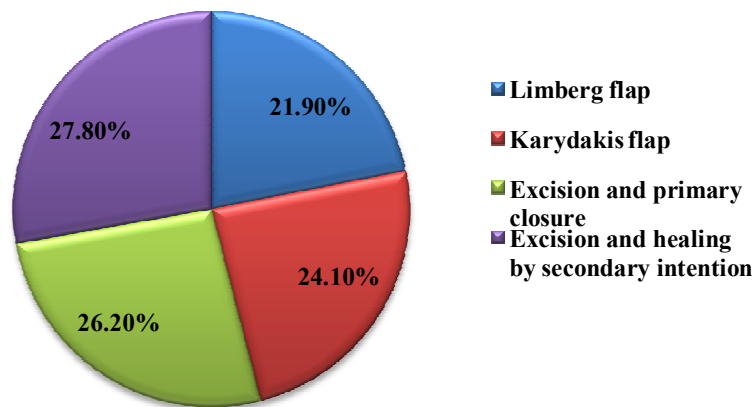


Figure 3: Distribution of Patients with PNS by Type of Operation

Distribution of Patients with PNS by Type of Operation

Figure 3 shows the Distribution of Patients with PNS by Type of Operation. Overall

patients was 192. (21.9%) of patients underwent LF, (24.1%) underwent KT, (26.2%) underwent EPC, meanwhile, (27.8%) of patients underwent EHSI.

Comparison of Type of PNS by Age and Sex

Table 2 shows the comparison of Type of PNS by Age and Sex. There was no

significant association between type of PNS line of treatment and each of age or sex.

Table 1: Comparison of Type of PNS by Age and Sex

Variable	Type of PNS				χ^2	P value
	LF (%)	KT (%)	EPC (%)	EHSI (%)		
Age Groups (years)						
< 20 years	10 (24.4)	16 (35.6)	15 (30.6)	14 (26.9)	2.084	0.912
20-30 years	25 (61.0)	23 (51.1)	26 (53.1)	28 (53.8)		
> 30 years	6 (14.6)	6 (13.3)	8 (16.3)	10 (19.2)		
Sex						
Male	31 (75.6)	31 (68.9)	34 (69.4)	36 (69.2)	0.641	0.887
Female	10 (24.4)	14 (31.1)	15 (30.6)	16 (30.8)		

*p value of ≤ 0.05 is significant

Comparison of Type of PNS with Type of Anesthesia, ASA, Complain and BMI

Table 2 shows the Comparison of Type of PNS with Type of Anesthesia, ASA,

Complain, BMI and complication. There were no significant Comparison of Type of PNS with ASA, Complain, BMI and complication.

Table 2: Comparison of Type of PNS with Type of Anesthesia, ASA, Complain, BMI and complication

Variable	Type of PNS				χ^2	P values
	LF (%)	KT (%)	EPC (%)	EHSI (%)		
Type of Anesthesia						
GA	27 (65.9)	28 (62.2)	32 (65.3)	31 (59.6)	16.224	0.013*
SA	14 (34.1)	13 (28.9)	11 (22.4)	8 (15.4)		
LA	0 (0.0)	4 (8.9)	6 (12.2)	13 (25.0)		
ASA						
I	36 (87.8)	34 (75.6)	41 (83.7)	44 (84.6)	2.535	0.469
II	5 (12.2)	11 (24.4)	8 (16.3)	8 (15.4)		
Complain						
Itching	15 (36.6)	15 (33.3)	18 (36.7)	18 (34.6)	1.159	0.979
Pain	14 (34.1)	18 (40.0)	15 (30.6)	17 (32.7)		
Discharge	12 (29.3)	12 (26.7)	16 (32.7)	17 (32.7)		
BMI						
Normal weight	16 (39.0)	17 (37.8)	20 (40.8)	21 (40.4)	1.409	0.965
Overweight	22 (53.7)	23 (51.1)	26 (53.1)	25 (48.1)		
Obese	3 (7.3)	5 (11.1)	3 (6.1)	6 (11.5)		
Complication						
Present	8 (19.5)	6 (13.3)	11 (22.4)	6 (11.5)	2.774	0.428
Absent	33 (80.5)	39 (86.7)	38 (77.6)	46 (88.5)		

*p value of ≤ 0.05 is significant

Comparison of Type of PNS by Complications

Figure 4 shows the comparison of Type of PNS by Complications. (60.0%) of recurrence were among EPC type of

operation. (50.0%) of seroma were for each of LF and KT. (35.7%) of infection were for each of EPC and EHSL. (67.7%) of partial dehiscence were by LF.

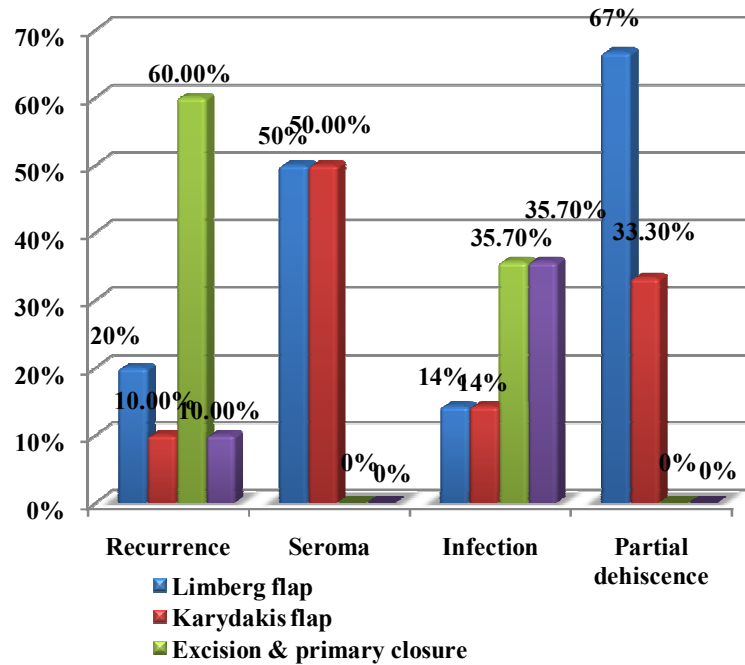


Figure 4: Comparison of Type of PNS by Complications

Comparison of Type of PNS with pain free time, removal of stitching, removal of drain, duration of operation and follow up

Table 3 shows the Comparison of Type of PNS with pain free time, Wound closure

and healing, removal of drain, duration of operation and follow up. There were significant Comparison of Type of PNS with pain free time, removal of stitching, removal of drain and duration of operation.

Table 3: Comparison of Type of PNS with pain free time, wound closure and healing , removal of drain, duration of operation and followup

Variable	Type of Operation	N	Mean	S.D	ANOV A	P value
Pain free time (day)	LF ^{C,D}	41	16.19	4.11	29.589	<0.001*
	KT ^D	45	14.26	4.27		
	EPC ^{A,D}	49	12.87	3.58		
	EHSI ^{A,B,C}	52	21.92	7.47		
	Total	187	16.45	6.28		
Wound closure and healing (day)	LF ^D	41	13.19	2.02	436.615	<0.001*
	KT ^D	45	12.51	1.71		
	EPC ^D	49	12.48	1.75		
	EHSI ^{A,B,C}	52	47.82	10.87		
	Total	187	22.47	16.84		
Removal of drain (day)	LF ^{B,C,D}	41	3.95	0.94	523.357	<0.001*
	KT ^{A,C,D}	45	2.91	0.82		
	EPC ^{A,B}	49	0.00	0.00		
	EHSI ^{A,B}	52	0.00	0.00		
	Total	187	1.56	1.83		
Duration of operation (min)	LF ^{C,D}	41	49.07	6.17	357.473	<0.001*
	KT ^{C,D}	45	48.84	6.56		
	EPC ^{A,B,D}	49	26.79	6.43		
	EHSI ^{A,B,C}	52	17.40	3.83		
	Total	187	34.37	15.06		
Follow up (month)	LF	41	21.58	3.86	1.497	0.217
	KT	45	22.00	2.86		
	EPC	49	20.45	4.73		
	EHSI	52	20.77	4.19		
	Total	187	21.60	4.01		

*p value of ≤ 0.05 is significant
A,B,C and D are the significantly differences of individual group from other groups

Discussion

The overall mean age of all patients with PNS was (24.05±5.93) years old and (54.5%) of patients were aged between 20-30 years. This agrees with [8][15][16][17] in which Pilonidal sinus disease (PSD) most commonly occurs in the 2nd and 3rd decade of life.

In our study (70.6%) of patients with PNS were males. This agrees with [15, 17, 18, 19, 29] in which invader (loose hair) in manis more common than woman and that support the path physiology beyond PNS formation.

There was no significant difference between the four lines of treatment in regard to age , sex, ASA and Complain.

Regarding BMI There were no significant deference between groups treated. Overweight and Obese patients form 61%, 62.2%, 59.2% and 59.6% in LF , KF, EPC and EHSI respectively. It appear that high BMI might be a risk factor for the development of PNS and might be a significant risk factors for the development of complication after surgery [3, 21, 22].

Duration of operation (min)

The mean operative time in the KF group was 48.84± 6.56 min, compared with 49.07± 6.17 min in the LF group, 26.79±6.43 min in EPC and 17.40 ± 3.83 min in EHSI. It was found that the operative time was significantly shorter in the EHSI and EPC groups than in the KF and LF groups (P = <0.001).This agree

with [22,23] in which the operative time in KT was (43.2 ± 8.9 , 45 ± 7.72 ,) respectively and (39.1 ± 6.8 , 23.4 ± 4.05 ,) respectively in open techniques and in [6] LF was 55.14 ± 7.8 and 40.7 ± 6.9 in EPC group.

Pain free time

The mean Pain free time in the LF group was 16.19 ± 4.11 days, compared with 14.26 ± 4.27 days in the KT group, 12.87 ± 3.58 days in EPC and 21.92 ± 7.47 days in EHSI. It was found that the Pain free time in EPC was significantly longer than other lines of treated groups ($P = <0.001$). EPC was significantly different from EHSI and LF and significantly differ from KT procedure.

Closed method (EPC) was found to be better than open method (EHSI) in term of pain free time and early return to work.[24] Karydakakis technique showed shorter hospital stay, earlier pain free time , healing, and shorter duration of work-off when compared with the open technique [23].

When comparing between LF and KT ,the mean pain free time is more in LF, may be because there were more tension in the suture line and big incision in LF in contrast to KT and that is agreed with [8]in which less postoperative pain and early return to work in KT group.

Type of Anesthesia

In regard to comparison of type of PNS treated groups with type of Anesthesia ,There was a significant difference between EHSI group and the other treated groups in which local anesthesia form 25% of treated group with EHSI. Patients in the general anaesthesia group spent more time in the operating theatre ,Two thirds of the patients in the local anaesthesia group left hospital on the day of surgery and postoperative analgesia requirements were greater in the general anaesthesia group[25].

Removal of stitches and wound closure(day)

The mean duration of removal of stitches and wound closure in the KF group was 13.19 ± 2.02 days, compared with 12.51 ± 1.71 days in the LF group, 12.48 ± 1.75

days in EPC and 47.82 ± 10.87 days in EHSI. It was found that the duration of wound closure was significantly longer in EHSI group than the other lines of treated groups ($P = <0.001$). This agreed with [9, 10, 26].

Follow up (month)

The mean duration of Follow up in the KF group was 21.58 ± 3.86 month, compared with 22.00 ± 2.86 month in the LF group, 20.45 ± 4.73 month in EPC and 20.77 ± 4.19 month in EHSI. It was found that the duration of Follow up was not significantly different in all lines of treated groups ($P = 0.217$).

Postoperative complications:

There were no significant differences between the four arms of treated groups in regard to postoperative complications in which 19.5% of complications occur in LF, 13.3% in KT ,11% in EPC and 11.5% in EHSI.

(60.0%) of recurrence in all treated group were among EPC type of operation, this agreed with [6][23] in which LF and KT are better than excision and primary repair in treatment of PNS in term of recurrence because it flattens the natal cleft, avoid dead space.

(50.0%) of seroma in all treated group were for each of LF and KT. This agreed with [27-29]in spite of using of drainage tubes because there were extensive dissection.

(67.7%) of partial dehiscence in all treated group were by LF. Despite the risk of wound complications, this method is particularly useful for complex sinuses with extended tracts where radical excision leaves a large defect [30, 31].

Limitations of the study:

Limitations of our study were exclusion of complicated patients. The recurrence rate should be further evaluated by increasing time of follow up and increasing sample size to be statistically of value. Adding other parameters like pain scores. Blinding of patients and the data interpreter is very important factor when studying subjective variable .In the absence of masking, bias

can occur and can be markedly influenced by the enthusiasm for the new technique.

Conclusion

KT and LF were better than EPC and EHSI in the treatment of PNS disease because healing time is short, morbidity is low, low rate of recurrence because it flattens the natal cleft. KT showed lower rate of partial dehiscence when compared with LF procedure. KT is a promising procedure for the treatment of sacrococcygeal PNS.

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