

OUTCOME OF OPEN VERSUS CLOSED SURGICAL TECHNIQUE FOR TREATMENT OF CHRONIC PILONIDAL SINUS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

OBJECTIVE: To compare the outcome of “excision with leaving open” versus “excision with primary closure” of chronic pilonidal sinus (PNS) of sacrococcygeal area in terms of hospital stay, wound healing, return to work and postoperative complications.

METHODOLOGY: This study was conducted at surgical unit Divisional Headquarter Hospital Kohat, Pakistan during the period April 2007 to April 2009. Thirty confirmed cases of chronic PNS were included in the study. Patients were randomly assigned to two groups i.e. group-A (excision with leaving open) & group-B (excision with primary closure). Data was collected prospectively on structured proforma. Patients were regularly followed up for 2 years for complications. Statistical analysis was done by using SPSS version 14.

RESULTS: Out of 30 patients, 26 (86.7%) were males and 4 (13.3%) were females with mean age of 28.47 +/-9.75 years. Group-A included 16 (53.30%) patients while Group-B included 14(46.70%) patients. The patients in group-B had shorter hospital stay (3.5 ± 0.6504 vs. 4.7 ± 0.5774 days, $p < 0.01$), faster recovery (2.78 ± 0.6993 vs. 7.15 ± 1.0602 weeks, $p < 0.01$) and earlier return to work (16.42 ± 5.4591 vs. 29 ± 3.7238 days, $p < 0.01$). No significant difference was found in both the groups in terms of short and long term postoperative complications. Wound Infection ($n=5/30$; 16.7%) and itching 5 ($n=5/30$; 16.7%) were the commonest short term complication while recurrence ($n=3/30$; 10%) and hypertrophic scar ($n=3/30$; 10%) were the commonest long term complications.

CONCLUSION: Closed method was found to be better than open method in chronic pilonidal sinus in terms of recovery, hospital stay and time of work.

KEY WORDS: Pilonidal sinus disease, Randomized controlled trial, Postoperative complications, outcome.

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INTRODUCTION

Pilonidal sinus (means nests of hair) is a blind ended track having lining of granulation tissue leading to a cystic cavity, which often contains loose hair.¹ The most common area affected is intergluteal cleft.² Sacrococcygeal pilonidal sinus disease a common surgical problem constituting a significant portion of the patients treated in surgery clinics worldwide.³ It commonly affects young men and does not occur in childhood, which suggests that it has an acquired etiology.⁴ The estimated incidence of sacrococcygeal pilonidal sinus disease is 26 per 100,000, people and males are affected twice often as women.⁵ The condition is more common in Caucasians than Asians or Africans due to different hair characteristics and growth.⁶ Hairy skin, obesity, excessive sweating, wearing of tight clothing, occupations such as barbers and sitting for long periods are among the predisposing factors leading to PNS of the natal cleft.⁷

Pilonidal sinus disease may present as an asymptomatic, acute, chronic or recurrent condition⁸ but the most common presenting complaints are discharge, pain and swelling.⁹ However, thorough examination with investigations is recommended in order to exclude associated pathologies.¹⁰ PNS can be associated with considerable morbidity and have signifi-

cant socioeconomic impact on individuals affected.

Various surgical techniques like laying the track open, electurization chemical treatment with phenol, marsupialization, wide excision, excision with primary simple midline or asymmetric closure and techniques involving various plastic procedures have been tried for sacrococcygeal pilonidal sinus disease. Ideal treatment for this disease is controversial¹¹ as all the treatments currently available have their pros and cons.¹² So widely acceptable and ideal treatment modality has still not yet been established and in majority of the cases surgeon uses his own surgical experience. Ideal treatment is one which encompasses decreased time, low cost, less early postoperative complications, rapid time of recovery, minimal hospital stay and rapid recovery to work and results in least number of long-term recurrences.¹³

The most commonly performed procedures are excision with primary closure and excision with laying the wound open for healing by second intention. All surgical procedures have their merits and demerits and the management of PNS is often unsatisfactory.¹⁴ In Pakistan various studies have been conducted on excision with or without primary closure of chronic pilonidal sinus with variable results. This study was conducted to compare the outcome of "excision with leaving open" versus "excision with primary closure" of chronic pilonidal sinus in our set up.

METHODOLOGY

This prospective analytical, randomized controlled trial was conducted at Surgical Unit Divisional Headquarter Hospital, Kohat, Pakistan during the period April 2007 to April 2009. Thirty confirmed patients of PNS of sacrococcygeal area were randomized by using computer-generated table of random numbers, irrespective of gender and

age in two groups for convenience of treatment as follows:

Group A (Open Group):- Excision alone or open method

Group B (Close Group):- Excision with primary closure

Inclusion criteria comprised of patients of PNS disease of sacrococcygeal area including simple, complex (complex case is one which is due to re-infection in neighboring hair follicles or chronic infection from entry of hair or debris into a postoperative wound) and recurrent, of either gender above the age of 14 years. Those patients who were suffering from any generalized or debilitating disease, diabetes mellitus, unwilling for follow-up, or patients unfit for general anesthesia and patients who were hepatitis B and C positive were excluded.

Approval from the ethical committee and prior informed consent was taken from the patients.

All the cases were thoroughly examined and the relevant investigations were performed. Fitness for general anesthesia was taken priorly. All the patients were given three injections of 1.5 gm Cefuroxime intravenously at the time of induction, after 8 hours and 16 hours postoperatively.

Techniques

Group-A (Open)

This group consists of patients of PNS disease who were treated with excision and then the wound was left open to heal by secondary intention. Patients were placed in prone position. After cleaning the skin with disinfectant, an elliptical incision was given to include all the sinus tracts. If any sinuses were situated laterally, the incision was extended to include that. Dissection was carried down to the fascia covering the coccyx. Then traction was given and by gauze dissection and scissors, the cyst was usually removed

intact. Hemostasis was secured with diathermy. The wound was then left open, followed by application of sterile dressing soaked in Pyodine. Over this, a firm dry dressing of gauze and wool is applied and secured gently with Nichiban. The wound was examined on the second post-op day. Daily bath irrigations and gauze dressings were changed regularly every day. Patients were kept in hospital for at least five days and were then seen in out-patient according to the follow-up schedule given in the proforma.

Group-B (Closed)

This group of patients was treated with excision followed by primary closure of the wound. Patients were placed in the prone position. After cleaning the skin with disinfectant, an elliptical incision was given to include all the sinus tracts. Hemostasis was secured with electrical diathermy. Suction drain (redivac drain) was put through a separate opening into the wound and secured with nylon sutures. The defect was then assessed for capacity to be closed primarily. Vicryl sutures were put deep down to reach the sacral fascia. Finally the skin was closed with prolene sutures. A firm gauze dressing was then applied. Post-operatively, patients were nursed on their backs and were advised to keep their movements in bed to minimum. They were advised to follow better toilet manners and avoid fecal contamination of wound. The patients were usually discharged on the third post-op day with the same advice of wound care. Then they were followed as out-patients according to the schedule given in the Proforma.

Data was collected prospectively on an especially designed structured proforma and consisted of patient demographics, medical history, presentation, any post-op complications, length of hospital stay, length of healing time, and time spent off work. Patients were regularly followed up for two year in the OPD for any complications.

The results were analyzed using the statistical package for social sciences (SPSS) Windows version 14. For comparison between groups, Fischer's exact probability test was applied. P-value < 0.05 was considered statistically significant.

RESULTS

A total of 3245 patients had reported in surgical outpatient department from April 2007 to April 2009. Among them, 1860 (57.62%) were admitted in hospital. Among 1870 indoor cases, 559 (29.9%) belonged to perianal disease and

30 (1.6%) were diagnosed with pilonidal sinus disease (PNS).

All 30 patients were managed for PNS during the above mentioned time period. Almost all patients presented in the out-patient department either as acute pilonidal abscess or chronic pilonidal sinus and some with complex or previously treated pilonidal sinus.

Out of 30 patients, 26 (86.67%) patients were male and 4 (13.33%) patients were female. The male to female ratio was 6:1.

Overall mean age was 28.47+9.75

years and the age range was 14-50 yrs. Out of 30 patients, 19 (63.3%) patients were less than 30 yrs of age, 6(20%) patients were from 30-40 years and 5 (16.7%) patients were above 40 years of age.

Local hair distribution in patients with pilonidal sinus show that 76.7% (n=23/30) patients had moderate hair distribution and 23.3% (n=4/40) cases had no local hair distribution.

In 16.7% (n=5/30) cases, pilonidal sinus was recurrent and the rest of the cases had the disease diagnosed for the first time.

TABLE I: COMPARISON OF CLOSE AND OPEN METHODS IN TERMS OF HEALING TIME, DURATION OF HOSPITAL STAY AND TIME OFF WORK

Variables	Method	Mean±SD	95% CI	t statistic	p-value
Healing Time in Weeks	Open Method	7.1563 ±1.0602	6.5913-7.7212	3.929	< 0.01
	Close Method	2.78 ±0.6993	2.3820-3.1895		
Duration of Hospital Stay in Days	Open Method	4.75±0.5774	4.4424-5.0576	9.4558	< 0.01
	Close Method	3.50 ± 0.6504	3.1244-3.8756		
Time off Work In Days	Open Method	29.0 ±3.7238	27.0157-30.9843	11.260	< 0.01
	Close Method	16.4286±5.4591	13.2766-19.5806		

TABLE II: COMPARISON OF CLOSE AND OPEN METHODS IN TERMS OF AGE OF PATIENTS

Operation Method	Age		t test value	p value
	Mean ± SD	95% CI		
Close Method	27.86±8.49	22.95-32.76	0.22	> 0.1
Open Method	29±10.98	23.15-24.85		

TABLE III: COMPLICATIONS OF CLOSE AND OPEN METHODS OF CHRONIC PILONIDAL SINUS

Complications		Open Methods (n= 16)	Close Method (n= 14)	Total (n=30)	p-value
Short Term Complications	Wound Infection	4 (25%)	1 (7.1%)	5 (16.7%)	> 0.05
	Itching	1 (6.25%)	4 (28.6%)	5 (16.7%)	> 0.05
	Chest Infection	1 (6.25%)	2 (14.3%)	3 (10%)	> 0.05
	Wound Dehiscence	0	2 (14.3%)	2 (6.7%)	> 0.05
	Hematoma	0	2 (14.3%)	2 (6.7%)	> 0.05
	Seroma	0	1 (7.1%)	2 (6.7%)	> 0.05
	Post-Op Pain	2 (12.5%)	0	2 (12.5%)	> 0.05
	Bleeding From Wound	1 (6.25%)	0	1 (3.3%)	> 0.05
Long term complications	Recurrence	2 (12.5%)	1 (7.1%)	3 (10%)	> 0.05
	Hypertrophic scar	0	3(21.4%)	3 (10%)	> 0.05

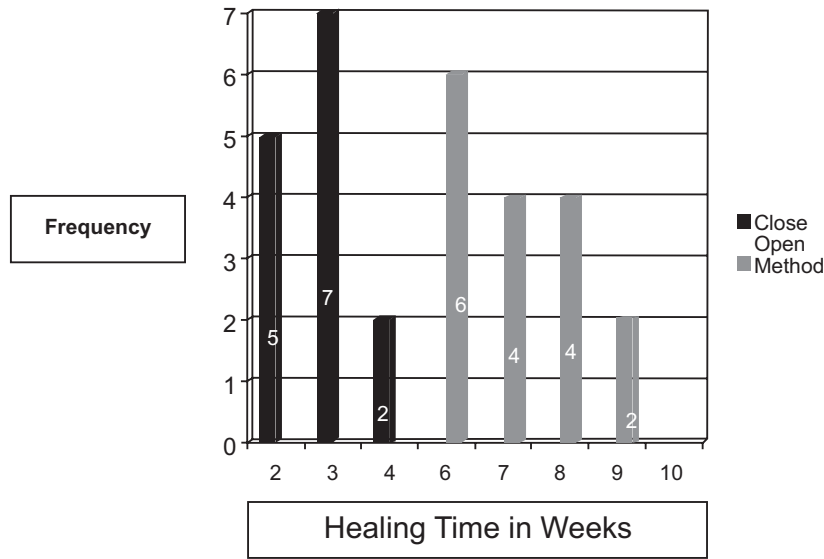


Figure 1: Healing time in weeks in open and closed methods

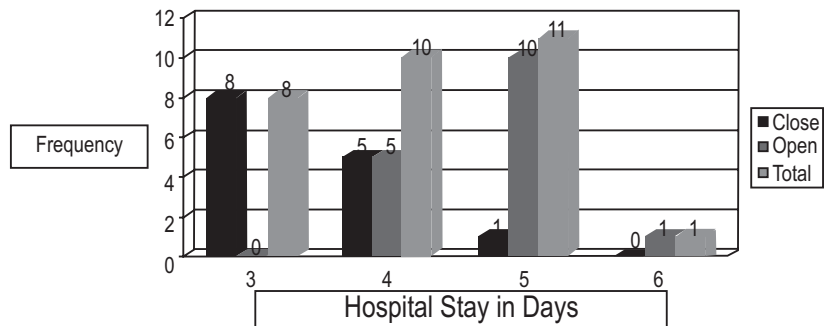


Figure 2: Days of hospital stay in open and closed methods

Duration of the pilonidal sinus was less than one year in 60% (n=18/30) cases, 2 years in 26.7% (n=8/30) cases and 3 years in 13.3% (n=4/30) cases.

Patients with pilonidal sinus disease were divided into two groups according to type and mode of treatment.

Group-A (open): It consisted of patients with chronic pilonidal sinus disease and were treated with excision alone. The group comprised of 16/30 (53.3%) patients.

Group-B (closed): It consisted of patients who had chronic pilonidal sinus disease and were treated with excision and primary closure of the wound. This group comprised of 14/30 (46.7%) patients.

Comparison of the two methods of treatments regarding healing time

showed significantly prolonged healing time in open method (Table I). Overall median healing time was 6 weeks. Fifty percent of patients (n=7/14) in close method had healing time of 3 weeks and 37.5% patients (n=6/16) of open method had healing time of 6 weeks (Figure 1).

Duration of hospital stay in days was significantly more in patients operated by open method as compared to close method (Table I). Overall median hospital stay was 4 days. In close method, 57.14% (n=8/14) patients had hospital stay of 3 days and in open method 62.5% (n=10/16) patients had hospital stay of 5 days (Figure 2). Time off work in days was significantly shorter in close than in open group (Table I). Mean time off work was 16.42+4.45 and 29.00+3.72 in close and open groups respectively with p-value < 0.01.

Both groups when compared regarding age showed no significant difference in age (Table II).

Short term complications showed no significant difference in both groups (Table III).

Overall wound infection and itching were the most common complications (16.7% each). In open method wound infection (25%) was the most common complication and in close method itching was more common (28.6%). Few stitches were removed in infected cases of group A. All the cases were managed conservatively by application of local antiseptics dressings and use of oral antibiotics according to culture and sensitivity reports. In all the infected cases staphylococcus aureus and streptococcus hemolyticus were grown which were sensitive to amoxicillin+clavulanic acid (augmentin).

Three patients in group B developed small postoperative haematoma/seroma but no intervention was needed and it resolved with conservative treatment. No significant difference was found in both the groups in terms of short and long term postoperative complications (Table III). Hypertrophic scar occurred in closed group only. Recurrence was 12.5% and 7.1% in open and close methods respectively in 24 months of follow-up. Overall recurrence rate was 10% (n=3/30).

DISCUSSION

In the management of pilonidal sinus disease, surgical treatment was introduced about a hundred years ago. During the last century several new methods and various modifications in the conventional approach have been tried, but still there is a controversy regarding the best management options of PNS. However, there is a consensus in the management of PNS that an ideal therapy should include complete eradication of the sinus tract with healing of the overlying skin,

permits patients to resume early their normal daily life activity, minimal wound care, less time off work, least rate of complications including prevention of reappearance.¹⁵⁻¹⁸

In our study two commonly used methods, excision with leaving the wound open and excision with primary wound closure of chronic pilonidal sinus were compared. Duration of hospital stay, healing time and time off work were significantly prolonged in patients operated by open method as compared to close method. In our study the mean duration of hospital stay was significantly shorter (35 ± 0.65 days) in close method than the open group (4.75 ± 0.57 days). Bukhari AJ et al¹⁹ in their study on wide excision and asymmetric closure by Karydak's technique showed a shorter hospital stay of 6.75 ± 3.11 days in Karydak's closure group as compared to 9.75 ± 4.16 days in the open group. Similarly Al-Salamah MS et al²⁰ have shown a significantly shorter hospital stay for excision with midline closure group (mean = 3.6 ± 1.4 days) than for excision without closure group (mean = 4 days). Malik AM et al²¹ had similar results showing the mean stay of 3.23 days and 6.74 days in Karydak's closure and open excision group respectively. These studies support close excision of PNS in terms of short hospital stay. In our study mean healing time was 2.78 ± 0.69 weeks in close method and 7.15 ± 1.06 weeks in open group.

Pilonidal sinus disease is a disease of the young, mainly occurring in the second and third decade of life.^{19,22} Our study also supports this fact as 63.3% of our patients were <30 years of age.

In our study 86.7% of the patients were males and only 13.3% were females. This supports other international and national studies reporting higher frequency of PNS in males.^{20,23}

In 60% of the cases duration of PNS before presentation was less than one

year. Weight and local hair distribution have got its unique importance in the development of pilonidal sinus disease. In our study 76.70% of the cases of PNS had local moderate hair distribution and 20% of the patients were overweight. Different authors have commented similarly in the studies regarding the weight and the local hair distribution in the occurrence of this debilitating disease.^{24,25}

Five (16.70 %) patients of PNS were recurrent in our study. Four of them had undergone excision with primary closure while one had been treated by excision with laying open technique in the past.

In our study, healing time was significantly reduced in closed group (3 weeks) as compared to open group (6 weeks). Other similar studies support this finding.^{14,21,26,27} The time off work was significantly shorter (mean 16.42 vs. 29.00 days) between these two groups (p-value <0.01) which is in accordance with other studies.²⁸⁻³¹

The mean hospital stay was less in closed group (3.50 days) as compared to the open group (4.75 days) which is statistically significant (p < 90.01). These results are comparable to those cited in the literature.^{28,29,32-34}

There was no significant difference in short term as well as long term complications in both the groups separately (p < 0.05). The recurrence rate in the closed group and open group was 3.7% and 3.00% respectively, which was statistically not significant. These figures correlate well with the prevailing literature.^{14, 20,29}

This series of 30 patients is too limited to permit final conclusions to be drawn concerning significant advantages of one form of treatment compared to the other. Nevertheless, primary closure offers the advantage of quicker healing time, fewer post-operative visits and shorter time off work. When a primary closure can be carried out, it should be routinely considered for socioeconomical and comfort reasons.

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

- STAS:** Conception and design, acquisition of data, drafting the manuscript, final approval of the version to be published
- MT & MN:** Acquisition and analysis of data, final approval of the version to be published
- SAP & KW:** Critical revision, drafting the manuscript, final approval of the version to be published

CONFLICT OF INTEREST

Author declares no conflict of interest

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