Original Article

Comparison of the Postoperative Pain, Septal Perforation and Synechiae Formation following Septoplasty done with Trans Septal Suturing Verus Nasal Packing

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- ¹ Manuscript Writing
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Abstract

Objective: To compare the efficacy of trans-septal suturing with nasal packing following septoplasty in patients with the deviated nasal septum, in terms of frequency of postoperative pain, septal perforation, and synechiae formation.

Materials and Methods: A randomized controlled trial was conducted in the ENT department of Benazir Bhutto Hospital Rawalpindi. Patients were divided into two groups. The total sample size of the study was 280 patients with 1:1 randomization in each group (140 in each group). Consecutive non-probability sampling was used for the recruitment of patients. All the patients underwent a septoplasty. Group A was provided with nasal packing while group B was with trans septal suturing. The study duration was 1 year (21-11-2016 to 21-11-2017). All the patients were followed at 24 hours for measurement of postoperative pain and at 1 and 4 weeks for septal perforation and synechiae formation. Ethical approval was taken from the ethical review board and consent was taken from patients. Data were analyzed using SPSS version 22. The Chi-square test was applied for observing the association between different variables.

Inclusion Criteria

- Patients with deviated nasal septum.
- Patients' ages ranged from 17-35 years.
- Patients of both genders were included.

Exclusion Criteria

- > Patients with diabetes mellitus.
- Patients with allergic rhinitis.
- Patients with coagulopathies, pulmonary and cardiovascular disorders.
- Patients taking warfarin, aspirin, or heparin.

Results: Among all the patients 280 (100%), there were 123(43.9%) males and 157(56.1%) females. The study found that the mean age of patients was 25.3±11.9. In group A patients 140, 110 patients showed efficacy while 30 patients did not show efficacy during the study time period. Similarly, 124 patients showed efficacy in Group B while 16 patients did not show efficacy. A significant association was found in both groups regarding pain at 24 hours (p=0.00) while an insignificant association was found with age (p>0.05).

Conclusion: To conclude, the trans-septal suturing technique applied in septoplasty causes minimal pain and complications like septal perforation and synechiae formation, and patients resume routine life activities shortly after the surgery.

Keywords: Septoplasty, nasal packing, trans-septal sutures, nasal septal perforation.

Introduction

One of the most common surgical procedures performed in the otorhinolaryngology department is septoplasty which is performed for nasal obstruction caused by a deviated nasal septum. Septoplasty is a conservative procedure in which only the most deviated parts of the septum are removed, and the rest of the septum is reconstructed.

After septoplasty has been completed anterior nasal packing is commonly done to support the opposition of septal flaps and to close the dead space between subperichondrial flaps and septal cartilage. In addition, nasal packing is done to prevent various postoperative complications like bleeding, haematoma formation, and synechiae. A variety of nasal packs are mentioned in the literature which includes Merocel, ribbon gauze with or without paraffin, fingerstall packs, Telfa², foam, cellulose, absorbable gelatin sponges, internal nasal splints, polyethylene oxide gel, and alginate. The choice of nasal packing depends on the preference of the surgeon and its availability.

Nasal packing itself is associated with multiple complications like injury to the mucosa, allergy, oedema of the nose and periorbital region, excessive lacrimation, worsening of breathing, postoperative infections, postoperative pain, toxic shock syndrome³ and even debilitating cardiopulmonary complications.4 Moreover, pack removal leads to severe pain and distress to the patient.⁵ As nasal packs are associated with various postoperative complications and their removal causes pain, different studies have been conducted to find out the techniques which can be used as an alternative to nasal packing. One of these is the transseptal suturing technique which has recently gained a much broader application area. Transseptal suturing has recently emerged as a new technique which according to various studies is believed to have a superior outcome as compared to nasal packing following septoplasty.6-8

One such study conducted in Nepal showed that in patients with transseptal sutures no pain was noted in 38% of the patients as compared to 0% in patients with the nasal packs. Similarly, mild pain was noted in 38% compared to 17%, moderate pain in 23% compared to 30% and severe pain was observed.

In 0% of patients with transseptal sutures compared to 52% in patients with nasal packs. Epistaxis occurred in 4.76% of the patients with transseptal sutures as opposed to 0% in patients with nasal packs. Synechiae formation occurred in 0% as opposed to 8.6% and perforation occurred in 0% of the patients with

transseptal sutures compared to patients with the nasal pack in which perforation occurred in 4.3% of the cases.⁸

This study has been conducted in western and a few Asian countries but no such study has been conducted in Pakistan before so this study will be the first of its kind. As septoplasty is one of the commonest procedures performed in the ENT department and nasal packing is frequently used in our hospitals causing severe pain and discomfort, this study will emphasize discouraging the use of nasal packing.

Materials and Methods

Approval has been taken from the institutional research forum of Rawalpindi Medical College. Informed consent was taken from all patients fulfilling the selection criteria. Patients were explained about the procedure. A total of 280 cases of deviated nasal septum were divided into two groups A (septoplasty with a nasal packing) and B (Septoplasty with trans septal sutures) by randomization with 140 in each group. All of the patients were operated on under general anesthesia by using the standard septoplasty operation technique. At the end of each operation, the patients were randomly selected to have either nasal packing or trans-septal sutures according to their allocation to the study group already assigned. In the nasal packing was placed following septoplasty. Pack material was fingerstall. The pack was removed after 24 hours. In group B, two vertical and one horizontal suture was placed to approximate the mucosal flap following septoplasty with no pack. Vicryl 3/0 was used as a suture material for this purpose. Postoperatively, patients in both groups were evaluated for pain levels on a visual analogue pain scale at 24 hours respectively, and for post-operative complications including septal perforations and synechiae formation. Patients were discharged on the 2nd postoperative day i.e. 48 hours after surgery on an antibiotic (amoxicillin/clavulanic acid) 625 mg TDS, analgesic (ibuprofen) 400mg TDS, and steroid nasal spray (fluticasone propionate). Follow-up visits were scheduled at 1 and 4 weeks respectively and patients were evaluated for septal perforation and synechiae formation.

Results

The study recruited a total of 280 patients with 1: 1 randomization. Among all the patients 280 (100%),

there were 123 (43.9%) males and 157 (56.1%) females. There were two groups in the present study; nasal packing 140 (50%) and trans septal suturing 140 (50%). Group A had 36 (26%) patients with septal perforation while 104 (74%) did not have a septal perforation. Similarly, Group B had 4 (3%) patients with septal perforation while 136 (97%) did not have a septal perforation. In Group A 27 (19%) had synechiae formation while 113 (81%) did not have synechiae formation. Similarly, in Group B 3 (2%) patients had synechiae formation while 137 (98%) did not have synechiae formation (Table 1). The study found that the mean age of patients was 25.3±11.9 (Table 2).

The study found out that in group A patients 140 (100%), there were 110 (78%) patients who showed efficacy while 30 (22%) patients did not show efficacy during the study time period. Similarly, there were 124 (88%) patients who showed efficacy in Group B while 16 (12%) patients did not show efficacy (Figure 1).

The study found out that after 24 hours of intervention, among all the patients in Group A 140 (50%), there were 70 (25%) patients with no pain (VAS score 0), 53 (18.9%) with mild pain (VAS score 1 to 3), 10 (3.6%) with moderate pain (VAS score 4 to 6) and 7 (2.5%) with severe pain (VAS score 7 to 10). While in Group B 36 (12.9%), 41 (14.6%), 36 (12.9%), and 27 (9.6%) with no pain (VAS score 0), mild pain (VAS score 1 to 3), moderate pain (VAS score 4 to 6) and severe pain (VAS score 7 to 10) respectively (Table 3). A significant association was found ($x^2 = 38.898$, d.f=3, p<0.05)

The study found that among all the patients in Group A 140 (50%), there were 53 (18.9%) males and 87 (31.1%) females. Similarly, in Group B 140 (50%), there were 70 (25%) males and 70 (25%) females. A significant association was found ($x^2 = 4.190$, d.f=1, p<0.05) (Table 4)

The study found that among all the patients in Group A 140 (50%), there were 61 (21.8%) patients in the age group 17-25 years while 79 (28.2%) in the 26-35 years age group. Similarly, in Group B 140 (50%), there were 65 (23.2%) in the age group 17-25 years and 75 (26.8%) in the age group 26-35 years. An insignificant association was found ($x^2 = 0.231$, $x^2 = 0.231$, $x^2 = 0.231$)

Efficacy in both groups

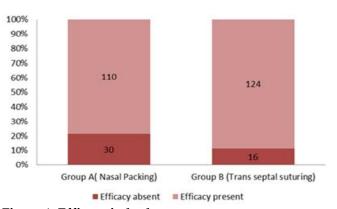


Figure 1: Efficacy in both groups

Table 1: Demographic and clinical characteristics

Demographic and	Frequency	Percentage
clinical characteristic	(N=280)	(100%)
Gender		
Males	123	43.9%
Females	157	56.1%
Study groups		
Group A (Nasal	140	50%
Packing)		
Group B (Trans septal	140	50%
suturing)		
Septal perforation		
Group A		
Yes	36	26%
No	104	74%
Group B		
Yes	4	3%
No	136	97%
Synechiae formation		
Group A		
No	113	81
Yes	27	19%
Group B		
Yes	3	2%
No	137	98%

Table 2: Mean age and standard deviation

Variable	Mean	Standard deviation
Age	25.3	11.9

Table 3: Comparison of pain at 24 hours in both groups

Interventional Groups	Pain after 24 hours			Total	P-value	
	No pain	Mild pain	Moderate	Severe	_	
			pain	pain		
Group A (nasal packing)	70 (25%)	53 (18.9%)	10 (3.6%)	7 (2.5%)	140 (50%)	
Group B (tran septal suturing)	36 (12.9%)	41 (14.6%)	36 (12.9%)	27 (9.6%)	140 (50%)	0.000
Total	106 (37.9%)	94 (33.6%)	46 (16.4%)	34 (12.1%)	280 (100%)	

 $(x^2 = 38.898, d.f = \overline{3, p < 0.05})$

Table 4: Gender distribution in both groups

Interventional groups	Gender		Total	P-values
	Male	Female		
Group A	53 (18.9%)	87 (31.1%)	140 (50%)	
Group B	70 (25%)	70 (25%)	140 (50%)	0.04
Total	123 (43.9%)	157 (56.1%)	280 (100%)	

 $(x^2 = 4.190, d.f=1, p<0.05)$

Table 5: Age distribution in both groups

Interventional groups		Age		P-values
	17-25 years	26-35 years		
Group A	61 (21.8%)	79 (28.2%)	140 (50%)	
Group B	65 (23.2%)	75 (26.8%)	140 (50%)	0.631
Total	126 (45%)	154 (55%)	280 (100%)	

 $(x^2 = 0.231, d.f=1, p>0.05)$

Discussion

The present study recruited total of 280 patients with 1: 1 randomization. Among all the patients 280 (100%), there were 123 (43.9%) males and 157(56.1%) females. Two groups were there in the present study; nasal packing 140(50%) and trans septal suturing 140 (50%). One of the most commonly used surgical procedures to correct the deviated nasal septum is septoplasty.9 A nasal pack placed after septoplasty has been used for approximation of mucoperichondrial flaps, to avoid septal haematoma and bleeding, provide support to the septal framework, stabilize the fragments of bone and cartilage which have been repositioned and avoid synechiae formation between the lateral nasal wall and septum.¹⁰ Many materials for packing are present including fingerstall packs, ribbon gauze, balloon catheter, alginate, telfa, cotton gauze strips, and cellulose.11 The study found out that in 140 group A patients, 110 patients showed efficacy while 30 patients did not show efficacy during the time period of the study. Similarly, 124 patients showed efficacy in Group B while 16 patients did not show efficacy (Figure 1).

Evidence suggests that the probable complications of placing a pack in the nasal cavity unavoidably lead to

pain. In addition, the removal of the pack from the nasal cavity also causes distress and pain, so methods for reducing the pain should be sought. Excruciating pain is felt by the patient when his pack is removed. 12,13

A nasal pack also restricts respiratory function and nasal respiration thus adversely affecting sleep quality. It can cause dryness of the oral cavity, throat irritation, hypoxia, aspiration, and even cardiovascular problems. Placing a pack in the nasal cavity bilaterally causes a reduction in nocturnal PaO₂, due to insufficient breathing from the mouth resulting in hypoxia being experienced much more strongly. In these cases, chronic obstructive pulmonary disease, obstructive sleep apnoea, and other systemic problems become evident, predominantly in old-age patients who already are suffering from ischaemic heart disease.¹⁴

A nasal pack placed after septal surgery is often to reduce and control bleeding, provide pressure mechanically, and avoid the formation of hematoma following the procedure. A literature review showed no difference in the formation of septal haematoma or bleeding if different materials for the pack are utilized versus if no nasal pack is placed.^{15,16} In our study, four patients of Group I and six patients of Group II had haemorrhage after septoplasty, but the difference

between both groups was not statistically important. Regarding the formation of septal haematoma, no difference could be found between the two groups as well. For structural and mechanical reasons, placing a pack in the nasal cavity not only causes irritation of the mucosa but also causes harm to the movement of its cilia. In research on sheep, Shaw and coworkers observed that packing the nasal cavity resulted in 50-68% destruction of cilia of the nasal mucosa. Consequently, the nasal packs can cause infections of the nasal cavity. A case of pyogenic granuloma resulting from nasal packing was reported by Lee and Vukovic along similar lines. 17,18

Toxic shock syndrome is the most grave complication that can occur because of infection.¹⁹ In contrast to this, in those patients in whom trans septal suturing was done there, preservation of mucosal ciliary activity, and reactions due to packing did not occur. As a result, the risk for infection decreases.^{20,21}

In a rhinoplasty series, Camirand noticed that complications can be avoided if packing is not placed inside the nasal cavity.¹⁶ The trans-septal suturing technique was applied to 226 patients by Lemmens and Lemkens.¹⁵ Complications for instance haemorrhage, formation of septal haematoma, perforation of the septum, and synechiae formation did not occur. In the present study, seven patients in Group I and five patients in Group II had nasal synechiae formation. In Group I the septal perforation incidence was 8 (2.2%) as compared to Group II in which it was 11 (3.2%). No significant difference was observed among the two groups regarding the nasal synechiae formation and perforated septum in concurrence with the results of the text.²²

The technique of trans-septal suturing was established in septoplasty to replace nasal packing. A study was done that compared the postsurgical outcomes of the trans-septal suturing technique with that of the anterior nasal packing for which merocel was used. 697 patients who had septoplasty were included in the study. After the procedure, the patients were randomly separated into two groups, one with transseptal suturing and the other with merocel pack. A visual analogue pain scale was used to assess the levels of pain. A comparison between postsurgical complications and symptoms was done. 697 nasal surgeries in total were assessed post-surgically taking into consideration pain, haemorrhage, formation of haematoma, perforated nasal septum, and synechiae formation. For bleeding, haematoma formation, synechiae formation, and perforated nasal septum, the results were not statistically significant (p > 0.05)

among the groups. Contrary to this, in those patients who underwent trans-septal suturing, the level of postsurgical pain was considerably low as compared to the group with Merocel pack (p < 0.05). Those in whom Merocel pack was placed had considerably increased pain and nasal irritation when examined seven days following the procedure. As a result, the technique of trans septal suturing is a better choice for the increased level of patient satisfaction. 23,24

The present study found out that after 24 hours of intervention, among all the patients in Group A 140 (50%), there were 70 (25%) patients with no pain (VAS score 0), 53 (18.9%) with mild pain (VAS score 1 to 3), 10(3.6%) with moderate pain (VAS score 4 to 6) and 7(2.5%) with severe pain (VAS score 7 to 10). While in Group B 36 (12.9%), 41 (14.6%), 36 (12.9%), and 27 (9.6%) with no pain (VAS score 0), mild pain (VAS score 1 to 3), moderate pain (VAS score 4 to 6) and severe pain (VAS score 7 to 10) respectively (Table 3). Many otorhinolaryngology surgical procedures are performed out of which septoplasty is the most common. It is routine to place the anterior nasal pack as a part of nasal surgery to augment the apposition of mucoperichondrial/periosteal flaps, stop haemorrhage and stabilize the operated septal cartilage and bones. But nasal packing is not an intervention without complications. Pain and discomfort in the post-surgical period are the most cumbersome for the patient when septoplasty is done with anterior nasal packing. A study was conducted that compared the postsurgical complications and outcomes of septoplasty done with or without anterior nasal packing. Forty-four patients were randomly allocated into two groups, Group A (n = 21) and Group B (n = 23). In Group A trans-septal suturing technique and in Group B anterior nasal packing were used after septoplasty. A comparison was made for postsurgical pain, complications occurring postoperatively, and surgical outcomes in both of these groups. Out of 44 patients, 31 patients were male and 13 were female. Majority of the patients i.e. 79.5% underwent surgery for the problem of nasal obstruction. In Group A only one patient had haemorrhage postsurgically which required anterior nasal packing. Increased postsurgical pain score, longer stay in the hospital, and more complications were noted in Group B patients. No difference was present in the satisfaction level of the patients postoperatively. Septoplasty can be done safely without nasal packing in the postoperative period and is preferred to avoid postsurgical pain, distress, and many other complications.²⁵

A similar study reported that the main concerns in nasal operations are stabilization of the nose in a good position, conserving the cartilage and bones as far as possible, and decreasing the danger of recurrence of deviation. Also, it is important to prevent the formation of synechia, stenosis of the nasal valve, hematoma formation, and haemorrhage. Because of the problems cited above and in order to solve and minimize them anterior nasal packing, nasal splints, and nasal mold have been advised. Those patients in whom the anterior nasal pack is placed may have troubles like a naso-pulmonary reflex, intractable pain, obstructive sleep apnea, infection, and very serious complication like toxic shock syndrome. Two patient groups and three surgeons took part in the study. One of the surgeons used an anterior nasal pack postoperatively in his patients while the other two did not. A comparison was made between these two groups with respect to complications and morbidities. Comparison between the two groups revealed that the rate of complications and morbidities were similar, and the differences were not significant with the exception of pain and discomfort experienced in the postoperative period and at the time of pack removal. Thus, septoplasty can be performed safely without the need for postoperative nasal packing. Nasal packing had no major advantages that could support its usage. The trans-septal suturing technique can be applied instead of nasal packing. Therefore, anterior nasal packing after septoplasty should be considered only for those patients with a high risk of haemorrhage. 26,27 In the present study among all the participants 280 (100%), there were 40 (14.3%) patients found with septal perforation while 240 (85.7%) were found without septal perforation. Among all the patients 280 (100%), there were 30 (10.7%) patients found with synechiae formation while 250 (89.3%) were found without synechiae formation (Table 1).

A study was done to demonstrate the likelihood of applying trans-septal suture in place of nasal packing and to increase efficiency. It was a prospective, descriptive, inferential cost study that included 92 patients. Analysis was done on two randomized groups of patients, one with nasal pack and the other with trans-septal suture.

In the group with trans septal suture, no patient developed hemorrhage postoperatively and a statistically significant decrease in postoperative pain and headache was observed. Simultaneously, efficiency was improved by a reduction in material expenses. The study concluded that the trans-septal suturing technique is safe and effective and thus can

replace nasal packing in septoplasty. Furthermore, it increases the efficiency of the procedure by reducing expenses.²⁷

Evidence supports that trans-septal suturing after septoplasty is a suitable substitute for nasal packing. After surgery on the septum most surgeons still routinely perform nasal packing since this is generally recommended. The indications of the anterior nasal pack are numerous: hemostasis, avoidance of hematoma, support septal flap apposition, the closing of dead space, and prevention of dislodgment of the replaced cartilage. However, nasal packing is not completely a safe procedure and may lead to cardiovascular complications, continuous bleeding, injury to the nasal mucosa, hypoxia, foreign body and infection. One of the major disadvantages of nasal packing is patient distress usually requiring a long hospital stay necessitating antibiotic administration. Therefore, alternatives were sought. In the eighties Sessions, Lee and Vukovic reported techniques of continuous septal suturing, but are not commonly used. A similar method of trans-septal suturing after septoplasty without nasal packing was implied in 226 consecutive operative procedures and reviewed retrospectively. postoperative haemorrhage, Complications like infection, septal hematomas, septal perforations, and synechia formation were not observed. In one patient a recurrence of the septal deviation was found. No discomfort or distress was reported by the patients. Moreover, in this way, septoplasty could be performed as a daytime procedure. Readmission of a patient was never necessary. Based on these observations the trans septal suturing technique is a suitable substitute for anterior nasal packing after septoplasty. 28,29

Another similar study reported that nasal packing and trans-septal suturing are used to avoid postsurgical complications in septoplasty. Trans-septal suturing is not used frequently, because it takes a lot of time and is technically hard to perform with the available instruments after septoplasty.

64 patients were included in this study on which septoplasty was performed. After septoplasty, the patients were separated into two groups: group 1 had trans-septal sutures applied using a novel device and group 2 had nasal packing with a tampon. The operative time, postsurgical symptoms, and complications were compared among the two groups.^{29,30}

All the postsurgical symptoms were considerably fewer in the group in which trans-septal sutures were used. The mean time period of the surgical procedure was 34.9 minutes in the group with nasal packs and 37.8 minutes in the group with trans-septal sutures, and the difference was significant (p = 0.026). No haemorrhage, sub mucoperichondrial/periosteal hematomas, infections, or abscess formation developed in any of the patients postoperatively, while perforation of the nasal septum was noted in one patient in each group. Two (5.4%) patients in group 1 and one (3.7%) patient in group 2 developed adhesions in the postoperative period. The study concluded that they had established a simple and economical device for applying trans-septal suturing that is easy to be used in the nasal cavity and the application of continuous septal suturing with this device is an easy modification of the standard procedure, with only a minimal increase in operative time.

Another study was done. The purpose of the study was to assess the outcomes of septoplasty with no nasal packing in the postoperative period.³¹⁻³³

Septoplasty was done by standard technique. A nasal pack was not placed in these cases. The study comprised seventy-eight patients. Most of the patients (64.1%; 50/78) underwent surgery on the morning list. Sixty-two patients were discharged the same day, the remaining others were discharged the next day. The bleeding rate after surgery was 7.7% (6/78) and in only 3.8% (3/78) of the patients, anterior nasal packing was done. Most of the patients (84.6%) were satisfied with the surgery at the follow-up after 3 months.

Septoplasty can be done safely with no anterior nasal pack in the postoperative period. Few patients 3.8% had nasal packing postoperatively in this study.³³⁻³⁵ Evidence supports that once commonly used, the anterior nasal packing following septoplasty was done to avoid various complications such as haemorrhage, septal hematoma, and development of adhesions.^{34,36-38} However, it was observed that not only is nasal packing useless in this regard, but it can also actually lead to these problems. In agreement with the world's literature, nasal packing should not be done. No truly randomized study had been conducted in Southwest Asia that can validate this recommendation. For that reason, a study was done which was a prospective randomized comparison of the incidence of a variety of postsurgical signs and symptoms in 88 patients, 15 years of age and older, who did (n = 44) and did not (n = 44) have nasal packing after septoplasty. They observed that those patients in whom nasal packing was done, had considerably more pain, headache, increased lacrimation, difficulty in swallowing, and sleep trouble on the night of the operation. Examination of the oral and nasal cavity 7 days after

surgery showed no considerable difference between the two groups in the incidence of haemorrhage, septal hematoma, formation of adhesions, and local infections. Finally, the group with a nasal pack complained of a moderate to severe intensity of pain during its removal. These observations confirmed that nasal packing following septoplasty is not only needless, in reality, are a cause of patient distress and other signs and symptoms.

Conclusion

To conclude, the trans-septal suturing technique applied in septoplasty leads to minimal pain and complications like septal perforation and synechiae formation following the surgical procedure, and patients resume routine life activities shortly following the surgery. In addition, postsurgical haemorrhage does not appear to be a problem with this technique. The study concluded that the usual practice of nasal packing is no longer recommended and has also increased the patient's comfort level following septoplasty by making use of the trans-septal suturing technique.

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