ROLE OF ANTIBIOTICS IN MANAGEMENT OF PATIENTS UNDERGOING SEPTOPLASTY- A COMPARATIVE STUDY

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ABSTRACT

Aim: The present study was undertaken to compare the post-operative results of Septoplasty in terms of possible complications when patients are not going to be given antibiotic cover after surgery vis-à-vis two control groups who are administered antibiotics either pre operatively and/or post operatively.

Methods: This was a prospective study carried out at Department of Otorhinolaryngology, Padmashree Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune from July 2011 to September 2013. Institutional Ethics Committee Clearance was obtained before start of study and written and informed consent for the procedure was obtained from all the patients. A total of 60 patients were divided in 3 groups each with 20 patients depending upon the pre-operative and post-operative administration of antibiotics.

Results: The comparison of age difference amongst the three groups was not statistically significant; hence the study could be compared among the groups. There was no statistically significant sex wise difference amongst the three groups. 11.67% (7 out of 60) patients had post operatively nasal discharge. In group A and group B 2 patients (3.33%) each had nasal discharge post operatively, whereas 3 patients in group C (5%) had nasal discharge post operatively which was statistically not significant. Condition of wound & nasal septum was not significant in the groups. Patency of nostril was equal among all the three groups. 11.67% (7 out of 60) patients had post operatively sinus tenderness. In group A and group B 2 patients (3.33%) each had sinus tenderness post operatively, whereas 3 patients in group C (5%) had sinus tenderness post operatively which was statistically not significant. The comparison of pain score individually in group A, group B and group C respectively on day1, day2, day3, 1week, 3weeks and 6weeks, it shows progressive statistically significant ($p<0.0001$) decrease in pain on the respective days in each group individually.

Conclusion: The incidence of nasal surgery complications is rare. Septoplasty is considered potentially contaminated surgery and does not require prophylactic use of antibiotics due to low risk of postoperative infection. Antibiotics do not have any effect on post-operative pain.

Keywords: septoplasty, antibiotics, complications

INTRODUCTION

Nasal obstruction is one of the commonest presenting symptoms in ear nose and throat practice. It can be caused by a number of conditions. As much as 75% to 80% of the general population is estimated to exhibit some type of anatomical deformity of the nose[1], the most common being deviated nasal septum. This deviation is often associated with compensatory hypertrophy of mucosa of inferior turbinate of the contra lateral nasal cavity. The use of antibiotics in otorhinolaryngological surgeries has become common practice among most ENT doctors, however there are few studies proving the efficacy and need for this practice, which is considered as unnecessary by some authors.[2-7]

Today world over there is a cognizant effort to reduce and at times even avoid the usage of antibiotics whenever possible. Though the human nose is one cavity rife with commensal pathogens many centers have developed protocols for operative work on the nose wherein antibiotic usage has been limited to minimum. 3.1 Nasal obstruction is a common complaint. In 1974, Vainio-Mattila found a 33% incidence of nasal airway obstruction among randomly chosen adults.[8]

In a study done by Ioannis Georgiou et al. in 2008 mentioned about prophylactic antimicrobial therapy during nasal surgery is common among surgeons worldwide, although the effectiveness of this practice is controversial. The authors reviewed the literature to evaluate the value of

antibiotic prophylaxis. The authors identified eleven studies written in English or German that addressed the effectiveness of prophylactic antibiotics, infection rate and bacteremia during nasal surgery. The studies failed to demonstrate a difference between patients who received antibiotic prophylaxis during nasal surgery and patients who did not; with the only exception being cases of complicated revision rhinoplasties. Preventive systemic antibiotics are indicated in complicated revision rhinoplasties, prolonged placement of nasal packs and for patients who are susceptible to infections.[8] Muhammad Ahmad et al. in 2008 mentioned about antibiotic prophylaxis were considered mandatory in patients who are at high risk for infection. They concluded that use of prophylactic peri-operative antibiotics is a common practice in facial plastic surgery. The documentation and pattern varies widely among the surgeons.[9]

The present study was undertaken to compare the post-operative results of Septoplasty in terms of possible complications when patients are not going to be given antibiotic cover after surgery vis-à-vis two control groups who are administered antibiotics either pre operatively and/or post operatively.

MATERIALS AND METHODS

This was a prospective study carried out at Department of Otorhinolaryngology, Padmashree Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune from July 2011 to September 2013. Institutional Ethics Committee Clearance was obtained before start of study and written and informed consent for the procedure was obtained from all the patients. A total of 60 patients were divided in 3 groups each with 20 patients depending upon the pre-operative and post-operative administration of antibiotics.

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Inclusion criteria –

- All patients were between 18 years to 50 years of age
- All patients had deviated nasal septum

Exclusion criteria –

- Patients with pre-operative upper respiratory tract infection
- Patients with any previous septal surgery
- Patients with other nasal conditions along with deviated nasal septum
- Patients with any other systemic disorder. (diabetes, hypertension, tuberculosis, asthma, etc.)
- Malignancy

Drug Regimen -

In group A and group B patients, tab Cefixime 200 mg. were given orally 12 hourly for 3 days prior to surgery and were also administered Inj. Cefotaxime 1gm. intravenously 1 hour prior to surgery pre operatively.

Only group A patients were administered Inj. Cefotaxime 1gm. post operatively intravenously 12 hourly for 3 days.

In case of group C patients, they were not administered any antibiotic pre operatively, intra operatively and/or post operatively.

All patients were administered diclofenac sodium 75 mg. intramuscular injection 12 hourly for first 24 hours, followed by diclofenac sodium 50 mg. orally 8 hourly for next 24 hours for pain management. All patients were administered tab. Levocetrizine 5 mg. prior to bed for nasal decongestion. Post operatively all patients nasal pack was removed after 48 hours and nasal douching was done with saline nasal spray daily for 15 days.

Evaluation was done on basis of

- Nasal discharge
- Condition of wound
- Condition of nasal septum
- Patency of nostril
- Tenderness over dorsum of nose
- Pain assessment by using visual analogue scale
- Septal perforation
- Septal abscess
- Tenderness over sinuses
- Patients were followed up post operatively on day 1, day 2, day 3, 1 week, 3 weeks and 6 weeks.

The results were analyzed using following statistical tests

- ANOVA test
- Chi – Square test
- Wilcoxon test

RESULTS

Table 1: Comparison of age in study groups

Parameters	**Group A**	**Group B**	**Group C**	**F Value**	**P Value**
	Mean ± SD (n=20)	**Mean ± SD (n=20)**	**Mean ± SD (n=20)**		
Age (Yrs)	32.95 ± 7.75	32.30 ± 7.83	31.30 ± 9.77	0.19	>0.05

Gr. A Vs Gr. B: P>0.05 Gr. B Vs Gr. C: P>0.05 Gr. A Vs Gr. C: P>0.05

The comparison of age difference amongst the three groups was not statistically significant; hence the study could be compared among the groups.

Table 2: Sex and nasal discharge wise distribution of cases in study groups

Sex	**Group A (%)**	**Group B (%)**	**Group C (%)**	**Total (%)**
Male	9 (15)	12 (20)	15 (25)	36 (60)
Female	11 (18.33)	8 (13.33)	5 (8.33)	24 (40)
Total	20 (33.33)	20 (33.33)	20 (33.33)	60 (100)
Chi-square = 3.75, P>0.05				
Nasal discharge				
Yes	2 (3.33)	2 (3.33)	3 (5)	7 (11.67)
No	18 (30)	18 (30)	17 (28.33)	53 (88.33)
Total	20 (33.33)	20 (33.33)	20 (33.33)	60 (100)
Chi-square = 0.32, P>0.05				

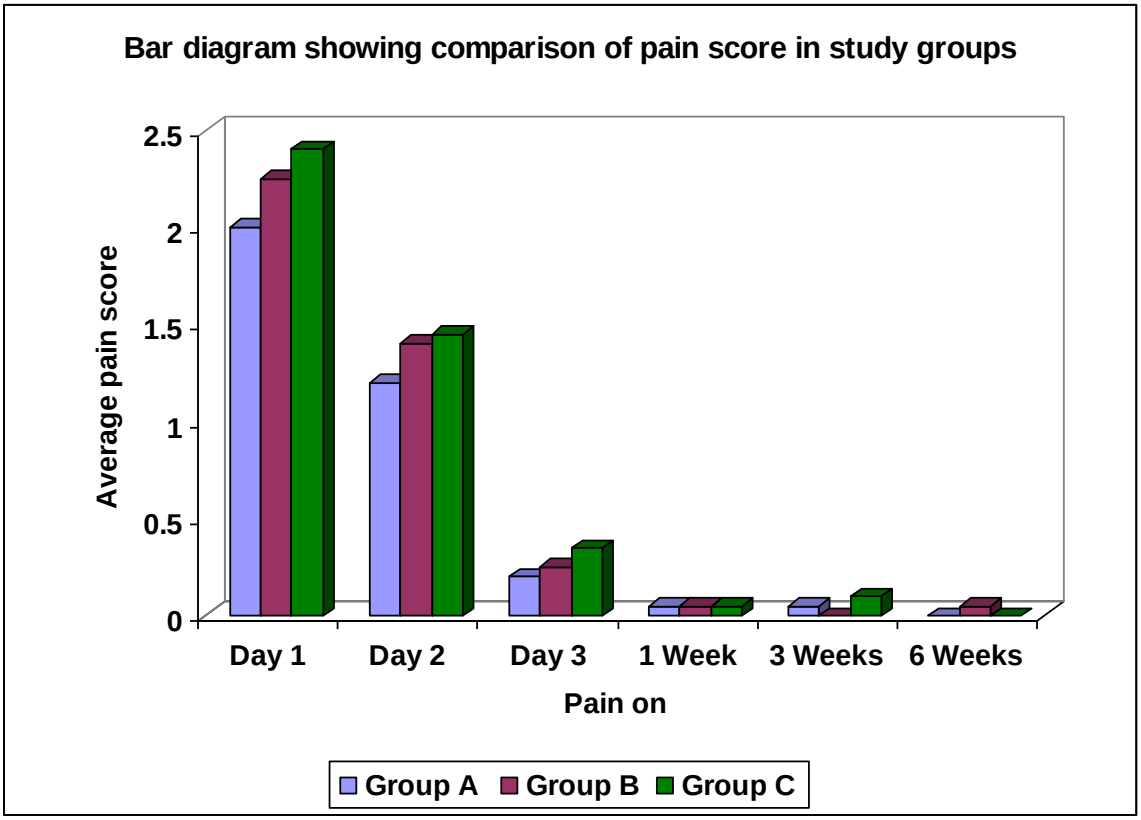
There was no statistically significant sex wise difference amongst the three groups. 11.67% (7 out of 60) patients had post operatively nasal discharge. In group A and group B 2 patients (3.33%) each had nasal discharge post operatively, whereas 3 patients in group C (5%) had nasal discharge post operatively which was statistically not significant.

Table 3: Condition of wound & nasal septum wise, Patency of Nostril wise and Sinus tenderness distribution of cases in study groups

Condition of wound & Nasal septum	**Group A (%)**	**Group B (%)**	**Group C (%)**	**Total (%)**
Healthy	20 (33.33)	20 (33.33)	19 (31.67)	59 (98.33)
Gapping	0	0	1 (1.67)	1 (1.67)
Total	20 (33.33)	20 (33.33)	20 (33.33)	60 (100)
Chi-square = 2.03, P>0.05				
Patency of Nostril				
Patent	19 (31.67)	19 (31.67)	19 (31.67)	57 (95)
Obstructed	1 (1.67)	1 (1.67)	1 (1.67)	3 (5)
Total	20 (33.33)	20 (33.33)	20 (33.33)	60 (100)
Chi-square = 0, P>0.05				
Sinus tenderness				
Yes	18 (30)	18 (30)	17 (28.33)	53 (88.33)
No	2 (3.33)	2 (3.33)	3 (5)	7 (11.67)
Total	20 (33.33)	20 (33.33)	20 (33.33)	60 (100)
Chi-square = 0.32, P>0.05				

Condition of wound & nasal septum was not significant in the groups. Patency of nostril was equal among all the three groups. 11.67% (7 out of 60) patients had post operatively sinus tenderness. In group A and group B 2 patients (3.33%) each had sinus tenderness post operatively, whereas 3 patients in group C (5%) had sinus tenderness post operatively which was statistically not significant.

Figure 1: Comparison of pain score in study groups



The result shows comparison of pain score done by visual analogue scale amongst all the three groups on day1, day2, day3, 1week, 3weeks and 6weeks, as well as among the two groups out of three in all probabilities on day1, day2, day3, 1week, 3weeks and 6weeks. It was found that for all the comparisons the p value was greater than 0.05 which proved it to be statistically insignificant.

Table 4: Comparison of pain score in study group A, group B and group C

Pain on	**Group A**	**Wilcoxon Z Value**	**P Value**
	Mean ± SD (n=20)		
Day 1	2 ± 1.21	-	-
Day 2	1.20 ± 0.83	3.02	<0.0001
Day 3	0.20 ± 0.52	3.58	<0.0001
1 Week	0.05 ± 0.22	3.58	<0.0001

3 Weeks	0.05 ± 0.22	3.58	<0.0001
6 Weeks	0 ± 0	3.68	<0.0001
Group B			
Day 1	2.25 ± 1.25	-	-
Day 2	1.40 ± 0.88	3.69	<0.0001
Day 3	0.25 ± 0.55	3.62	<0.0001
1 Week	0.05 ± 0.22	3.68	<0.0001
3 Weeks	0 ± 0	3.69	<0.0001
6 Weeks	0.05 ± 0.22	3.69	<0.0001
Group C			
Day 1	2.40 ± 1.05	-	-
Day 2	1.45 ± 0.95	3.76	<0.0001
Day 3	0.35 ± 0.67	3.90	<0.0001
1 Week	0.05 ± 0.22	3.88	<0.0001
3 Weeks	0.10 ± 0.31	3.87	<0.0001
6 Weeks	0 ± 0	3.88	<0.0001

The table shows comparison of pain score individually in group A, group B and group C respectively on day1, day2, day3, 1week, 3weeks and 6weeks, it shows progressive statistically significant ($p<0.0001$) decrease in pain on the respective days in each group individually. None of the patients in any of the groups suffered from septal abscess and/or septal perforation.

DISCUSSION

This was a prospective study carried out at tertiary care centre from July 2011 to September 2013, comparing three groups in the management of septoplasty with and without prophylactic use of antibiotics. The most common complication of nasal surgeries is hemorrhage, with incidence rate between 0.7 to 3.6% of the cases.[10] The second most common complication is infection. Most infectious complications occur in the surgical site, even though more diffused

complications have been reported. Despite the lack of evidence about the efficacy of antibiotic prophylaxis in preventing complications after septoplasty the use of antibiotics in nasal surgery is a common pradice.[3-5,7,11] According to a survey among the members of the American Rhinologic Society, the most common reasons for antibiotic prophylaxis are the prevention of postoperative infections (60.4%), avoidance of toxic shock syndrome (31.5%), and self-protection against legal-medical proceedings (4.9%).[11]

Our results confirm the findings of Lilja et al., who reported no significant difference in post septoplasty infection rate between patients submitted to preoperative i.v. cefuroxime prophylaxis and placebo group.[12] In particular, our study does not show a statistically significant difference among patients treated with preoperative antibiotic prophylaxis, pre- and postoperative prophylactic treatment, and no antibiotic in terms of postoperative complications (nasal discharge, septal hematoma or abscess, nasal bleeding, or sinus tenderness and pain). Moreover, no significant difference in nasal purulent discharge (considered as a sign of local infection) 2 was noticed among the groups. None of the patients presented a relevant amount of purulent rhinorrhoea (grade 3 or 4) in nasal endoscopy performed 3 weeks after surgery. Patients with modest rhinorrhoea (grade 1 or 2) were treated only with abundant nasal lavage with saline solution (0.9%) with complete resolution. The patients selection criteria (exclusion from the study of subjects with nasal-related confounders, i.e., rhinosinus diseases and previous nasal surgery), equal in number of patients in all groups and statistical analysis allow a reliable comparison of findings among the different groups.

Such results confirm that antibiotic prophylaxis in septoplasty with short-duration (24 hours) nasal packing has no role in preventing infection/complications after septal surgery. The septoplasty technique (with the 'back-to-front' mattress suture of the nasal septum) used by the authors,[13] together with radiofrequency inferior turbinate reduction,[14] allows early removal of nasal packing with no risk of septal hematoma and low frequency (0.3%) of postoperative nasal bleeding. Topical antibiotic in nasal packing does not seem to affect the frequency on local infection, because infection rates in our study were comparable with those reported by other authors using topical antibiotic in nasal packing.[4]

According to several authors, the risk of infection after septoplasty seems to be related to nasal packing duration rather than to the surgical procedure itself.[2,6,15] Kaygusuz et al. found bacteremia in 9 of 53 patients (16.9%) after packing removal.[17] Herzon observed bacteremia in 12% of 33 patients submitted to anteroposterior packing because of epistaxis.[16] Although surgical field (nasal fossa) is contaminated, bacteremia does not seem to be a relevant issue during nasal surgery[5,7,17] and if it occurs normally it is not likely to result in major clinical complications.[17] In their study on 50 patients submitted to septoplasty, Silk et al. found that although 46% of the patients had nasal mucosa colonized with Staphylococcus aureus, none of the blood swabs collected during surgical procedures showed bacterial growth.[5] Therefore, the

systematic use of antibiotic prophylaxis does not seem justified. Avoiding antibiotic abuse allows a reduction of pharmacologic costs, prevents antibiotic induced allergic reactions, and reduces the development of bacterial antibiotic resistance.[18] Antibiotic prophylaxis in septal surgery should be restricted to selected cases (i.e., patients with cardiac valvulopathy, immunodepression, etc.) to avoid possible evolutions of bacteremia to endocarditis, arthritis, and osteomyelitis.[7,17,19]

CONCLUSION

The incidence of nasal surgery complications is rare. Septoplasty is considered potentially contaminated surgery and does not require prophylactic use of antibiotics due to low risk of postoperative infection. Antibiotics do not have any effect on post-operative pain. With proper administration of pain killers post operatively irrespective of prophylactic use of antibiotics there is progressive significant decrease in pain post operatively.

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