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Prophylactic Use of Antibiotics in Septoplasty: is it Always Necessary?

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ABSTRACT

Objective: To study the role of antibiotic prophylaxis in septoplasty.
Study design: Quasi-experimental study.
Place and Duration of Study: Department of Otolaryngology Surgery, Combined Military Hospital (CMH), Murree, Pakistan, from July 2022 to July 2024.
Methodology: This study evaluated the necessity of prophylactic antibiotics in septoplasty, where a total of 60 patients, with symptomatic deviated nasal septum were randomly assigned to two groups, Group A (n=30) and Group B (n=30). Both groups received a 1.20 g test dose of intravenous (I/V) co-amoxiclav, followed by a main dose 30 minutes before surgery, while postoperatively, Group A continued with co-amoxiclav 625 mg orally every 8 hours for five days, while Group B received no further antibiotics. Clinical parameters, including pain, fever, and nasal discharge, were assessed on postoperative days 1, 7, and 14 following nasal pack removal. Statistical analysis of all collected data was done using Statistical Package for the Social Sciences (SPSS) version 26.00.
Results: In Group A, 93.00% of participants experienced mild symptoms, while 7.00% had moderate symptoms. In Group B, 90.00% reported mild symptoms, while 10.00% had moderate symptoms. No cases of severe symptoms were observed in either group. Statistical analysis revealed no significant difference in symptom severity between the two groups (p = 0.64). These findings suggest that routine postoperative antibiotic use in septoplasty may not be necessary.
Conclusion: Septoplasty is a clean contaminated procedure and does not need antibiotic prophylaxis in the post-operative period because of the low risk of infection.

Keywords: Antibiotic prophylaxis, Nasal discharge, Septoplasty

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INTRODUCTION

Septoplasty is a routine surgery that is done to correct deviated nasal septum (DNS), a condition, which leads to having a blocked nasal passage, difficulty in breathing and recurrent sinusitis,[1] however, there is controversy about the usage antibiotics in septoplasty, especially in prophylactic administration. Some studies suggest that antibiotic prophylaxis lowers the infection rates after surgery, but others argue that antibiotics should not be administered routinely because the incidence rates of infection are low.[2] Globally, a number of studies have quoted different incidences of post-septoplasty infection, ranging from 12.00% reported in 100 patients,[3] to 0.48% in 1,040 patients of which none had received antibiotics as a prophylactic measure.[4] Similar data from our region suggests that otorhinolaryngologists do not have a clear trend in the choice of antibiotics, which, after nasal operations, are used topically, although there is no evidence for their effectiveness. A search of the Pakistani literature has revealed scarce information regarding postoperative complication rate after septoplasty or the practice of prophylactic antibiotic usage. This lack of detailed national indicators and advocacy on the guidelines elaborates a knowledge gap in the available studies, however, high frequency use of antibiotics has created antibiotic resistance worldwide, along with leading to serious side effects such as toxic shock syndrome; endocarditis; meningitis; as well as cavernous sinus thrombosis.[3-5] An attempt was made in this study to address these gaps with local data, and to give evidence in relation to the need for the use of prophylactic antibiotics in septoplasty. It is hoped that the analysis of outcomes comparing those with and without antibiotic use will assist in furthering the advancement of surgical practice and best clinical practices for antibiotic use.

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METHODOLOGY

This quasi-experimental study was conducted at Combined Military Hospital (CMH), Murree, Pakistan, from July 2022 to July 2024, to compare the effects of

postoperative antibiotic use versus no antibiotics in septoplasty patients. Ethical approval was obtained from the Ethics Review Committee (Approval Number: 001/7/22) and written informed consent was obtained from all participants. The sample size was calculated using the OpenEpi sample size calculator. The calculation was based on a reference prevalence of postoperative infections in septoplasty patients, which was estimated to be 5%.[5] The confidence interval was set at 95.00%, and the power was set at 80.00%. Based on these parameters, the estimated sample size required was 60 patients, with 30 patients in each group. Participants were selected based on clinical history, systematic evaluation, and (Ear, Nose, Throat) ENT examination, including otoscopy, nasopharyngoscopy, tympanometry, and fiber optic laryngoscopy. A non-random consecutive sampling technique was used to assign participants to either of the two groups. Patients were allocated based on their sequence of admission, where odd-numbered patients were assigned to Group A, while even-numbered patients were assigned to Group B.

Inclusion Criteria: Patients belonging to either gender, between the ages of 17 to 45 years, with asymptomatic DNS, and having the intent of correction by surgery, patients with asthma, chronic obstructive pulmonary disease (COPD), or other known respiratory pathology were included.

Exclusion Criteria: Patients with history of anticoagulant therapies, suspected infection, or who had previously undergone nasal surgeries were excluded.

Sample collection was done for all patients, including a complete blood count (CBC), prothrombin time (PT), activated partial thromboplastin time (aPTT), hepatitis profile and chest X-ray (CXR). Informed consent was sought from all participants prior to enrollment. Patients were divided into two groups where patients in Group A and were given preoperative dose of co-amoxiclav 1.2 g 30 min before surgery and received co-amoxiclav 625 mg orally every 8 hours for 5 days postoperatively, while in Group B, patients received only one dose before the operation of co-amoxiclav 1.2 g with no other antibiotics after the operation. All surgeries were done by a single surgeon and using a common technique for septoplasty with traditional surgical approach. Light anterior nasal packing was used and left in place for 24 hours. ENT evaluations, following nasal pack removal on the first postoperative day, were thereafter done on the seventh and fourteenth postoperative day. Pain was measured by self-administered Visual Analog Scale (VAS), ranging from 0 (no pain) to 10 (the worst pain possible), nasal discharge was divided into three sub-categories: 1 = Low, 2 = Medium and 3 = High, meaning low, moderate and high amount respectively while fever was documented as body temperature more than 38 degree Celsius. Pain relief, antipyretics, and antiemetics were given as necessary for symptomatic relief of moderate-severe symptoms. Surgical procedures were performed under standardized aseptic conditions by the same surgeon to minimize variability. Postoperative care included nasal packing for 24 hours, and symptoms were assessed on days 1, 7, and 14. Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences) version 26.00. Descriptive statistics were used for patient characteristics. The normality of the data was checked using the Shapiro-Wilk test. Fisher's Exact Test was conducted for categorical variables as the expected cell frequencies were < 5 in some cases. Independent t-tests was used to compare means. Statistical significance was set at $p < 0.05$.

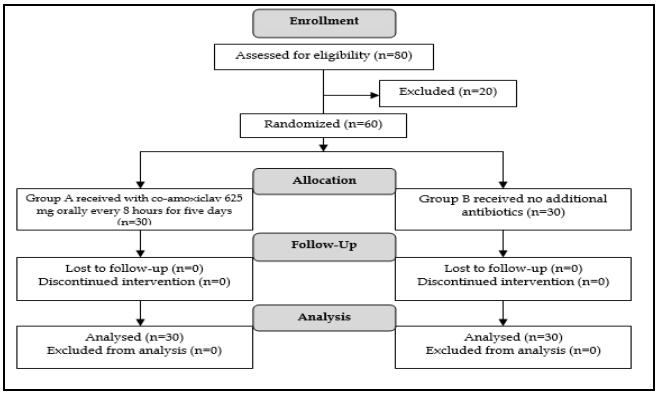

Figure: Patient Flow Diagram (n=60)

RESULTS

A total of 60 participants were included, comprising 44 males (73.30%) and 16 females (26.70%) where mean age of Group A was 33.50 ± 8.18 years and Group B was 35.00 ± 9.30 years, although this age difference was not statistically significant ($p = 0.51$), as shown in Table I.

Table-I: Patient Characteristics (n=60)

Variable	Group-A Mean ± SD	Group-B Mean ± SD	*p*-value
Age (years)	33.50 ± 8.18	35.00 ± 9.30	0.51*
**Independent t-test.*			

Postoperatively, none of the participants developed septal hematoma or abscess. All 60 patients (100.00%) exited the surgical room with minimal anterior nasal packing (paraffin gauze), with no significant difference between groups (p = 0.22). The comparison of pain and temperature between the two groups revealed that 3 participants (10.00%) in Group A and 4 participants (13.30%) in Group B suffered with pain and fever following surgery. The majority of participants in both groups (90.00% in Group A and 86.70% in Group B) did not report pain or fever. Statistical analysis showed no appreciable variation in terms of postoperative pain and fever among the groups (p = 1.000) as shown in Table II.

Table-II: Comparison of Pain and Fever Between Groups (n=60)

Group	Pain, Fever n (%)	No Pain, Fever n (%)	*p*-value
Group A (n=30)	3(10.00%)	27(90.00%)	1.00
Group B (n=30)	4(13.30%)	26(86.70%)	

By the 7th and 14th postoperative days, no pain, fever, or purulent discharge in the nasal fossa/vestibule were observed in either group, as shown in Table III. Statistical comparisons revealed no significant differences between Group A and Group B in age (p = 0.79), nasal packing use (p = 0.22), or postoperative symptom incidence (p > 0.05). The overall complication rate was low, with no clinically meaningful associations between group assignments and outcomes.

Table-III: Association of Nasal Discharge Severity between Both Groups (n=60)

Group	Mild *n* (%)	Moderate *n* (%)	Profuse *n* (%)	Total *n* (%)	*p*-value
Group A(n=30)	28 (93.30%)	2 (6.70%)	0 (0.00%)	30(100.00%)	1.00
Group B(n=30)	27 (90.00%)	3 (10.00%)	0 (0.00%)	30(100.00%)	

DISCUSSION

The application of anterior nasal packing has been reduced after surgical operation, limiting the number of infections that may occur, however, when anterior nasal packing is required for 24 to 48 hours after septal surgery, the risk of bacteremia or infection doubles, where bacteremia was identified in 16.90% patients in one study6, similar to another study7 where one group received ampicillin 500 mg, starting 12 hours before surgery and continuing for five days post-procedure, while another group did not receive antibiotics, after which patients were evaluated and no significant differences were observed. Infection-related complications typically present at the surgical site but can extend to the sinuses or result in severe intracranial issues such as cavernous sinus thrombosis, meningitis, osteomyelitis, or intracranial abscess formation.[8,9] In high-risk patients, such as those with valvular heart disease and immunocompromised condition, antibiotic prophylaxis may be indicated to prevent severe sequelae as the likelihood of post-septoplasty infection is anticipated to be around 5%, even in instances involving nasal foreign bodies such intranasal splints (ISS).[10, 11] Research investigations have demonstrated that prophylactic antibiotics frequently do not successfully inhibit bacterial colonization and biofilm development on ISS,[12,13] as biofilm formation, in particular, presents a substantial obstacle to the treatment of infections, as it increases the resistance of bacteria to antibiotics and contributes to the infection's persistence,[14,15] therefore, the indiscriminate use of antibiotics may lead to the development of bacterial resistance, which is a major issue in the medical profession.9 Over the past few decades, infections from resistant bacteria have risen significantly leading to increased morbidity, mortality, and healthcare costs.[10,13,16] One study compared a true postoperative antibiotic regime of penicillin that took twelve days with a placebo involving one hundred patients who were candidates for secondary rhinoplasty and with the results showed that the postoperative infection rate decreased from 27% to 4%. These results along with those from other studies, lead to questions concerning the effectiveness of antibiotics during the perioperative period.[17,18] The effects of antibiotic prophylaxis on open rhinoplasty have only been studied in a single randomized controlled trial and urgently require attention from more high-powered studies.[18,19] One author found that individuals who had septoplasty without the use of preventative antibiotics had an overall infection incidence of 2% which supports the idea that clean-contaminated nasal operations have a minimal risk of postoperative infection.[20] Another study with 1,040 patients found an infection rate of 0.48%, even though no postoperative antibiotics were administered.[21] Local research supports limited antibiotic use in nasal surgeries where one study reported a 2% infection rate in Pakistani patients undergoing septoplasty without antibiotics while other regional studies indicate that routine antibiotic use increases resistance and should be restricted to high-risk patients.[22]

LIMITATIONS OF STUDY

The study lacked microbiological confirmation of infection, which would provide stronger evidence of bacterial involvement. The subjective nature of pain assessment using VAS may introduce variability in patient-reported outcomes. The study also did not include long-term follow-up, limiting insight into delayed postoperative complications. The impact of antibiotic use on microbial resistance patterns was also not assessed, which could be valuable for future research.

CONCLUSION

Septoplasty is a clean contaminated procedure and does not need antibiotic prophylaxis in the post-operative period because of the low risk of infection.

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Authors' Contribution

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

AAS & NJ: Data acquisition, data analysis, critical review, approval of the final version to be published.

JAF & UAM: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

RA & MAM: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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