

**Critical Review Form
Therapy**

PGY- 1

[Antibiotics in septoplasty: evidence or habit? Am J Rhinol Allergy. 2012
May-Jun;26\(3\):194-6.](#)

Objectives: "to evaluate the difference in surgical outcome and frequency of postseptoplasty infectious complications in patients treated with preoperative antibiotics (cefazolin), pre- and postoperative antibiotic treatment (cefazolin and amoxicillin), and no antibiotic prophylaxis." (p. 194)

Methods: The prospective randomized controlled trial was performed on patients undergoing septoplasty at the Citta di Castello Civil Hospital in Perugia, Italy between 2005 and 2010. Patients with rhinosinus diseases and previous nasal surgery were excluded. All subjects completed the [Nasal Obstruction Septoplasty Effectiveness \(NOSE\) questionnaire](#) prior to surgery. Septoplasty was performed on all patients using general or local anesthesia; anterior nasal packing (without topical antibiotic) was used in all patients and was removed on the 1st postoperative day.

Patients were randomized to one of three groups based on the log number from the hospital chart:

1. Patients in Group A received no antibiotics, either intra- or postoperatively.
2. Patients in Group B received 1 gram of IV cefazolin at induction of anesthesia, but no postoperative antibiotics.
3. Patients in Group C received 1 gram of IV cefazolin at induction of anesthesia as well as oral amoxicillin for 7 days postoperatively (1 gram every 12 hours).

On post-operative day #1 patients were asked to grade their pain on scale from 0 (no pain) to 10 (maximal pain). Patients also underwent nasal endoscopy on postoperative day #14 by a rhinologist blinded to treatment group. The degree of purulent discharge was graded as follows: 0 = none, 1 = small amount, 2 = moderate amount, 3 = moderate to large amount, and 4 = massive amount. Finally, the NOSE questionnaire was repeated by all patients at postoperative day #30.

A total of 630 patients were enrolled, with 252 in Group A, 197 in Group B, and 181 in Group C. Of these, 66% were male, and the mean age was 37.8 (range 6 to 67). The 3 groups were similar with respect to the percent male, the mean age, and the mean preoperative NOSE questionnaire scores (Table 1).

Guide		Comments																
I.	Are the results valid?																	
A.	Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?																	
1.	Were patients randomized?	Yes. "Patients were randomly divided into three groups according to the log number from the hospital chart. Patients with chart numbers ending in 0–3 were included in group A, in 4–6 were included in group B, and in 7–9 were included in group C." (p. 195)																
2.	Was randomization concealed (blinded)? <i>Was the method of group allocation concealed to prevent subversion of the randomization scheme?</i>	No. Randomization was based on the chart "log number" and hence treatment group could be easily discerned. This would make it difficult to blind participants to group allocation, but would not allow subversion of the randomization process.																
3.	Were patients analyzed in the groups to which they were randomized?	Yes. The authors do not specifically mention an protocol violations, and it must be assumed that an intention to treat analysis was used.																
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	<p>Yes. The 3 groups were similar with respect to the percent male, the mean age, and the mean preoperative NOSE questionnaire scores (Table 1).</p> <p>Table 1. Baseline characteristics</p> <table border="1"> <thead> <tr> <th></th> <th>Group A (N = 252)</th> <th>Group B (N = 197)</th> <th>Group C (N = 181)</th> </tr> </thead> <tbody> <tr> <td>Percent male (n)</td> <td>69 (175)</td> <td>68 (133)</td> <td>60 (109)</td> </tr> <tr> <td>Mean age (range)</td> <td>37.4 (18-67)</td> <td>38.8 (17-59)</td> <td>37.27 (6-57)</td> </tr> <tr> <td>Mean preoperative NOSE score (±SD)</td> <td>82.09 (±16.68)</td> <td>79.05 (±22.33)</td> <td>78.36 (±22.88)</td> </tr> </tbody> </table>		Group A (N = 252)	Group B (N = 197)	Group C (N = 181)	Percent male (n)	69 (175)	68 (133)	60 (109)	Mean age (range)	37.4 (18-67)	38.8 (17-59)	37.27 (6-57)	Mean preoperative NOSE score (±SD)	82.09 (±16.68)	79.05 (±22.33)	78.36 (±22.88)
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B.	Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?																	
1.	Were patients aware of group allocation?	Yes. The authors make no mention of blinding via the use of placebo infusions or oral medications. It seems unlikely that performance bias on the part of the patients would have affected outcomes.																

2.	Were clinicians aware of group allocation?	Yes. It is possible that performance bias on the part of the clinicians could have affected the manner in which treatment was administered,																				
3.	Were outcome assessors aware of group allocation?	<p>Yes and no. The patients and clinicians were not blinded to group allocation. This could potentially have led to observer bias with regards to postoperative pain scores, NOSE questionnaire results, or the evaluation of postoperative complications (bleeding, infectious symptoms).</p> <p>The rhinologist performing endoscopy at postoperative day #14 was blinded to group allocation. Hence the evaluation of purulent nasal discharge would not be subject to observer bias.</p>																				
4.	Was follow-up complete?	Yes. The authors do not mention any attrition, and presumably all patients were evaluated by endoscopy on postoperative day #14, and all patients completed the NOSE questionnaire on postoperative day #30.																				
II.	What are the results (answer the questions posed below)?																					
1.	How large was the treatment effect?	<ul style="list-style-type: none"> • None of the patients developed a postoperative hematoma or septal abscess, and none had a fever. • There were 2 cases (0.3%) of nasal bleeding requiring repeat nasal packing: 1 in Group A and 1 in Group C. • Postoperative pain was similar in all 3 groups, with a mean (\pmSD) of 3.4 (\pm2.39) in Group A, 3.47 (\pm2.48) in Group B, and 3.42 (\pm2.44) in Group C. • Mean (\pmSD) 30-day NOSE questionnaire results were similar among the groups: 7.74 (\pm6.51) for Group A, 7.99 (\pm6.24) for Group B, and 7.91 (\pm6.42) for Group C. • The evaluation of nasal discharge by endoscopy at postoperative day #14 demonstrated similar degrees of discharge in the 3 groups, with a slightly higher rate of grade 2 discharge in group A. No patient showed grade 3 or 4 discharge (Table 2). <p>Table 2. Purulent nasal discharge grades</p> <table border="1"> <thead> <tr> <th></th> <th>Group A (N = 252)</th> <th>Group B (N = 197)</th> <th>Group C (N = 181)</th> </tr> </thead> <tbody> <tr> <td>Grade 0</td> <td>217 (86.11%)</td> <td>174 (88.32%)</td> <td>162 (89.50%)</td> </tr> <tr> <td>Grade 1</td> <td>29 (11.51%)</td> <td>22 (11.17%)</td> <td>19 (10.50%)</td> </tr> <tr> <td>Grade 2</td> <td>6 (2.38%)</td> <td>1 (0.51%)</td> <td>0 (0%)</td> </tr> <tr> <td>Grade 3 or 4</td> <td>0 (0%)</td> <td>0 (0%)</td> <td>0 (0%)</td> </tr> </tbody> </table>		Group A (N = 252)	Group B (N = 197)	Group C (N = 181)	Grade 0	217 (86.11%)	174 (88.32%)	162 (89.50%)	Grade 1	29 (11.51%)	22 (11.17%)	19 (10.50%)	Grade 2	6 (2.38%)	1 (0.51%)	0 (0%)	Grade 3 or 4	0 (0%)	0 (0%)	0 (0%)
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2.	How precise was the estimate of the treatment effect?	See above.																				

III.	How can I apply the results to patient care (answer the questions posed below)?	
1.	Were the study patients similar to my patient?	<p>No. These were postoperative patients with packing placed following septoplasty. Given the surgical procedure involved, one might expect a higher rate of infection in such patients compared to those with simple anterior epistaxis. However, in such cases the nasal packing is placed under sterile conditions, which potentially could reduce this rate. Additionally, all patients in the study had their packing removed on postoperative day 1, while it is not unusual for patients with packing in place for epistaxis to have their packing removed 2 or 3 days after placement.</p> <p>Additionally, the prevalence of comorbid conditions (e.g. diabetes) was not reported in this study. The study was performed in Italy among surgical patients in more controlled conditions. I would suspect the incidence of diabetes and the concomitant use of antiplatelet and anticoagulant agents would be much higher among patients requiring anterior nasal packing for epistaxis.</p>
2.	Were all clinically important outcomes considered?	No. The authors considered postoperative pain, symptoms of obstruction, and infectious complications. The rates of adverse reactions to antibiotics (e.g. diarrhea, rash) were not evaluated in this study. Patient satisfaction was also not addressed.
3.	Are the likely treatment benefits worth the potential harm and costs?	Uncertain. This study demonstrates no clear advantage with the use of systemic prophylactic antibiotics among postoperative septoplasty patients with nasal packing. While this would suggest that there is no advantage in patients with anterior nasal packing for epistaxis, differences between the two populations make it difficult to draw a firm conclusion.

Limitations:

1. **This study evaluated the efficacy of antibiotics in post-operative patients with nasal packing removed the next day, and hence the results may not apply to our patient population ([external validity](#)).**
2. **A pseudo randomization method was used to allocate patients to their groups based on chart number ([allocation concealment](#)).**
3. **Neither practitioners nor patients were [blinded](#) to group allocation.**
4. **The authors fail to report several items from the [CONSORT checklist](#), including:**
 - a. **Failure to define a primary outcome and secondary outcomes.**

- b. Failure to report important demographic data (such as the incidence of diabetes) that would affect outcomes.**
- c. Failure to report study limitations.**

Bottom Line:

This randomized controlled trial evaluating the use of intraoperative and postoperative antibiotic prophylaxis among patients with nasal packing following septoplasty found no difference in pain scores, nasal obstructive symptoms, or the incidence of postoperative infection among patients receiving no antibiotics, intraoperative IV antibiotics alone, or a combination of intraoperative and postoperative antibiotics. While these findings suggest that antibiotics offer no advantage in patients with anterior nasal packing for epistaxis, differences between the two populations make it difficult to draw a firm conclusion. Further studies on patients with nasal packing specifically in the setting of spontaneous epistaxis will need to be evaluated.