## Critical Review Form Therapy

Are systemic prophylactic antibiotics indicated with anterior nasal packing for spontaneous epistaxis? Acta Otolaryngol. 2009 Feb;129(2):179-81.

<u>Objectives:</u> "to investigate the need for the use of prophylactic antibiotics in cases of spontaneous epistaxis where anterior nasal packing was used." (p. 179)

Methods: This was a prospective study involving patients with epistaxis admitted to the otolaryngology service of a large teaching hospital in Bristol, UK between August 1, 2005 and January 31, 2006) for spontaneous epistaxis managed with anterior nasal packing. Antibiotics (amoxicillin with clavulanic acid) were administered only when nasal packing remained in place for more than 24 hours. Following removal of nasal packing, nasal swabs were obtained and sent for bacterial culture from both the packed and unpacked nares in those cases of unilateral packing. In cases where bilateral nasal packing was employed, cultures were not obtained. All patients underwent rigid nasal endoscopy following removal of nasal packing to assess for signs of infection. All patients were also evaluated in clinic one week following discharge from the hospital.

During the study period, 41 patients were admitted for epistaxis, of whom 28 were managed with anterior nasal packing, and hence were included in the study. Of these, 16 cases involved merocel packing and 12 involved use of the Rapid-rhino. There were 21 patients with unilateral packing in place, in whom nasal swabs were obtained, and 7 with bilateral anterior nasal packing. Eleven patients (40%) were prescribed antibiotics due to their packing remaining in place for over 24 hours; 2 other patients were prescribed antibiotics for a co-existing medical condition.

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?	No. This was a "case control" trial in which the unpacked naris was used as the control. The side packed was determined by the location of the epistaxis.
2.	Was randomization concealed (blinded)? Was the method of group allocation concealed to	N/A

prevent subversion of the	
randomization scheme?	
Were patients analyzed in the groups to which they were randomized?	N/A. This was, again, a non-randomized trial.  Microbiological culture results from the packed sides were compared to culture results from the unpacked side.
Were patients in the treatment and control groups similar with respect to known prognostic factors?	In essence, yes. Patients were used as their own control. The only difference between the two sides was the presence (or absence) of packing.
Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?	
Were patients aware of group allocation?	N/A
Were clinicians aware of group allocation?	N/A
Were outcome assessors aware of group allocation?	N/A
Was follow-up complete?	Yes. All patients with unilateral nasal packing underwent nasal swabbing for culture. All patients included in the study underwent rigid nasal endoscopy, and all patients were evaluated at one-week follow-up.
What are the results (answer the questions posed below)?	
How large was the treatment effect?	<ul> <li>Microbiology</li> <li>The microbiological results were similar between the packed and non-packed sides following pack removal. The organisms that grew included coagulase-negative staphylococci, Staphylococcus aureus, strep viridans, and one case of Moraxella catarrhalis.</li> <li>There was no significant difference in growth noted between those who received antibiotics and those who did not.</li> <li>Complications</li> <li>No clinical infections were encountered in any patient throughout the study. None of the patients</li> </ul>
	were patients analyzed in the groups to which they were randomized?  Were patients in the treatment and control groups similar with respect to known prognostic factors?  Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?  Were patients aware of group allocation?  Were clinicians aware of group allocation?  Were outcome assessors aware of group allocation?  Was follow-up complete?  What are the results (answer the questions posed below)?  How large was the treatment

2.	How precise was the estimate of the treatment effect?	This was not assessed.
III.	How can I apply the results to patient care (answer the questions posed below)?	
1.	Were the study patients similar to my patient?	No. These were patients admitted to the otolaryngology service in Bristol, UK for anterior epistaxis. Our patients are primarily treated in the ED and released, even when anterior nasal packing is employed. Having said that, the nasal environment would likely be similar in this admitted to the hospital and discharged. Baseline characteristics and demographics for these patients was not provided; specifically, it would be helpful to know the age range of the included patients, the incidence of diabetes, and the presence of other conditions associated with immunocompromise.
2.	Were all clinically important outcomes considered?	No. The primary outcome assessed involved the results of cultures obtained from packed and non-packed nasal cavities. While there was reportedly no difference in the findings, this represents a <u>surrogate outcome</u> , and does not necessarily correlate with the incidence of more <u>patient-oriented outcomes</u> , such as infection, toxic shock syndrome, and adverse drug events.
3.	Are the likely treatment benefits worth the potential harm and costs?	Uncertain. This was a small case control study in which patients acted as their own controls. The primary outcomes reported (culture results) do not necessarily correlated with clinically important outcomes, and were poorly reported (percentages for each not reported). While there were no infectious complications reported in any of the patients, all patients with anterior nasal packing for more than 24 hours received antibiotics, and hence there was no comparison. This study neither supports nor refutes the need for prophylactic antibiotics in patients with anterior nasal packing for epistaxis.

## **Limitations:**

- 1. These were patients admitted to the otolaryngology service, rather than those seen in the emergency department and discharged, and may hence be sicker patients with more severe epistaxis (external validity).
- 2. No reporting of demographic or epidemiologic data.

- 3. The primary outcomes reported involved the results of microbiologic testing of swabs from the packed and non-packed nasal cavities of the included patients. The findings therefore represent a <u>surrogate outcome</u>, and do not necessarily correlate with the incidence of more <u>patient-oriented outcomes</u>, such as infection, toxic shock syndrome, and adverse drug events.
- 4. There is incomplete reporting of the microbiological results. While we are told that the growth patterns were the same for packed and non-packed sides, the percentage of patients with growth of various bacteria is not reported.
- 5. All patients with anterior nasal packing received oral antibiotics, hence there is no group with which to compare the incidence of infectious complications.

## **Bottom Line:**

This small, prospective observational study reportedly revealed similar microbiologic growth patterns between packed and non-packed nasal cavities in patients with anterior nasal packing for epistaxis. The study also demonstrated no infectious complications in all patients enrolled. This was a small study in which patients acted as their own controls. The primary outcomes reported (culture results) do not necessarily correlated with clinically important outcomes, and were poorly reported (percentages for each not reported). While there were no infectious complications reported in any of the patients, all patients with anterior nasal packing for more than 24 hours received antibiotics, and hence there was no comparison. This study neither supports nor refutes the need for prophylactic antibiotics in patients with anterior nasal packing for epistaxis.