



summary

Prophylactic antibiotics reduce infectious complications of orthognathic surgery

Zijderveld SA, Smeele LE, Kostense PJ, Bram Tuinzing D. Preoperative antibiotic prophylaxis in orthognathic surgery: a randomised, double-blind, and placebo-controlled clinical study. *J Oral Maxillofac Surg* 1999; 57:1403–1406

Objective To evaluate the need for antibiotic prophylaxis in orthognathic surgery.

Design Double-blind, randomised, controlled trial.

Intervention Patients undergoing Le Fort I osteotomy with various mandibular osteotomies were randomised to receive either amoxicillin clavulanic acid (AC), cefuroxime (CF) or placebo (P) intravenously 30 minutes before surgery.

Outcome measures Appearance of the wound at day 3 and 7 and at 1 month were assessed by a clinician not involved with the surgery using the following four categories: normal, oedematous, exudate with drainage of non-purulent material, or abscess with drainage of purulent material. Wound dehiscence was scored separately.

Results Fifty-four patients were treated over the study period, of whom 15 developed infection. There was a statistically significant increased risk of infectious complication with no antibiotic

	AC	CF	P
Number of patients	18	17	19
Number of wound infections	2	3	10
Percentage of infections	11.1	17.6	52.6
NNT (calculated from presented data)	3	3	NA

prophylaxis. Calculating the NNT you would only need to provide antibiotic cover to three patients to prevent one patient suffering an infectious complication.

Conclusion There is a statistically significant increased risk of having an infectious complication after orthognathic surgery if no antibiotic prophylaxis is given.

Address for reprints: Dr Smeele, Department of Oral and Maxillofacial Surgery, University Hospital Vrije Universiteit/ACTA, PO Box 7057, NL-1007 MB Amsterdam, The Netherlands. E-mail: le.smeele@azvu.nl

Commentary

The use of systemic antibiotic therapy in the clinical practice of oral and maxillo-facial surgery is variable, is commonly based on anecdotal evidence and is generally poorly substantiated. This article was a refreshingly scientific analysis. Based on these results, we believe there is strong evidence to support the use of preoperative systemic antibiotics to decrease the risk of postoperative wound infections for patients undergoing orthognathic surgery. In addition, there is weak evidence to suggest that there may be value in repeated doses of antibiotics for longer operations (>150 minutes).

Most of our criticisms of the study are minor and probably do not affect the outcome, but illustrate some of the problems associated with implementing a randomised clinical trial (RCT), ie, patient enrollment and early stopping of the trial. The authors conducted interim analyses due to a slow accrual rate. It would be interesting to know why the accrual rate was slow and if there was any significant difference between patients who enrolled in the study and those who declined. The potential of selection bias does exist, in that patients who enrolled

could be somehow “different” from usual orthognathic patients.

Interim analyses (‘peeking early’) should not be undertaken lightly or without the approval of the scientific committee supervising the study, as they can have serious implications. For example, the original sample size was calculated under one set of assumptions of infection rates, antibiotic efficacy, rates of enrolment, etc. The new sample size was based on significant revisions of the protocol, i.e., merging the results of the two antibiotic groups, and new assumptions regarding the difference in infection rates between the treatment and experimental groups. These decisions imply, first, that there was no difference in the infection rates in the two antibiotic groups and, second, that the observed difference in infection rates based on the interim analysis is more ‘correct’ than the postulated difference used for calculating the original sample size. Third, the decisions imply that the observed difference in infection rates will be maintained throughout the study and is not a spurious finding. Although we do not disagree with the authors’ rationale for

changing the protocol, since the study was interrupted prematurely there is no way to confirm or refute the assumptions noted above.

Fridrich wrote a very good discussion¹ of the article and reported a much lower postoperative infection rate (3.1–7.1%) compared with the 14.3% of this study. This suggests there may be some differences in the definition of postoperative infection or a role for peri-operative systemic antibiotic therapy instead of only preoperative antibiotic therapy.

As clinicians who regularly perform orthognathic surgery, it is reassuring that the use of antibiotic prophylaxis to prevent postoperative wound infections is well supported by strong evidence in the literature.

1. Fridrich KL. Preoperative antibiotic prophylaxis in orthognathic surgery: a randomized, double-blind, and placebo-controlled clinical trial (Discussion). *J Oral Maxillofac Surg* 1999; 57:1406–1407.

**Thomas B Dodson
 and Leslie R Halperin**
*Harvard School of Dental Medicine,
 Massachusetts General Hospital,
 Boston, Massachusetts, USA*