Prescribing antibiotic prophylaxis in orthognathic surgery: a systematic review

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Abstract. There is no consensus on the use of antibiotic prophylaxis in orthognathic surgery to prevent infections. A systematic review of randomized controlled trials investigating the efficacy of antibiotic prophylaxis was performed to make evidence-based recommendations. A search of Embase, Ovid Medline, and Cochrane databases (1966–November 2012) was conducted and the reference lists of articles identified were checked for relevant studies. Eleven studies were eligible and were reviewed independently by the authors using two validated quality assessment scales. Three studies were identified to have a low risk of bias and eight studies a high risk of bias. Most studies compared preoperative and perioperative antibiotic prophylaxis with or without continuous postoperative administration. Methodological flaws in the included studies were no description of inclusion and exclusion criteria and incorrect handling of dropouts and withdrawals. Studies investigating the efficacy of antibiotic prophylaxis are not placebo-controlled and mainly of poor quality. Based on the available evidence, preoperative antibiotic prophylaxis appears to be effective in reducing the postoperative infection rate in orthognathic surgery. However, there is no evidence for the effectiveness of prescribing additional continuous postoperative antibiotics. More trials with a low risk of bias are needed to produce evidence-based recommendations and establish guidelines.

Orthognathic surgery is a common oral and maxillofacial surgery procedure. Corrections of dentofacial and craniofacial deformities and improvements in patient aesthetics are made with good results. However, there is an inevitable risk of complications with this type of surgery. Pain, swelling, fever, neurosensory deficits, and postoperative infections are well known problems. The postoperative infection rate varies from 2% to 33.4%.[1–3] It is important to minimize the occurrence of these infections as they result in an adverse quality of life and account for extra costs due to longer hospital stays, additional surgery, and work-related absence.[4–6]

Only a few studies reported in the literature have investigated the efficacy of antibiotic prophylaxis in orthognathic surgery. There is still no consensus concerning the use, timing, type, and doses of antibiotic prophylaxis because of the diverse study outcomes.

One meta-analysis and one systematic review plus meta-analysis on this subject were published in 2011.[7,8] The results of the study performed by Danda and Ravi[8] showed that continuous postoperative antibiotic prophylaxis is effective in reducing infections. The systematic review plus meta-analysis by Tan et al.[7] demonstrated that antibiotics given postoperatively are of

no extra value. Given this contradiction in two recently published meta-analyses, this thorough review of the existing available literature was done.

In order to conduct a meta-analysis or a systematic review, it is necessary to accurately assess the design of the included randomized controlled trials (RCTs) to make an estimation of the effect of the risk of bias. Bias means any deviation of results or inferences from the truth, or processes leading to such a deviation. There are several lists to assess the design of an RCT. Tan et al.[7] used the Cochrane Collaboration tool for their meta-analysis. However, more than 72% of the outcomes of the quality appraisal were noted as unclear, which makes the quality assessment doubtful. Danda and Ravi[8] did not use a list of methodological criteria for their systematic review and meta-analysis, but divided the studies into three quality categories based on the rigour of the study.

The most reliable methodological quality checklists for RCTs are the Delphi list[9] and the Jadad scale,[10] as published previously by Olivo et al.[11] These lists are tools to assess an article on the most important risk of bias items for internal and external validity and for statistical analyses. Therefore these scales, shown in Table 1, were used in the present study.

The aim of the present study was to provide evidence-based recommendations on the efficacy of different antibiotic regimens in preventing postoperative infections after orthognathic surgery by reviewing the available RCTs after an extensive evaluation of their risk of bias.

Materials and methods

This study was conducted in accordance with the PRISMA statement.[12]

Study identification

An electronic search of the Embase, Ovid Medline, and Cochrane databases (1966–November 2012) was conducted to identify eligible studies. Key search words that were used in various combinations with Boolean operators and truncations were: orthognathic surgery, osteotomy, infection, antibiotic treatment, antibiotic prophylaxis, and prophylactic antibiotics. A search with Medical Subject Heading (MeSH) terms was performed. The terms used in several combinations were 'Orthognathic Surgery', 'Osteotomy', 'Antibiotic Prophylaxis', 'Anti-bacterial Agents', and 'Wound Infection'.

As exclusion criteria, restrictions were placed on the language 'English' and solely human studies. By using the Med-

line search strategy for identifying RCTs, the studies were limited to clinical trials. There was no limitation with regard to the year of publication.

Reference lists of the articles identified were searched manually for additional useful RCTs. All selected articles were assessed independently by two of the authors (YG and MO) with reference to the inclusion criteria.

Inclusion criteria for RCTs were: a comparison of any type of systemic antibiotic treatment with a placebo, no treatment, or any other type of systemic antibiotic treatment to reduce the infection rate after orthognathic surgery. All systemically administered antibiotics were included, regardless of the type, concentration, duration, frequency of use, and administration scheme.

Data extraction

Studies that met the inclusion criteria were assessed. Data and details concerning the antibiotic treatment for orthognathic surgery were entered on a predesigned data collection sheet. Data extracted consisted of demographic information, type of surgery, type of intervention, follow-up period, definition of infection, and infection rate. This was performed by one author (YG) and later checked by another author (MO).

Table 1. Jadad scale and Delphi list.

	Jadad scale	Answers	Scores
1	Randomization		0–2
	Was the study described as randomized?	–/+	0/1
	Give 1 additional point: the method to generate the sequence of randomization was described and it was appropriate (e.g. table of random numbers, computer-generated)		Plus 1
	Deduct 1 point: the method to generate the sequence of randomization was described and it was inappropriate (e.g. patients were allocated alternately, or according to date of birth or hospital number)		Minus 1
2	Double-blinding		0–2
	Was the study described as double-blind?	–/+	0/1
	Give 1 additional point: the method of double-blinding was described and it was appropriate (e.g. identical placebo, active placebo, dummy)		Plus 1
	Deduct 1 point: the study was described as double-blind but the method of blinding was inappropriate (e.g. comparison of tablet versus injection with no double-dummy)		Minus 1
3	Withdrawals and dropouts		0–1
	Was there a description of withdrawals and dropouts? (The number and the reasons for withdrawal in each group must be stated)	–/+	0/1

	Delphi list	Answers	Scores
1a	Was a method of randomization performed?	–/+	0/1
1b	Was the treatment allocation concealed?	–/+	0/1
2	Were the groups similar at baseline regarding the most important prognostic indicators?	–/+	0/1
3	Were the eligibility criteria specified?	–/+	0/1
4	Was the outcome assessor blinded?	–/+	0/1
5	Was the care provider blinded?	–/+	0/1
6	Was the patient blinded?	–/+	0/1
7	Were point estimates and measures of variability presented for the primary outcome measures?	–/+	0/1
8	Did the analysis include an intention to treat analysis?	–/+	0/1