J Oral Maxillofac Surg
69:e333-e339, 2011

Prophylaxis Versus Placebo Treatment for Infective and Inflammatory Complications of Surgical Third Molar Removal: A Split-Mouth, Double-Blind, Controlled, Clinical Trial With Amoxicillin (500 mg)

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Although there are many conflicting reports regarding third molar removal, few studies investigating the impact of prophylactic or therapeutic antibiotic administration on the control of postoperative infection have been published.[1] With estimated infection rates associated with dentoalveolar surgery ranging from 1% to 25%,[2-5] controversy regarding the use of antibiotics for this type of procedure is increasing, although dentoalveolar surgery is considered potentially contaminated.[6] The lack of detailed information leads to the use of antibiotics in the absence of a precise indication. In extreme cases, patients may lack confidence in professionals who do not prescribe antibiotics.[7] The rationale behind the administration of antibiotics is clearly important in frequently performed procedures such as third molar surgery,[8] and protocols for antimicrobial prescription must be established.[6]

Rigorous compliance with biosafety guidelines usually results in a low frequency of infections. Hence, a 7-day postoperative prophylactic therapy with antibiotics is not currently justified.[9] This controlled clinical trial evaluated the effect of the preoperative prophylactic administration of amoxicillin on the control of postoperative inflammatory/infectious events associated with third molar extraction.

Materials and Methods

STUDY DESIGN

A single-center, randomized, double-blind clinical trial using a split-mouth design was conducted on patients who presented at the School of Dentistry, Federal University of Ceará, Brazil, between January and November 2008. The study was approved by the Ethics Committee on Human Research of the Dentistry Academy of Ceará (Protocol No. 074/08) and was in accordance with the Helsinki statements. Healthy patients (American Society of Anesthesiologists [ASA] classifications I or II) from both genders, ranging in age from 18 to 35 years, with no periodontal disease and with indication for removal of all four third molars, were included in this study, after signing a detailed informed consent. In addition, to standardize the sample, there had to be similar patterns of

Received from the Post-Graduation Program in Dentistry of the Federal University of Ceará, Ceará, Brazil.

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0278-2391/11/6911-0010$36.00/0
doi:10.1016/j.joms.2011.03.055

teeth and root formation, position, and degree of impaction between upper and lower third molars of the right and left sides of the mouth.

Exclusion criteria consisted of tobacco use, patients with orthodontic bands on the second molars, pregnant or breast-feeding women, contraceptive users, patients with chronic systemic disorders, patients with a history of allergies or adverse effects associated with antibiotics, and individuals who had used antibiotics over the previous 3 months. On the day of surgery, presence of any pre-existing acute inflammatory or infectious condition was also grounds for exclusion. Surgical procedures were timed; thus when a procedure required more than 2 hours, the patient was removed from the study sample.

POPULATION

The study sample was derived from 800 patients who sought the dental school for third molar extraction throughout the duration of this study. Of these, 45 subjects met the inclusion criteria, but 9 chose not to participate. One patient were removed from the study for lack of compliance with the postoperative evaluation appointment, and a second patient became pregnant. Thus, the final study sample consisted of 34 patients.

Each patient was submitted to 4 surgical procedures in 2 clinical sessions for removal of 4 third molars. One upper and one lower third molar of the same side were removed during each session. Preoperatively, patients were treated with either two 500 mg capsules of amoxicillin (NeoQuímica, São Paulo, Brazil) or with a placebo, administered orally 1 hour before the procedure, as recommended for healthy patients.[10] Placebo consisted of 2 capsules containing 500 mg of starch each and were the same size and color as the amoxicillin treatment. This split-mouth methodology allowed control of the variables related to the biological response or surgical difficulties encountered between the experimental and control sides.

The right and left sides of the mouth were allocated randomly into 1 of 2 groups, a blind collaborator placed the amoxicillin and placebo matching capsules in transparent and sterile boxes identified as "Patient no. ___ A" and Patient no. ___ B." After recording which drug was deposited in each box, the boxes were shown to the patient, who chose one of the vials to be administered on the first clinical session and the other for the second session. Subsequently, a coin was used to decide which side to do first. With this strategy, researcher and patient were left blind to which medication was administered in each case.

During the first appointment, the initial parameters of maximum mouth opening (Therabite Range-of-Motion Scales), symptomatology (numerical rating scale of pain), and linear distances between facial landmarks (tragus-gnathion; tragus-chelion; tragus-alare; gonion-alare; gonion-exocanthion) were recorded.

Surgery was performed by the same team on all patients, and a standardized technique was used. The same surgical technique was used on the right and left sides of the mouth in an attempt to render an equivalent level of transoperatory trauma. The surgeon (TPB) was a specialist in oral and maxillofacial surgery with 7 years of experience in dentoalveolar surgery. Surgery was performed on an outpatient basis under local anesthesia, rigorously following biosafety guidelines. Standard postoperative treatment was prescribed for both groups with Nimesulid 100 mg (EMS, São Paulo, Brazil) every 12 hours for 4 days and dipyrone 500 mg (Boehringer, São Paulo, Brazil) every 6 hours for 2 days.

Postoperative data were collected from all patients after 3, 7, and 14 days and were evaluated regarding local (soft tissue edema or ulcer on the surgical field), inflammatory (pain, edema, limitation of mouth opening), or infective (presence of purulent secretion, alveolitis, and body temperature >37.5°C) events. Patients rated pain on a numeric rating scale. For the comparison of edema and maximum mouth opening, the measurements performed during the first assessment were repeated on all postoperative evaluation sessions. An increase in body temperature was measured with a thermometer placed under the armpit for 5 minutes. The presence of local swelling/ulcer, purulent material, and alveolitis was evaluated clinically. Alveolitis sicca was diagnosed as the presence of postoperative pain in and around the extraction site, which increased in severity at any time between 1 and 3 days after the extraction, accompanied by a partially or totally disintegrated blood clot within the alveolar socket, with or without halitosis.[11] Purulent material and local swelling/ulcer were defined as present when detected by clinical examination.

The data collected were analyzed statistically with the SPSS 15.0 program. Continuous variables were analyzed using the parametric Student t test for independent samples. Categorical variables were analyzed by the χ^2 test. Bilateral tests were used for comparisons, with the level of significance set at $\alpha = 0.05$. A P value $\leq .05$ was considered significant.

Results

Most participants were females (n = 23, 67.6%), with age ranging from 18 to 31 years (mean: 21.26 ± 3.42 years). Many patients presented more than 1 indication for surgery. Thus, 34 patients presented 61 complaints, in which history of pain (n = 16, 26.2%) and history of pericoronitis (n = 13, 21.13%) were most frequently observed.

Most impacted teeth (n = 58, 44.1%) were partially erupted, 41.2% (n = 56) were submucosal, and 14.7% (n = 20) consisted on intraosseous impaction. Fifty percent of the third molars had their occlusal surfaces positioned between the occlusal plane and cemento-enamel junction of the second molar (class B). Among the lower molars, in 67.6% (n = 46) of the cases there was insufficient space between the anterior border of the mandibular ramus and distal surface of the second molar for the entire crown (class 2). In addition, most upper teeth were disto-angulated, and most lower teeth were mesio-angulated (Table 1).

The mean duration of surgery was similar for the experimental and control groups, with an overall mean of 35 minutes, 31 seconds for each clinical session. Osteotomy was performed in 24 cases (70.6%) and tooth sectioning in 15 (44.1%). These procedures were performed only in the mandible because no upper tooth offered enough resistance to require osteotomy.

Although 50% of the patients presented inflammatory/infectious events on the third postoperative day, this incidence did not differ significantly between the experimental and control groups on any of the reassessments (Table 2).

Comparison of the mean numerical rating of the pain scores showed a significant difference ($P = .021$) between the experimental and control groups only on day 7 (Table 3). In the 2 groups, the mean pain scores were lower on the last assessment compared with the first. This difference was statistically significant for both the experimental group ($P = .000$) and the control group ($P = .028$).

No significant difference was observed in the level of edema between groups at any reevaluation time point. The maximum mouth opening value was significantly higher in the experimental group compared with the control group on day 3 ($P = .029$; Table 4). On day 14, no significant difference between initial and final mouth opening values was observed in the experimental group ($P = .058$), whereas these values remained lower than the initial mouth opening values in the control group ($P = .012$).

Swelling of the soft tissues around the third molar extraction site was the most frequent finding after surgery, in both groups. Two cases of alveolitis were reported postoperatively (1 in the experimental group on day 3 and 1 in the control group on day 7) and drainage of purulent material was observed in 3 cases of the control group (1 on postoperative day 3 and 2 on day 7).

Difference in the frequency of inflammatory/infectious events was not observed between the experimental and control groups when osteotomy and tooth sectioning were performed. The duration of the surgical procedure was not significantly associated with

Table 1. CLASSIFICATION OF TOOTH POSITION

Tooth	Vertical			Horizontal			Angulation				Total
	A	B	C	1	2	3	Horizontal	Mesio	Vertical	Disto	
Upper right third molar	10 (29.4%)	17 (50.0%)	07 (20.6%)	—	—	—	—	09 (26.5%)	11 (32.4%)	14 (41.2%)	34 (100.0%)
Upper left third molar	10 (29.4%)	17 (50.0%)	07 (20.6%)	—	—	—	—	09 (26.5%)	11 (32.4%)	14 (41.2%)	34 (100.0%)
Lower left third molar	13 (38.2%)	17 (50.0%)	04 (11.8%)	11 (32.4%)	23 (67.6%)	—	04 (11.8%)	17 (50.0%)	10 (41.2%)	03 (8.8%)	34 (100.0%)
Lower right third molar	13 (38.2%)	17 (50.0%)	04 (11.8%)	11 (32.4%)	23 (67.6%)	—	04 (11.8%)	17 (50.0%)	10 (41.2%)	03 (8.8%)	34 (100.0%)

The vertical position of the occlusal surface of the third molar is in relation to the occlusion plane and cementoenamel junction of the second molar. The horizontal position is according to Pell and Gregory classification.[12] Angulation position is according to Winter classification.[13]

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Table 2. CORRELATION OF INFLAMMATORY/INFECTIOUS EVENTS BETWEEN BOTH GROUPS

Evaluation	Inflammatory/Infectious	Experimental	Control	*P* Value*
3 days (n/%)	Absent	21 (61.8%)	17 (50.0%)	.329
	Present	13 (38.2%)	17 (50.0%)	
7 days (n/%)	Absent	25 (73.5%)	20 (58.8%)	.200
	Present	09 (26.5%)	14 (41.2%)	
14 days (n/%)	Absent	28 (82.4%)	30 (88.2%)	.493
	Present	06 (17.6%)	04 (11.8%)	

*χ^2 test.

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the presence or absence of inflammatory or infectious events in either group.

Discussion

When the oral and maxillofacial surgeon performs a more invasive or difficult procedure, there is an increased amount of trauma to the surgical site and surrounding tissues. A greater amount of tissue injury leads to increased inflammation in the perisurgical site.[14] Careful surgical technique is effective in limiting tissue damage; however, the efficacy of a decreased bacteremia generated by preoperative antibiotic treatment in reducing inflammation of the perisurgical area remains controversial. A meta-analysis of randomized controlled clinical trials on the effectiveness of antibiotic prophylaxis in third molar surgery states that a well-designed randomized clinical trial is necessary to reach a definitive conclusion regarding antibiotic therapy for third molar surgery.[15] Divergent terminology, classification, and treatment options make it difficult to establish an appropriate level of scientific evidence to support the use of antibiotic treatment before surgical procedures.[9] These divergences are demonstrated by differences in the prevalence of postoperative complications after third molar surgery.[16]

This study was carefully designed to control for the wide array of variables associated with this clinical trial. Thus, the same patient was submitted to the experimental and control procedures at different times with random side/group selection. In this methodology, aspects of the subjects' biological response, operational surgical difficulties, mouth opening, dentition, and systemic differences were standardized between groups. In contrast, other studies have used different subjects in the control and experimental groups without considering existing biological variations.[3,16-19] In addition, inclusion criteria standardized for size, type, and classification of impaction to better control for the level of surgical trauma was also presently employed. Other studies did not standardize the procedure, with patients requiring the presence of at least 1 impacted third molar,[1,20] only 1 lower third molar,[3,16,19,21] or a lower third molar germectomy[18] for inclusion in the study, with the type and extent of the surgical procedures adapted for each case. Also, the surgical team and the procedure were standardized, in contrast to studies that failed to mention the surgeon[1] or included different surgeons.[16,22] This variation is important on the basis of studies that more experienced surgeons were associated with less patient-reported pain during the immediate postoperative period.[17,22] In relation to the reassessments, these evaluations should be performed by the same examiner at scheduled times to avoid interobserver interferences and alterations that may occur over time. In contrast, in one study, reassessments were

Table 3. MEAN SPONTANEOUS PAIN VALUES BETWEEN THE GROUPS, MEAN (SD)

Evaluation	Experimental	Control	*P* Value*
Initial	2.47 (±3.10)	2.03 (±2.52)	.521
3 days	1.47 (±2.64)	2.56 (±2.70)	.098
7 days	1.59 (±2.36)	3.12 (±2.95)	.021
14 days	0.44 (±1.05)	0.71 (±1.49)	.400

*χ^2 test.

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Table 4. MEAN MAXIMAL MOUTH OPENING VALUES BETWEEN THE GROUPS, MEAN (SD)

Evaluation	Experimental	Control	*P* Value*
Initial	51.41 (±7.44)	50.35 (±6.96)	.546
3 days	42.12 (±10.45)	36.35 (±10.84)	.029
7 days	46.88 (±8.37)	43.00 (±10.17)	.090
14 days	50.12 (±7.26)	47.97 (±8.00)	.251

*Student *t* test.

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Table 5. LITERATURE REVIEW ABOUT INDICATION OF ANTIBIOTIC PROPHYLAXIS

	Sample	Medication	Experimental Group	Control Group	Indicates Prophylaxis	*P* Value
Halpern and Dodson[1]	118	Penicillin or clindamycin	Endovascular 1 h before surgery	Placebo	Yes	.03
Lacasa et al[3]	225	Amoxicillin + clavulanic acid	Oral antibiotic 1 h before + placebo after	Oral antibiotic 1 h before + antibiotic 24/24 h, 5 days	Placebo before/after	Yes	.034
Ataoğlu et al[20]	150	Amoxicillin + clavulanic acid	Oral antibiotic 1 h before	Oral antibiotic 1 h after	No medication	No	—
Arteagoitia et al[16]	490	Amoxicillin + clavulanic acid	Oral antibiotic after		Placebo	Yes	<.001
Poeschel et al[19]	288	Amoxicillin + clindamycin clavulanic acid	Oral antibiotic after		No medication	No	—
Capuzzi et al[17]	146	Amoxicillin	Oral antibiotic after		—	No	—
Monaco et al[18]	141	Amoxicillin	Oral antibiotic after		No medication	No	—

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performed by both the researcher and collaborators on average on postoperative day 7. However, the day of reassessment ranged from 5 to 14 days, variations that may permit the resolution of discrete short-term inflammatory/infectious episodes or indicate neglected observational evaluation.[1] Others have used patients' self-evaluation to register edema.[18]

The observed incidence of postoperative inflammatory/infectious events of 43.05% in our study was higher than the previously reported incidences of 8.0%[3] and 12.9%.[16] These differences might be because those studies classified alveolitis and surgical wound infections as inflammatory/infectious events, whereas events such as swelling and traumatic ulcers evaluated in our study were not considered as such. By choosing to exclude these other inflammatory/infectious categories, the incidence of alveolitis and drainage of purulent material had an incidence of 7.35%, a rate lower than the previously reported rates.

Lacasa et al[3] observed a clear difference in mouth opening on the third day of assessment between the group receiving pre- and postoperative antibiotic therapy and the placebo group. In the present study, antibiotic was only administered during the preoperative period, but differences in mouth opening were also observed between groups on day 3. In contrast, Poeschel et al[19] did not demonstrate significant differences in the limitation of mouth opening between groups. In our study, no significant difference in the formation of edema was observed between the groups, which agrees with the literature.[22]

Alveolar osteitis and infection of the surgical field are the 2 most common postoperative complications related to third molar removal.[23] Only 2 cases of alveolitis were observed in this research (2.76%). A meta-analysis reviewing 16 methodologically standardized studies reported a frequency of alveolitis of 6.2% among patients receiving some type of antibiotic prophylaxis and of 14.4% among those who did not.[15] With respect to surgical wound infection, the meta-analysis demonstrated a frequency of 4.0% among patients receiving some type of antibiotic prophylaxis and 6.1% for the control group.[15] In our study, surgical wound infection was observed in 3 patients of the control group (4.14%), with no significant difference compared with the experimental group.

The occurrence of alveolitis is associated with infections, surgical trauma, experience of the surgeon, smoking, contraceptive use, inadequate blood supply, and deficient oral hygiene.[24] In view of the standardizations and results obtained in our study, the cases of alveolitis observed are possibly related to oral hygiene deficiency or deficient blood supply in the surgical bed after surgery.

Some investigators have reported a linear correlation between the duration of the procedure and the

incidence of infection ($P < .027$).[3,17] In our clinical trial, this factor was not significantly correlated.

Standardization of the medication used was important to reduce drug-related bias. Amoxicillin is effective in reducing the incidence of alveolitis and surgical wound infection.[15,25] However, the dose regimen should be standardized for comparisons. This was not the case in a study in which allergic patients received a modification of the drug[1] but were not excluded from the study, which would have hindered methodological accuracy. In relation to the prophylactic use, preoperative administration yielded results that demonstrate its effectiveness in reducing the incidence of alveolitis. However, for surgical wound infection, it was not compatible with a significant reduction.[15]

Surgical difficulties have been directly related to the occurrence of infection. Lacasa et al[3] affirmed that difficulty is characterized by the need for osteotomy during the surgical procedure, and it can increase the incidence of infections from 3.5% to 12.7%. However, no association has been observed between postoperative pain or edema and surgical difficulty.[17] In our study, osteotomy or tooth sectioning was not associated with an increased incidence of inflammatory/infectious events.

A review of studies published in the literature regarding the use of antibiotic prophylaxis (Table 5) shows no consensus among results. In our study, numerical data indicated a benefit to using an antibiotic, but this could not be confirmed statistically.

The use of antibiotic prophylaxis for third molar surgery should be justified by factors other than the induction of transient bacteremia. Arteagoitia et al[15] questioned this approach and stated that patient age and the characteristics of the impacted tooth should be considered in the decision-making process of whether or not to prescribe antibiotic prophylaxis. In addition, the authors stated that prevention of 1 case of alveolitis would require the prescription of antibiotic treatment to at least 13 patients.[15]

Indiscriminate use of antibiotics increases the risk of antibiotic-related toxicity, allergic reactions, secondary infections, and bacterial resistance.[19,26] The prevalence of adverse events after antibiotic therapy ranges from 6% to 7%.[20] In one study involving 52 patients who received amoxicillin in combination with clavulanic acid after third molar surgery, 9 presented with nausea, and 21 had diarrhea.[21] Thus, antimicrobial therapy is only indicated for surgical procedures that present a significant risk of infection[7,19] and in which the advantages of its use exceed the risks of undesired effects.[26] In cases in which the prediction of the occurrence of postoperative infectious events is not possible because the surgical procedure is traumatic and difficult, the decision of whether to use antibiotics should be made after surgery.[19] This approach would prevent the patient from being routinely exposed to antibiotics. Our results have shown that the use of prophylactic antibiotics before third molar removal surgery did not significantly reduce the presence of associated inflammatory/infectious events. Thus, this therapeutic strategy does not seem to impose additional benefits to a young, healthy, adult population.

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