

The Efficacy of Long-Term Post-Operative Antibiotic Therapy Versus Placebo on Dental Implants

Neda Moslemi^{1,2}; Zahra Karami¹; Aysan Shahnaz Miandoab²; Samane Masoumi²; Yadollah Soleimani Shayesteh²; Abbas Karimi^{3,*}; Zahra Ghoncheh⁴

¹Laser Research Center of Dentistry, School of Dentistry, Tehran University of Medical Sciences, Tehran, IR Iran

²Department of Periodontics, School of Dentistry, Tehran University of Medical Sciences, Tehran, IR Iran

³Department of Oral and Maxillofacial Surgery, School of Dentistry, Tehran University of Medical Sciences, Tehran, IR Iran

⁴Department of Oral and Maxillofacial Radiology, Faculty of Dentistry, Tehran University of Medical Sciences International Campus, Tehran, IR Iran

*Corresponding author: Abbas Karimi, Department of Oral and Maxillofacial Surgery, School of Dentistry, Tehran University of Medical Sciences, P. O. Box: 14395433, Tehran, IR Iran. Tel: +98-2122374866, Fax: +98-2122646541, E-mail: abbaskarimi@yahoo.com

Received: June 9, 2015; Accepted: June 10, 2015

Background: Because of the cost and adverse effect of antibiotics, necessity of its prescription in simple implant surgery is questionable.

Objectives: The current study aimed to evaluate the effect of post-operative antibiotic therapy on reduction of post-operative morbidity and failure of dental implants.

Patients and Methods: This triple blind randomized controlled clinical trial included 46 patients (23 in the control and 23 in the intervention groups). Patients in each group were given amoxicillin, 500 mg or placebo every 8 hours for seven days, post operatively. Early infection (occurring in seven days after the surgery) and late infection (occurring in one, three and six months after the surgery) were assessed in all patients.

Results: Sixteen patients (66.7%) in antibiotic group and 20 patients (90.9%) in placebo group had post-operative swelling and pain. The average pain in the antibiotic and placebo groups were (31.04 + 26.29) and (37.73 + 23.69) respectively, and the difference was not statistically significant (P value = 0.37). One patient in each group had probing depth between 5 to 7 mm in six months after surgery (P value = 1). There was no significant statistical difference between the two groups in implant failure. It occurred in two patients in the placebo group (P value = 0.22).

Conclusions: The current study results showed that administration of prolong prophylactic/postoperative antibiotics in simple dental implant surgery might not be beneficial.

Keywords: Amoxicillin; Dental Implants; Antibacterial Agents; Antibiotic Prophylaxis

1. Background

The major goal of modern dentistry is the ideal reconstruction of form, function, speech and health for those who have lost one or more teeth due to periodontal disease, trauma, missing or other reasons (1). Nowadays, intraosseous dental implants have a high survival rate but the failure of the implants and the biological effects are not fully inevitable. The biological complications of dental implants are classified as early or late (2-4). Early failure is defined as failure occurring until connection of the implant abutment, which is easier to diagnose due to lack of osseointegration (5).

It is believed that a certain number of early dental implant failures are due to bacterial contamination at implant insertion (6). Since the microbial contamination is considered as one of the important factors in early implant failures, strategies to prevent infection

in patients undergoing dental implant surgery are routinely performed in dental clinics. The use of prophylactic antibiotic before oral surgical procedure in patients at the risk of infective endocarditis, joint infections and in severely immunocompromised patients is well established (7). However, the use of antibiotic in conjunction with implant surgery in healthy patients is highly controversial. In addition, controlled clinical trials provided conflicting data on their efficacy. The routine use of antibiotic may have negative impact on patients and cause unnecessary economic waste, and side effects including anaphylaxis. Moreover, there is the possibility for the development of resistant bacterial strains (8).

Few studies evaluated the effectiveness of post-operative antibiotics to prevent implant failure.

2. Objectives

Considering the conflicting data regarding the effect of antibiotics on post-operative morbidity and failure of dental implants, the current study aimed to evaluate the effect of post-operative antibiotic therapy on reduction of the post-operative morbidity and dental implant failures.

3. Patients and Methods

The triple blind randomized clinical trial included 46 patients referring to the Implant Department of Tehran University of Medical Science for dental implant (2010 - 2011).

The patients were randomly divided into the intervention and control groups. The intervention group consisted of 23 patients who received amoxicillin, 500 mg (Kosar pharmaceutical company) orally for seven days after surgery. The control group included 23 patients who received placebo (Kosar pharmaceutical company) after implant surgery.

3.1. Inclusion Criteria

- 1) The patients' age range was 20 - 60 years.
- 2) Partially edentulous patients with replacement of maximum two implants (if the patient was a candidate for replacing two dental implants).
- 3) Implant installation with non-submerged method.
- 4) All patients signed the informed consent.

3.2. Exclusion Criteria

- 1) The need for bone grafting or guided bone regeneration
- 2) Necessity of implant installation with submerged method
- 3) Patients with poor oral hygiene and poor compliance
- 4) Smokers
- 5) History of periodontal disease
- 6) Any systemic condition
- 7) Using any other antibiotics within a week prior to surgery "any other" antibiotic.

3.3. Blindness

The patients, researchers and analyzers were masked in this study.

3.4. Randomization

In this study the balanced block randomization was used.

All patients received dental hygiene instructions or scaling/root planning before operation. They were asked to rinse their mouth with 0.2% chlorhexidine, 30 seconds before surgery.

After implant installation all patients were justified to clean the surgery site with the same agent twice daily for one week and use their medication according to the instructions.

3.5. Criteria of Infection

The patients were asked to contact the clinician if they had the symptoms of infection such as: fistula, suppuration, localized swelling, pain and tenderness, erythema and fever.

The sutures were pulled after one week from surgery and the following criteria were recorded: Pain was recorded by asking patients to score their pain from 0 (no pain) to 100 (sever pain) and also swelling rate was recorded by observation and questioning the patients. The prosthesis was installed 2 - 3 months after suture removing.

One and three months after the surgery the following criteria were recorded:

- 1) Pain or tenderness in function
- 2) Gingival index (by observing periimplant tissues)
- 3) Bleeding on probing around implant sulcus
- 4) Mobility of implant
- 5) Suppuration (by pressing periimplant tissue)
- 6) Plaque index (by observing plaque accumulation around the healing abutment)

After six months the following criteria were recorded, additionally:

- 1) Probing depth in mesial, distal, buccal and lingual of each implant
- 2) Evaluation of interproximal bone loss by periapical radiography with parallel technique.

It should be noted that in patients with two implant placements the worst condition was considered. Quantitative data were mentioned as mean \pm SD and qualitative data were expressed as a percentage.

Comparison of quantitative data between the groups was analyzed by T-test. Fisher test was used for distribution of qualitative variables.

4. Results

Demographic information of patients and the number of implants installed in each group are demonstrated in Table 1 and 2, respectively.

Table 1. Demographic Information of Patients (n = 23)^a

	Intervention Group	Control Group
Gender		
Female	15 (65.2)	14 (60.8)
Male	8 (34.7)	9 (39.1)
Mean age of patients, y	46.5	46.05

^a The values are presented as No. (%).

Table 2. The Number of Implants Placed in Each Groups ^a

Number of Implants	Maxilla	Mandible
Intervention group	12 (50)	12 (50)
Control group	13 (59.1)	9 (40.9)

^a The values are presented as No. (%).

4.1. Implant Failure

The implant failure was only observed in two patients of the control group. However, the differences between the groups were not statistically significant (P value = 0.22).

4.2. Pain

The mean pain intensity was 37.37 ± 23.69 and 31.04 ± 26.29 in the control and intervention groups, respectively. The difference was not statistically significant (P value = 0.37).

The means of the days with high-score pain were 1.70 ± 1.90 and 3.30 ± 3.21 in the control and intervention groups, respectively. However, the two groups did not show any significant difference regarding pain score (P value = 0.65).

4.3. Using Analgesics

The numbers of analgesics used by patients in the control and intervention groups were 5.00 ± 3.66 and 9.14 ± 10.04 , respectively. However, this difference was not statistically significant (P value = 0.07).

There were no significant differences in the period that analgesics were used in the two groups (P value = 0.09). This period was 3.32 ± 2.40 days in the control and 3.30 ± 3.21 in the intervention group.

4.4. Swelling

In the control and intervention groups 20 (90.9%) and 16 (66.7%) patients experienced swelling, respectively. The difference was not statistically significant (P value = 0.07).

4.5. Plaque Accumulation

Plaque accumulations were observed in 2 (9.1%) and 1 (4.2%) patients of the control and intervention groups, respectively; however, the difference was not statistically significant (P value = 0.60).

The following factors such as pain and tenderness through function, gingival index, mobility, bleeding on probing, exudate and plaque index in one, three, and six months after surgery did not show any significant differences between the two groups. The detailed information is provided in Table 3.

Table 3. The Number of Patients With Post-Surgical Variables in Each Group at One, Three and Six Months After Implant Surgery ^a

Parameters	Intervention	Control	Intervention	Control	Intervention	Control
	One Month		Three Months		Six Months	
Pain or tenderness through function	0	0	0	0	0	0
Gingival Index						
Grade 0	21 (96.8)	21 (95)	20 (92.7)	21 (95)	19 (92.7)	21 (95)
Grade 1	1 (4.2)	1 (5)	2 (8.3)	1 (5)	2 (8.3)	1 (5)
Grade 2	0	0	0	0	1 (4.2)	0
Mobility	0	0	0	0	0	0
Bleeding on probing	0	1 (5)	1 (4.2)	0	3 (12.5)	0
Exudate	0	0	0	0	1 (4.2)	0
Plaque	10 (41.7)	9 (45)	7 (29.2)	8 (40)	2 (8.3)	1 (5)
Probing depth (< 5 mm)	22 (100)	22 (100)	22 (100)	22 (100)	21 (96.8)	21 (95)
Probing depth (5 - 7 mm)	0	0	0	0	1 (4.2)	1 (5)
Interproximal bone loss	0	0	0	0	0	0

^a Data are presented as No. (%).

5. Discussion

The current study aimed to evaluate the influence of prolonged post-operative antibiotic consumption on dental implant failure and post-operative morbidity. The result of the study demonstrated no statistically significant difference in the patient reported outcomes, early or late infection between the intervention and control group. The result of the current study is consistent with that of Abu-Ta'a et al. (9) concluding that post-operative antibiotic therapy. However, a study by Esposito et al. (10) demonstrated that a single dose of preoperative antibiotic coverage reduced the failure rate of dental implants.

In the present study two patients in the placebo group lost three implants: a 43-year-old female with one implant in the premolar of maxilla and sever swelling on the 7th day.

The reason might be due to unsatisfactory oral hygiene practice and plaque accumulation in the oral cavity. The other one was a 20-year-old female with two implants in anterior region of maxilla that one month after implant installation presented mobility of the implant and the possible cause was overload due to orthodontic appliance. It should be considered, that in the current study all patients undergoing dental implants were healthy individuals and for all of the patients participating in this study high standard of infection control for the implant surgical procedure was applied.

Moreover great emphasis on oral hygiene practice was performed within one week, one, three and six months after surgery. In the current study amoxicillin, 500 mg was selected since this antibiotic has an appropriate first-line antimicrobial effect on patients with dentoalveolar infection (11).

The antibiotic regimen used in the study was prolonged post-operative antibiotic indicated in mild to moderate infections caused by susceptible microorganisms (12). In the light of the fact that the risk of infection after dental implant surgery is influenced by several factors including proper tissue management by surgeon and application of the basic principles of surgery and asepsis, patient health, and others (13, 14). These are probably important factors to protect patient from post-operative infection.

Because of high survival rate of implants (12) in today's clinical practice and low infection rate even without antibiotics (15, 16), routine prescription of antibiotic might be problematic due to obvious risks from hypersensitivity to anaphylaxis and development of microbial resistance in the oral cavity (9).

To define whether antibiotic treatment offers benefits, large sample size and different administration regimens of antibiotic are required. Based on the result of the current study, administration of long term post-operative antibiotic therapy for routine dental implant surgery in healthy patients offers no advantage compared to placebo.

Acknowledgements

This research was supported by Tehran university of medical sciences.

Authors' Contributions

Neda Moslemi developing original idea, and the protocol, and data analysis; Abbas Karimi, Zahra Karami, Zahra Ghoncheh, and Yadollah Soleimani Shayesteh developing the protocol, Aysan Shahnaz Miandoab and Samane Masoumi manuscript writing.

Funding/Support

This research was supported by Tehran university of medical sciences.

References

- Lian Z, Guan H, Ivanovski S, Loo YC, Johnson NW, Zhang H. Effect of bone to implant contact percentage on bone remodeling surrounding a dental implant. *Int J Oral Maxillofac Surg*. 2010;**39**(7):690-8.
- Berglundh T, Persson L, Klinge B. A systematic review of the incidence of biological and technical complications in implant dentistry reported in prospective longitudinal studies of at least 5 years. *J Clin Periodontol*. 2002;**29** Suppl 3:197-212.
- Alsaadi G, Quirynen M, Komarek A, van Steenberghe D. Impact of local and systemic factors on the incidence of late oral implant loss. *Clin Oral Implants Res*. 2008;**19**(7):670-6.
- Alsaadi G, Quirynen M, Michiles K, Teughels W, Komarek A, van Steenberghe D. Impact of local and systemic factors on the incidence of failures up to abutment connection with modified surface oral implants. *J Clin Periodontol*. 2008;**35**(1):51-7.
- Charalampakis G, Leonhardt A, Rabe P, Dahlen G. Clinical and microbiological characteristics of peri-implantitis cases: a retrospective multicentre study. *Clin Oral Implants Res*. 2012;**23**(9):1045-54.
- Esposito M, Cannizzaro G, Bozzoli P, Consolo U, Felice P, Ferri V, et al. Efficacy of prophylactic antibiotics for dental implants: a multicentre placebo-controlled randomised clinical trial. *Eur J Oral Implantol*. 2008;**1**(1):23-31.
- Dajani AS, Taubert KA, Wilson W, Bolger AF, Bayer A, Ferrieri P, et al. Prevention of bacterial endocarditis. Recommendations by the American Heart Association. *Circulation*. 1997;**96**(1):358-66.
- Chrcanovic BR, Albrektsson T, Wennerberg A. Prophylactic antibiotic regimen and dental implant failure: a meta-analysis. *J Oral Rehabil*. 2014;**41**(12):941-56.
- Abu-Ta'a M, Quirynen M, Teughels W, van Steenberghe D. Asepsis during periodontal surgery involving oral implants and the usefulness of peri-operative antibiotics: a prospective, randomized, controlled clinical trial. *J Clin Periodontol*. 2008;**35**(1):58-63.
- Esposito M, Grusovin MG, Maghaireh H, Worthington HV, Esposito M. Interventions for replacing missing teeth: different times for loading dental implants. *Cochrane Database Syst Rev*. 2013.
- Kuriyama T, Williams DW, Yanagisawa M, Iwahara K, Shimizu C, Nakagawa K, et al. Antimicrobial susceptibility of 800 anaerobic isolates from patients with dentoalveolar infection to 13 oral antibiotics. *Oral Microbiol Immunol*. 2007;**22**(4):285-8.
- Tan WC, Ong M, Han J, Mattheos N, Pjetursson BE, Tsai AY, et al. Effect of systemic antibiotics on clinical and patient-reported outcomes of implant therapy - a multicenter randomized controlled clinical trial. *Clin Oral Implants Res*. 2014;**25**(2):185-93.
- Flemmig TMN. Antimicrobials in implant dentistry. *Antibiotics/antimicrobial use in dental practice*. Chicago: Quintessence Pub; 1990. pp.187-200.
- Dent CD, Olson JW, Farish SE, Bellome J, Casino AJ, Morris HF, et al. The influence of preoperative antibiotics on success of endos-

- seous implants up to and including stage II surgery: a study of 2,641 implants. *J Oral Maxillofac Surg*. 1997;**55**(12 Suppl 5):19-24.
15. Lawler B, Sambrook PJ, Goss AN. Antibiotic prophylaxis for dentoalveolar surgery: is it indicated? *Aust Dent J*. 2005;**50**(s2):54-9.
16. Powell CA, Mealey BL, Deas DE, McDonnell HT, Moritz AJ. Post-surgical infections: prevalence associated with various periodontal surgical procedures. *J Periodontol*. 2005;**76**(3):329-33.