

Preemptive Ibuprofen and Orally Administered Dexamethasone for Prevention of Pain and Swelling following Implant Surgery

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Introduction: The post-operative pain and swelling are frequently observed after different surgical procedures. Orofacial pain management is a challenging topic for the dental-medical profession. The main objective of this study was to compare the effects of two designed medical regimens in the context of post-operative management of pain and swelling following simple dental implant surgery. **Materials and Methods:** In this randomized and double-blinded controlled clinical trial, a total of 39 implants were placed in 31 patients by one clinician. Patients were divided into the test and control groups. Before surgery, each patient in the control group received 1gr of amoxicillin and 400 mgr of ibuprofen, and each one in test group received 1gr of amoxicillin, 400 mgr of ibuprofen and 0.5 mgr of dexamethasone. Antibiotic regimen, together with analgesics and anti-inflammatory treatment was provided after surgery for both groups. Pain was measured using visual analogue scale in days 1, 3 and 6 after surgery. Swelling was evaluated by a verbal scale in day 6. Also, the impact of following factors gender, age, duration of surgery, type and number of implant on pain and swelling was measured by the general linear model analysis. **Results:** The majority of patients in both study groups reported the pain to be mild, with peak intensity occurring at 24 hours after operation. No significant difference was observed across the groups for any given time. Also, there was no significant difference between two groups regarding their swelling profile. **Conclusion:** The experiments provide evidence that both of these methods are effective in pain and swelling reduction.

Keywords: Pain; Swelling; Dexamethasone; Ibuprofen; Dental implants

Introduction

Dental implant has been widely used for the management of tooth loss in the past 40 years (1, 2). This method is highly effective and has high rates of clinical success and patient satisfaction, which makes it a suitable option when replacing natural teeth (1, 3).

The post-operative pain and swelling are frequently observed after different surgical procedures due to various reasons, such as surgical trauma or endotoxins (4, 5). The intensity of pain also depends on the extent of the tissue damage (4). Likewise, after dental implant placement different degrees of pain and swelling are usually experienced (6). Orofacial pain management is a challenging topic for the dental-medical profession (7). The pain and swelling after impacted third molar surgeries are extensively discussed in the literature (5, 8-12). However, few studies have focused on the post-operative effects in the implantology (3, 4, 7). Therefore, no standard and extensive medication protocol

exists to manage the patient's post-operative discomforts (13). In the past, different therapeutic agents, including non-steroidal anti-inflammatory drugs (NSAIDs), antibiotics, and others have been suggested for pain and swelling treatment (5).

Evidence shows that NSAIDs are effective to manage oral surgical pain (14). However, based on Barroso *et al.* (5), this treatment might not sufficient, particularly in cases where swelling coincides with pain. In such cases, an additional drug may be required (14). As an example, Moore *et al.*, (15) showed that when performing third molar surgery, the inclusion of dexamethasone in combination with NSAIDs is more effective in controlling the post-operative pain. Moreover, in this combination, a reduced dose of dexamethasone is required to reach satisfactory anti-inflammatory effects (5). It is important to note that the effect of dexamethasone on pain relief after oral surgical procedures is not clearly established (14). Several studies support the efficacy of this medicine (15-17), whilst others claimed that it does not have considerable positive impact (18, 19).

Table 1. Inclusion and exclusion criteria

| Patient inclusion criteria | |
|----------------------------|---|
| 1- | Male and female |
| 2- | Age range 20-70 |
| 3- | ASA (American Society of Anesthesiologists) 1 & 2 classification |
| 4- | Implant location posterior to canine in mandible |
| 5- | Partially edentulous patients (free extremes or inter dental spaces) |
| 6- | Implant type; bone level |
| 7- | Without bone bed preparation, maxillary sinus lift or bone regeneration procedures. Normal drilling, no osteotomy |
| Patient exclusion criteria | |
| 1- | Patients used any medications likely to interfere with the action, absorption or disposition of the study medications |
| 2- | Where the use of corticosteroids are contraindicated |
| 3- | Patients used antibiotic administration 48 hours before their surgery |
| 4- | Patients taken analgesics, steroids or anti-inflammatory drugs within 24 hours before their surgery |
| 5- | Smokers |
| 6- | Patients with pain, swelling and difficulty in mouth opening before their surgery |
| 7- | Difficult follow-up and carry out the treatment |

Table 2. Measurement and statistical comparison for pain and swelling

| Group | Test | Pain (day) | | | Swelling |
|---------|------|-----------------|-----------------|-----------------|----------|
| | | 1 st | 3 rd | 6 th | |
| Test | Min | 1 | 1 | 1 | 1 |
| | Max | 5 | 4.52 | 5.00 | 3 |
| | Mean | 2.09 | 1.69 | 1.39 | 1.6 |
| | SD | 1.17 | 0.89 | 0.98 | 0.76 |
| Control | Min | 1 | 1 | 1 | 1 |
| | Max | 9 | 5 | 2.70 | 3 |
| | Mean | 2.69 | 1.83 | 1.22 | 1.67 |
| | SD | 2.11 | 1.13 | 0.48 | 0.79 |

In this study, the focus is on simple dental implant surgeries. The main objective is to compare the effect of the prophylactic combination of amoxicillin, orally administered dexamethasone and ibuprofen against amoxicillin and ibuprofen alone, on the post-operative management of pain and swelling following simple implant surgeries.

Materials and Methods

In this randomized, double-blinded controlled clinical trial, two prophylactic oral medication patterns were compared after dental implant placements. A total of 31 patients (11 males and 20 females, aged 26-66) received 39 threaded dental implants (Xive, FRIADENT, Mannheim, Germany-TBR, Toulousm, France-Simple line, Dentium, Seoul, Korea) at a private dental office. The implants were positioned by one surgeon under local anesthesia (2% Lidocaine with adrenaline 1:80,000). Patients were randomly assigned by a blocking randomization scheme to two groups (17 in the test group and 14 in the control group controls). Inclusion and exclusion criteria are shown in Table 1.

The implant surgeries were performed on a two-stage basis, and followed the standard surgical protocols with the insertion torque of 30-40 N/cm. The duration of each operation was recorded by minutes *i.e.*, from crestal incision until suturing. The

patients went through simple surgery without any releasing flap, sinus lift, guided bone regeneration, bone graft and osteotomy.

All patients were informed about the study verbally and written consent forms were obtained from them. Clinical Research Ethics committee of Tehran University of Medical Sciences approved the research protocol, including the requirement procedures, exclusion/inclusion criteria and the informed consents. Two observers examined all the participants.

Patients in group I (control group) received 1gr of amoxicillin (Amorax[®], Daana Pharmaceutical Co, Tabriz, Iran) and 400 mgr of ibuprofen (Gelofen[®], Daana Pharmaceutical Co, Tabriz, Iran) 1 hour before surgery. Patients in group II (Test group) received 1gr of amoxicillin, 400 mgr of ibuprofen and 0.5 mgr of dexamethasone (Dexamethasone, Iran Hormone, Tehran, Iran) orally 1 hour before their surgery. An antibiotic regimen together with analgesics and anti-inflammatory treatment was provided after surgery for both groups (amoxicillin 500 mgr, every 8 hour for 5 days, ibuprofen cap 400 mgr for 2 days every 6 hours). Post-surgical care was standardized for both groups.

The pain intensity was recorded through a questionnaire based on the visual analogue scale (VAS from 1 to 10). Inflammation was recorded by verbal rating scale (VRS). In this scale, number 1 stands for the absence of inflammation. Patients with an intra-oral swelling in the surgical zone are scored 2.



Table 3. Measurement and statistical comparison for duration of surgery, number of implants and pain and swelling

| Group | Surgery duration (min) | Implant (n) | Pain (day) | | | Swelling | |
|----------------|------------------------|-------------|-----------------|-----------------|-----------------|----------|------|
| | | | 1 st | 3 rd | 6 th | | |
| Test | Min | 8 | 1 | 1 | 1 | 1 | |
| | Max | 20 | 2 | 5 | 4.52 | 5.00 | 3 |
| | Mean | 13.00 | 1.28 | 2.09 | 1.69 | 1.39 | 1.6 |
| | SD | 3.87 | 0.45 | 1.17 | .89 | .98 | 0.76 |
| Control | Min | 8 | 1 | 1 | 1 | 1 | |
| | Max | 20 | 2 | 9 | 5 | 2.70 | 3 |
| | Mean | 12.53 | 1.20 | 2.69 | 1.83 | 1.22 | 1.67 |
| | SD | 4.03 | 0.41 | 2.11 | 1.13 | .48 | 0.79 |

Table 4. Distribution of swelling, gender and implant system among two study groups

| Group | Swelling on 6 th day | | | Gender | | Implant system | | |
|----------------|---------------------------------|-----------|-----------|-----------|------------|----------------|-----------|-------------|
| | 1 | 2 | 3 | Male | Female | Xive | TBR | simple line |
| Test | 10 (58.8%) | 4 (23.5%) | 3 (17.6%) | 4 (23.5%) | 13 (76.5%) | 10 (58.8%) | 6 (35.3%) | 1 (5.9%) |
| Control | 7 (50.0%) | 4 (28.6%) | 3 (21.4%) | 7 (50.0%) | 7 (50.0%) | 11 (78.6%) | 3 (21.4%) | 0 (.0%) |

Any extra-oral swelling in the surgical zone is scored 3. Number 4 signifies an intense inflammation exhibited by extra-oral swelling extended beyond the surgical zone.

Statistical analysis

Data analysis was performed by Statistical Package for Social Sciences (SPSS 20.0.1 for windows; SPSS Inc, Chicago, IL). The impact of related factors including gender, age, duration of surgery, type and number of implant, pain and swelling was measured by the general linear model analysis. Mann-Whitney test was used to compare patients swelling in each group on the 6th day. The repeated measurement ANOVA was used in order to compare the two groups with respect to pain on 1st, 3rd and 6th day. For each group, the process of pain reduction was studied and then compared between the two groups. Statistical significance was considered $P \leq 0.05$.

Results

Based on the VAS scores, peak pain intensity was recorded at 24 hours after the surgery in both groups *i.e.*, 54.8% of patients totally and was classified as mild pain *i.e.*, VAS intensity score=2.1 in test group and 2.2 in control group (Table 2).

Using repeated measurement ANOVA, in each group the pain intensity at 24 hours, after the operation, was more than that measured on the 3rd ($P=0.005$) and 6th day ($P<0.001$). Moreover, in each group, the comparison of the data related to the 3rd and 6th day showed a statistically significant difference ($P=0.02$) for each group. Therefore, for each group, the pain

intensity reduced significantly during the consecutive three time intervals ($P=0.002$) (Figure 1).

Considering the pain measurement across the two different groups, the results showed no significant difference; *i.e.* the pain profiles were statistically similar ($P=0.39$) across the groups on days 1, 3 and 6 (Table 2).

With respect to swelling, 54.8% of the patients *i.e.*, 58.8% of patients in test group and 50% of the control group had no swelling on day 6 after the surgery. The Mann-Whitney test implies that for this particular point of time, there is no significant difference between the two groups ($P=0.64$).

General linear model analysis demonstrated that none of the factors of age, gender, implant number or surgery duration had any significant relation with the pain in days 1, 3 and 6 and swelling on day 6 after the surgery ($P>0.05$) (Tables 3 and 4).

Discussion

In spite of the high number of dental implant placement procedures (1, 2), there is no medication protocol widely accepted for reduction of pain and swelling (13, 20). Steroids, such as dexamethasone, have generally shown to be useful for post-surgical morbidity reduction (14). Moreover, for dento-alveolar surgeries, several studies have verified the effectiveness of steroids and often suggested corticosteroids during and after surgeries. Despite their beneficial effect, yet there is no established protocol for type of the steroid, dosage and duration of the administration of steroids. Considering this may potentially lead to improper use of steroids due to empirical dosing strategy.



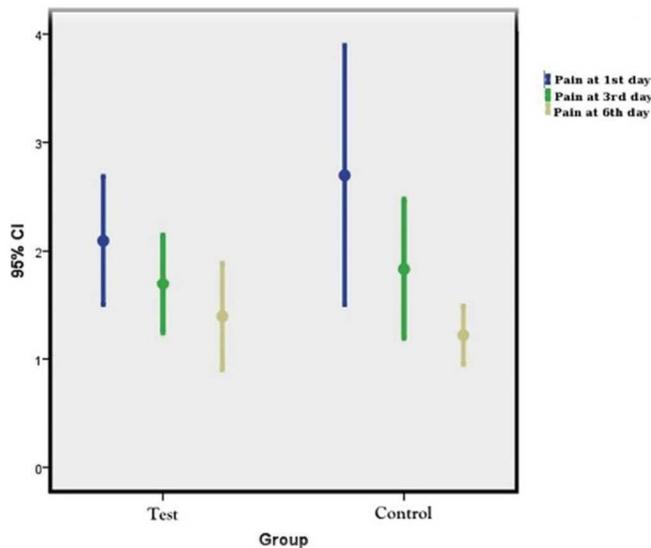


Figure 1. Pain reduction as rated by the visual analogue scale, compared in both groups

Therefore, an important open question concerns forming a comprehensive guidance for using steroids in oral surgeries (14, 20). In this study, we had focused on implant surgeries and dexamethasone has been used as a steroid since it is one of the most common steroids and has a safe administration assuming that the time and dosages are strictly managed (14, 21).

Route of administration: In dento-alveolar surgeries, corticosteroids are administered by local injection, orally and parenterally (14, 20). According to a study by Antunes *et al.*, (17) administration of dexamethasone both orally and by local injection has the same efficacy in reducing pain and edema. Since the oral administration of dexamethasone is more convenient for patients and surgeons, in this study the oral administration was adopted. protocol for type of the steroid, dosage and duration of the administration of steroids. Considering this may potentially lead to improper use of steroids due to empirical dosing strategy. Therefore, an important open question concerns forming a comprehensive guidance for using steroids in oral surgeries (14, 20). In this study, we had focused on implant surgeries. and dexamethasone has been used as a steroid since it is one of the most common steroids and has a safe administration assuming that the time and dosages are strictly managed (14, 21).

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oral administration was adopted.

Time of administration: It has been shown that the prophylactic use is the most effective route, since the administration takes place before the infliction of tissue damage (20). In the present study, dexamethasone was administered orally one hour prior to the surgery.

Limited studies have focused on post-implant discomforts (3, 4, 7). Thus, for validation, the pain and swelling profiles collected in this study are mainly compared with the results of more frequently discussed operations such as third molar surgeries (14, 16, 17, 21).

Swelling: 54.8% of patients had no swelling on the 6th day after surgery. Approximately, 28.8% of them experienced mild swelling, 19.4% had moderate swelling and none suffered from severe swelling. There was no significant difference between the two treatment groups. In a study by Huffman *et al.*, (22) 125 mg and 40 mg methylprednisolone have been used intravenously immediately before the third molar surgeries. They concluded that the administration of corticosteroids reduced edema when measured 24 and 48 hours after surgeries. However, no advantage was reported when measured after one week (22). In a similar study, it has been shown that 125 mg intravenously administered methylprednisolone, is capable of reducing the swelling on days 1, 2, 3, 4 and 7 (23).

Neupert *et al.*, used a different corticosteroid. They administered 4 mg dexamethasone intravenously before the surgeries and on swelling reduction was reported (18). Filho *et al.*, (21) extended the previous work by comparing the effects of two dosage of preoperative dexamethasone *i.e.*, 4 and 8 mg. They showed that administration of 8 mg dexamethasone was more effective than 4 mg in reducing facial swelling (21). In other study two routes of 8 mg dexamethasone administration *i.e.*, orally and local injection, were compared. Result showed that two routes had the same efficacy in reduction of edema (17).

In a study by Buyukkurt *et al.*, (24) the combination of NSAID and corticosteroid (25mg of prednisolone and dyclofenac) immediately after surgery were evaluated. Result showed that the combination is effective in reducing swelling on the 7th day after the surgery (24).

Pain: The method employed for pain measurement in this study was VAS since it a valid, easy and inexpensive method. In the evaluation of post-operative pain, 54.8% of patients scored the highest pain at 24 hours after operation. At that time point, pain was scored as mild (mean=2.15) in patients in both test and control groups. After 24 hours until 6 days after operation, pain decreased significantly in each group. Both regimens were effective in pain reduction, however, no advantage was found for the combination of dexamethasone and ibuprofen compared to ibuprofen alone.

In a study by Neupert *et al.*, 4 mg prophylactic intravenous dexamethasone was used. There was no difference in daily pain, however, global pain was significantly decreased in the steroid group (18). A similar study shows that single-dose 8 mg intramuscular injection of dexamethasone reduces post-operative pain (16). Filho *et al.*, showed that both dosages of 4 and 8 mg dexamethasone have the same efficacy (21). Baxendale *et al.*, administered 8 mg of dexamethasone 2 hours before surgery orally. After 4 hours, they showed that the pain was significantly reduced (25). Antunes *et al.*, compared the route of administration and they showed taking 8 mg dexamethasone either orally or by local injection is equally effective (17). Finally, Pochapski *et al.*, considered pain reduction for endodontic surgeries. They showed that a single dose of dexamethasone administered orally 1 hour before the surgery substantially reduces post endodontic pain (26).

Other factors. Age, sex, the duration of surgery and other environmental factors potentially affect the discomforts experienced after implant surgeries. However the effects of these factors are yet not fully established. Some studies suggest that women exhibit higher levels of anxiety (27, 28) and pain (3), compared to men. On the contrary, certain studies declare no relation between pain and gender (6, 27, 28). Santana *et al.*, (6) showed that pain is stronger in elderly, whilst Weisense stated no significant difference in different age groups. However, there is a distinct relation between duration of surgery and post-operative pain. Patients with longer surgery experienced more pain post-operatively (28).

In the present study, the two control and test groups were uniform with respect to given factors; the patients were chosen to be in the same age range, the groups had approximately the same number of men and woman and the duration of the surgeries were all between 8 to 10 minutes.

Conclusion

Based on the outcome of the present study, the combination of dexamethasone and ibuprofen is effective in reducing pain and swelling after implant surgery. Also, we have shown that using this combination has the same efficacy as ibuprofen alone. However, the outcomes of this study needs to be evaluated using a larger number of samples to improve the reliability of the findings. Additionally, the effects of taking different dosages of dexamethasone needs to be investigated. Finally post-operative discomforts should be measured at more time points and analyzed in a more detailed manner.

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Conflict of Interest: 'None declared'.

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