Evaluation of effects of two dexamethasone formulations in impacted third molar surgeries*

Avaliação dos efeitos de duas formulações de dexametasona em cirurgias de terceiros molares inclusos

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ABSTRACT

BACKGROUND AND OBJECTIVES: Submucosal dexamethasone injection directly in the surgical area has been used in different dental procedures, but there are still few studies evaluating its efficacy as compared to oral route for impacted third molar surgeries. So, this study aimed to evaluate postoperative pain, edema and trismus after impacted third molar surgeries using oral or submucosal local injection of dexamethasone.

METHODS: This was a prospective, controlled, crossover and randomized study involving 36 patients with indication of lower third molar surgeries, who were randomly distributed in two groups: group A – submucosal local injection of dexamethasone (4mg/1mL) after local anesthesia, and group B – oral dexamethasone tablet (4mg) one hour before procedure. Edema and trismus were clinically evaluated in the postoperative period and in the 1st, 2nd, 3rd and 7th postoperative days. Patients were oriented to record pain intensity in the visual analog scale in periods zero (preoperative), 1h, 2h, 4h, 12h, 1 day, 2 days and 3 days and one week after surgery. Data were submitted to statistical analysis with significance level of 5%.

RESULTS: There were no significant differences in surgical time with regard to operated sides (p=0.4). Edema and trismus values were not statistically different between observed groups (p>0.05). Mean pain values recorded in the visual analog scale were not statistically different between groups and patients have not reported major postoperative discomfort and had no need to prolong analgesic medication (p>0.05).

CONCLUSION: Both dexamethasone administration routes were effective to control pain, edema and trismus after lower third molar surgeries, presenting similar results.

Keywords: Dexamethasone, Edema, Oral surgery, Pain.

RESUMO

JUSTIFICATIVA E OBJETIVOS: A utilização da injeção submucosa de dexametasona diretamente na área cirúrgica tem sido realizada em vários procedimentos odontológicos, mas ainda são escassos os estudos que avaliaram a sua eficácia em comparação com a via oral para exodontias de terceiros molares inclusos. Desta forma, o objetivo do presente estudo foi avaliar a dor, edema e trismo no pós-operatório de cirurgia de terceiros molares inclusos utilizando-se dexametasona, por via oral, ou por injeção local submucosa.

MÉTODOS: Estudo prospectivo, controlado, cruzado e randomizado envolvendo 36 pacientes com indicação cirúrgica de terceiros molares inferiores que foram divididos em dois grupos: grupo A - injeção local submucosa de dexametasona (4mg/1mL) após a anestesia local e grupo B - 1 comprimido de dexametasona (4mg), por via oral, uma hora antes do procedimento. Edema e trismo foram avaliados clinicamente no pré-operatório, 1º, 2º, 3º e 7º dia de pós-operatório. Os pacientes foram orientados a registrar a intensidade de dor na escala analógica visual nos períodos 0 (pré-operatório), 1h, 2h, 4h, 12h, 1 dia, 2 dias, 3 dias e uma semana após as cirurgias. Os dados obtidos foram submetidos a análise estatística com nível de significância de 5%.

RESULTADOS: Não revelaram diferenças significativas no tempo cirúrgico em relação aos lados operados (p=0,4). Os valores de edema facial e trismo não demonstraram diferenças estatisticamente significativas entre os grupos observados (p>0,05). Os valores médios de dor registrados na escala analógica visual não mostraram diferença estatística significativa entre os grupos e os pacientes não relataram grande desconforto pós-operatório e não necessitaram prolongar o fármaco analgésico (p>0,05).

CONCLUSÃO: As duas vias de administração da dexametasona mostraram-se eficazes no controle da dor, edema e trismo após cirurgias de terceiros molares inferiores, apresentando resultados semelhantes.

Descritores: Cirurgia bucal, Dexametasona, Dor, Edema.

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INTRODUCTION

Impacted third molar extraction involves soft and bone tissue trauma and may result in considerable pain, edema and trismus. These postoperative pathophysiological events are associated to the release of inflammatory mediators resulting from arachidonic acid metabolism, which may bring discomfort to patients and affect their quality of life[1-3].

Several professionals have emphasized the need for better controlling the postoperative inflammatory process of such surgical procedures, and different drugs have been proposed for such. Corticosteroids may inhibit the onset of inflammatory mediators synthesis and are considered potent drugs to control pain, edema and trismus[4-7].

Dexamethasone has been widely used in dentistry in different doses and administration routes to decrease postoperative discomfort and when used for a short period presents less interference with chemotaxis for leucocytes[8,9]. Among administration routes, submucosal injection has been reported by previous studies with significant effects on postoperative edema, but just a limited effect on trismus and pain[10-13].

Notwithstanding several scientific investigations on this subject, there is still no consensus with regard to patients selection, corticosteriods dosage, time and administration route. Drug choices to control postoperative sequelae after oral surgery is normally supported by professional experience and personal preferences, and in this sense, crossover and randomized studies are important to explain and guide the best therapeutic choices[14].

This study aimed at comparing the efficacy of oral or submucosal dexamethasone for impacted third molar extraction.

METHODS

This is a prospective, crossover and randomized study where 36 volunteers of both genders, aged from 18 to 25 years and without systemic changes that could contraindicate the surgical procedure were selected. All volunteers had indication for bilateral extraction of lower third molars with similar impaction pattern, classified as Class I or II and in position B, according to Pell and Gregory[15] and vertical or mesio-angulated impaction according to Winter[16]. In the initial visit, patients were evaluated according to a clinical record where patients' identification medical and dental history, results of preoperative tests (blood count and coagulation time), date and time of surgery, surgery duration, operated side, number of anesthetic tubettes used and administration route of dexamethasone used during the session were recorded[8,12,14,17,18].

Randomization and study groups

To accurately control patients and for better fidelity of results a randomized clinical trial was proposed for the operated side and therapy, based on items 8-10 of the 2001 checklist of the Cochrane Collaboration (Oral Health Group, University of Manchester, UK), which determines the randomized method to generate sequence, to hide groups' letterings and blindness of involved parties[19-21]. Two pharmacological protocols were proposed to control postoperative pain and edema: Group A – local submucosal injection of 1mL of 4 mg/mL dexamethasone (Decadron®, Aché Laboratórios Farmacêuticos S.A., Guarulhos, SP, Brazil) immediately after locoregional anesthesia; Group B – 1 oral 4mg dexamethasone tablet (Decadron®, Aché Laboratórios Farmacêuticos S.A., Guarulhos, SP, Brazil), one hour before the procedure.

Surgical procedures

Each volunteer was submitted to two surgical procedures performed by the same surgeon with proven experience and with 21-day interval between the first and the second surgery[22]. This crossover study has determined that in every surgical procedure the same patient should receive one of the proposed therapies for each operated side – submucosal injection of dexamethasone (4mg/mL) in impacted third molar vestibular region or oral dexamethasone tablet (4mg).

For each surgical procedure patients were oriented to vigorously mouthwash with 0.12% chlorhexidine solution (Proderma®, Piracicaba, SP, Brazil) for one minute, were submitted to extraoral antisepsis with 2% chlorhexidine solution (Proderma®, Piracicaba, SP, Brazil) and received postoperative recommendations about diet, rest and oral hygiene[23].

For teeth extraction, all surgical technique and asepsis principles were strictly followed. Inferior alveolar lingual and buccal nerves were blocked with 2% lidocaine with 1:100000 epinephrine (Alphacaine®, Rio de Janeiro, Brazil)[24]. Immediately after, group A has received subcutaneous dexamethasone in the side determined by randomization. Sulcular incision was performed with knife blade 15 (MedGoldman®, São José, Brazil) and after detachment a mucoperiosteal flap was obtained. Osteoctomy and dental section were performed with rotary tool with abundant sterile saline irrigation. Nylon thread 3.0 (Polysuture®, São Sebastião do Paraíso, Brazil) was used for suture.

After surgical procedure, all patients received a vial with 8 paracetamol tablets (750mg) (Tylenol®, Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda., São José dos Campos, SP, Brazil) and were oriented to take one tablet every 6h for two days. If analgesia had to be prolonged, volunteers were oriented to record quantity and times of additional analgesics use.

Edema and trismus evaluation

Evaluation was carried out in moments: preoperative, 1st, 2nd, 3rd and 7th postoperative days by linear measurements. Edema was measured between the tragus and the wing of the nose and between tragus and labial commissure, at the operated side, with silk thread 2.0. Trismus was evaluated by the interincisal distance, taken as from the incisal edge of upper and lower central incisive teeth at the operated side. Measures were taken with patients in maximum mouth opening, using a gauged digital caliper rule (Pantec®, São Bernardo do Campo, Brazil) in the preoperative, 1st, 2nd, 3rd and 7th postoperative days.

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Pain evaluation

The visual analog scale (VAS) printed in 10 pages of a booklet with explanations about filling was used. Each page of this booklet represented one pain measurement moment (preoperative, immediate postoperative, 1, 2, 4, 12 hours; 1, 2, 3 and 7 postoperative days).

Patients were oriented to mark with a trace on the horizontal line to reflect pain intensity, considering zero as no pain and 10 as maximum possible pain[26]. Volunteers were asked to personally return the booklet with filled VAS when they returned for the seventh postoperative day consultation. Their marks were then measured by gauged digital caliper rule (Pantec®, São Bernardo do Campo, Brazil), considering the distance from zero to the trace recorded by patients in every measurement moment[27].

Statistical analysis

Descriptive statistical techniques were used through absolute and percentage distributions and inferential statistical methods. Paired t, Levene, Shapiro-Wilks, ANOVA and Tukey tests were used with significance level of 5%, being that calculations were obtained with the BioEstat 5.0 program (Fundação Mamirauá, Belém, PA).

This study was approved by the Human Beings Research Ethics Committee, Center of Dental Research and São Leopoldo Mandic Dentistry School (Process 2009/0110), in compliance with Resolution 196/1996. All patients were informed about the objectives of the study and have accepted to participate by signing the Free and Informed Consent Term (FICT).

RESULTS

The analysis (paired t test) of surgical moments has shown no statistically significant differences (p=0.7109) between the surgical time needed for surgeries of group B medicated by oral route, and of group A, by parenteral route. Levene test has shown that "tragus-wing of the nose" (p=0.9973), "tragus-commissure" (p=0.1262), "mouth opening" (p=0.1210) and "pain" (p=0.0935) were homogeneous, being that Shapiro-Wilks test has shown normal distribution for the same measurements. So, measurements were submitted to ANOVA for repeated measures and to Tukey test. Figures 1 and 2 show edema evaluation results.

With regard to tragus-wing of the nose measurement, data analysis has shown no statistically significant differences between groups in moments: preoperative (p=1.0), 1 day (p=0.8141), 2 days (p=0.8693), 3 days (p=0.8610) and 7 days (p=0.8508). However there have been statistically significant differences between each moment, both for group A (p<0.0001) and group B (p<0.0001).

Except for period "3 days" (p=0.0690), there have been no statistically significant differences (p>0.05) between groups in remaining evaluated times. There have also been no statistically significant differences between "preoperative" and "7 days" (p=0.3385); between "1 day" and "2 days" ((p=0.3146); and between "3 days" and "7 days" ((p=0.2120) for group B. Remaining combinations of periods have shown significant differences (p<0.05) for this group. For group A, there have been no statistically significant differences in "preoperative" and "7 days" (p=0.6032); and "1 day" and "2 days" (p=0.6002), being that remaining periods had significant differences (p<0.05).

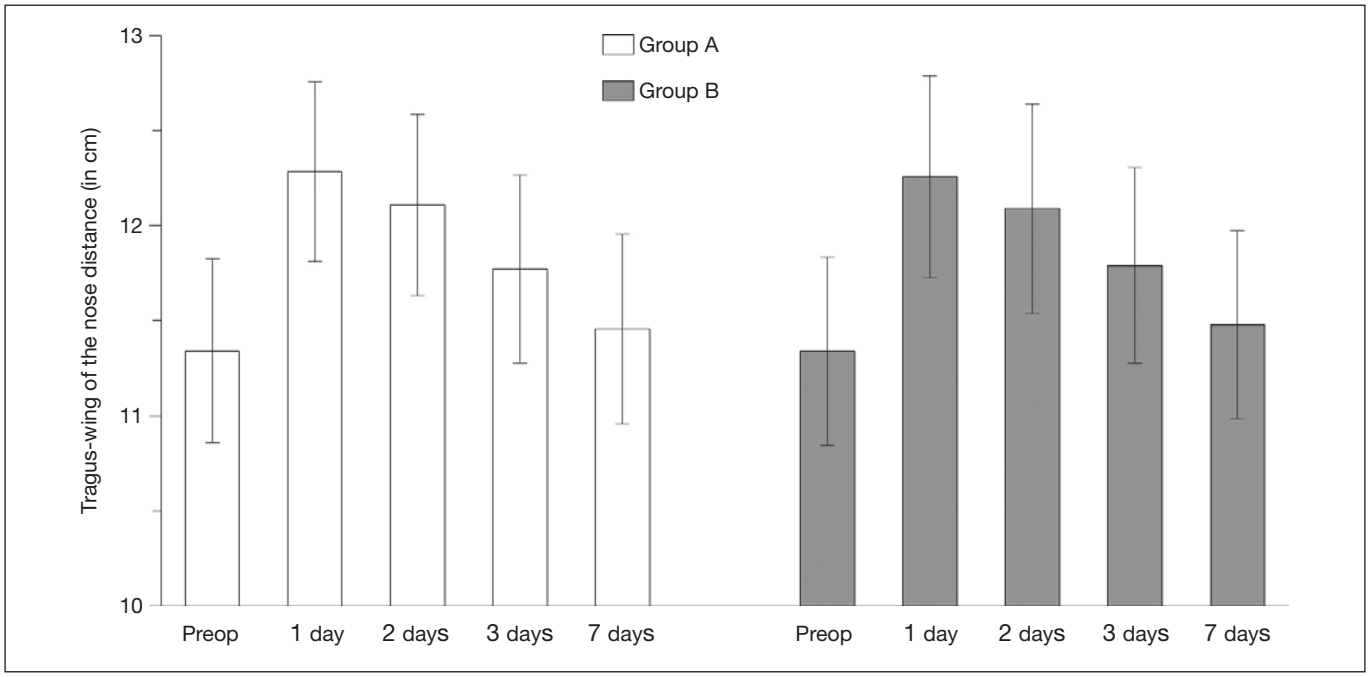

Figure 1. Tragus to wing of the nose distance (mean ± standard deviation) as a function of therapies used)

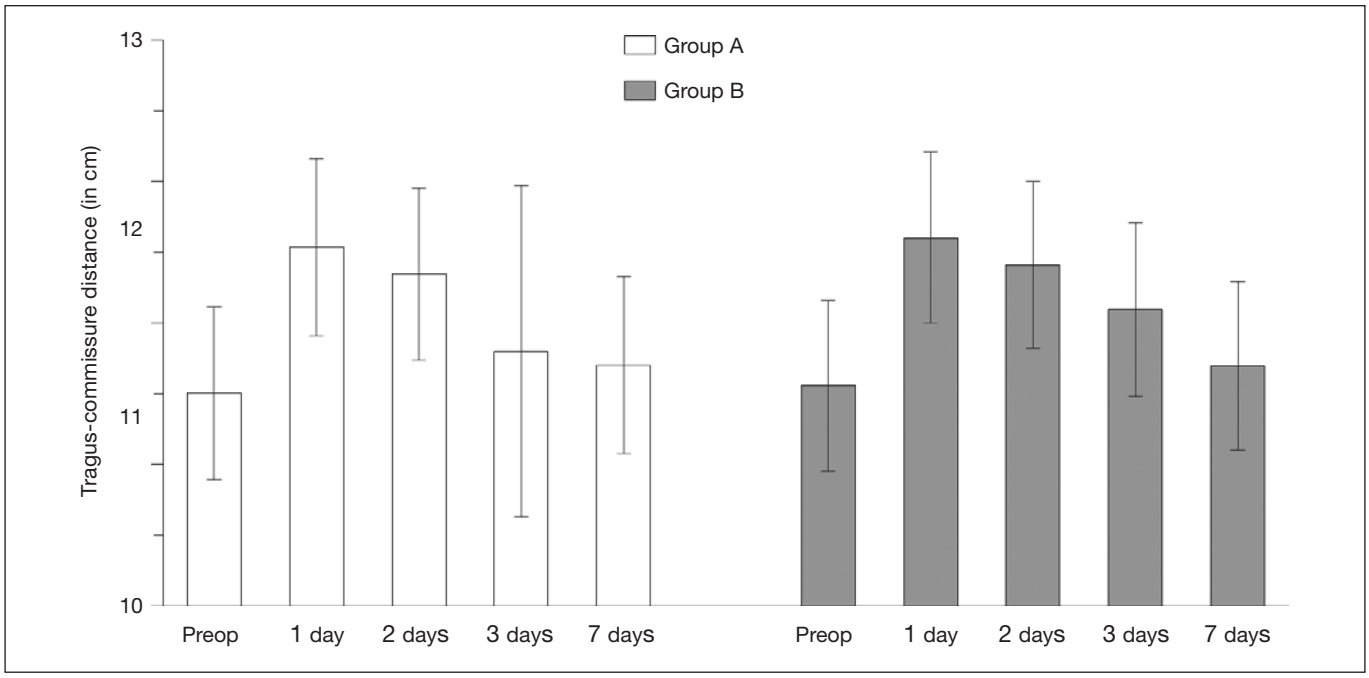

Figure 2. Tragus to labial commissure distance (mean ± standard deviation) as a function of therapies used

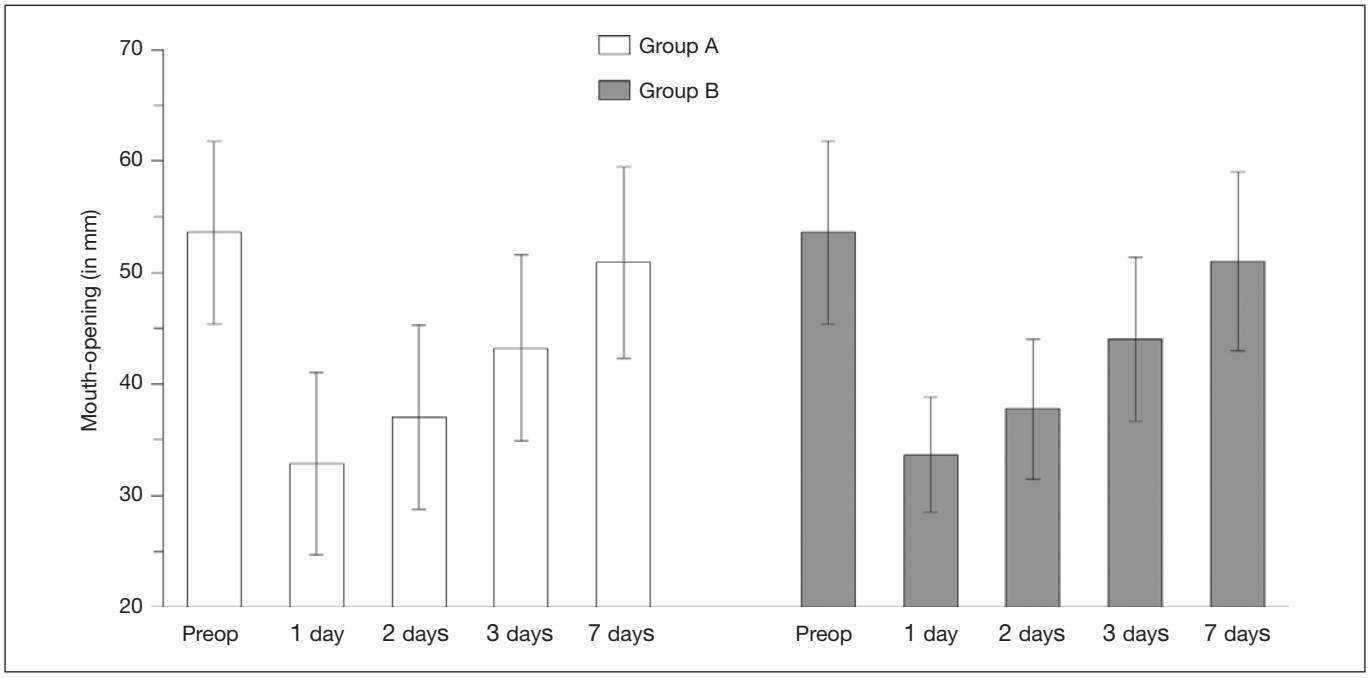

Figure 3. Mouth opening values (mean ± standard deviation) as a function of therapies used

With regard to mouth opening, data analysis has shown no statistically significant differences between groups in preoperative (p=1.0), 1 day (p=0.6667), 2 days (p=0.6799), 3 days (p=0.6632) and 7 days (p=0.9539). However, there have been statistically significant differences between each moment when considering just group A (p<0.0001) and just group B (p<0.0001).

With regard to pain evaluation, data analysis has shown no statistically significant differences between groups in any evaluated moment: preoperative (p=0.8981), 1 hour (p=0.8268), 2 hours (p=0.3254), 4 hours (p=0.2813), 12 hours (p=0.1978), 1 day (p=0.1185), 2 days (p=0.2180), 3 days (p=0.4030) and 7 days (p=0.7435). However, there have been statistically significant differences (p<0.0001) between the periods: preoperative, 1h, 2h, 2 days and 3 days both for group A and group B. However, periods "4h" and "12h" and "1 day" and "7 days" were not statistically different for both groups (p>0.05).

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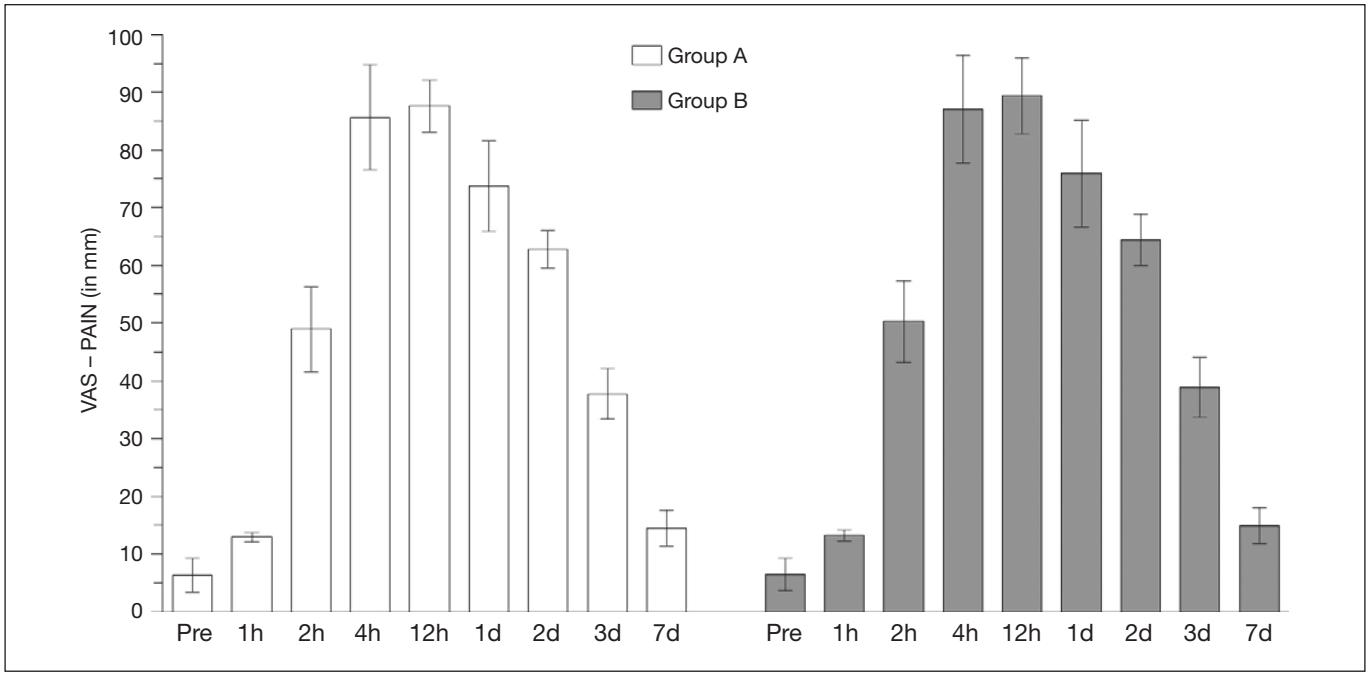

Figure 4. Means ± standard deviation obtained as from visual analog scale (VAS in mm) as a function of therapies used

DISCUSSION

Impacted third molar extraction is in general associated to moderate to severe postoperative discomfort, even when the technique is subtly used, as shown in figure 4, which shows higher painful sensitivity in the periods of 4, 12 and 24h after the procedure[1-3,10]. There is a broad discussion about the best drug to minimize postoperative discomfort in dentistry and among the best drugs of choice, dexamethasone is being evaluated by several scientific studies due to its efficacy to control inflammatory complications as compared to its non-use[5-7].

Meechan and Seymour[28] have studied different complications that appear after impacted third molar surgery and have concluded that the observation of such complications is important to comparatively evaluate the efficacy of several therapeutic measures. Other authors have shown that surgical procedure and immediate postoperative observations are a clinical model for the evaluation of the efficacy of different drugs[14,18,29,30]. In the crossover model used in our study, the same patient was submitted to both proposed treatments (submucosal injection and oral route), one for each operated side during randomization. This model is an advantage for the prospective evaluation of clinical pharmacology, since patients assure the quality of their own control.

Some studies suggest the systemic use of corticosteroids for impacted third molar surgeries[5-7,12,13]. Markiewicz et al.[4] in a meta-analysis have concluded that corticosteroids administered in the preoperative period were of great value to decrease postoperative inflammatory signs and symptoms. Specifically, patients receiving corticosteroids had significantly less postoperative edema, pain and trismus, both the early (after 1-3 days) and the late period (after 4-7 days). Notwithstanding such results, there is still no consensus about the best administration route, dose and duration of treatment, in addition to differences in methods used to evaluate clinical variables.

Oral dexamethasone administration involves later onset of effect, which is inherent to its pharmacokinetics and requires patients' cooperation[31]. However, it is a convenient, safe and low-cost route. Our study data showed that oral dexamethasone was effective to control pain and edema during the studied period, which is in line with other similar studies[6,7,11,12].

Submucosal dexamethasone injection had significant effect on edema in two previous studies and both have reported significant decrease of edema in the immediate postoperative period as compared to controls[1,13]. Our results have shown that submucosal dexamethasone injection has significantly decreased edema in the first postoperative days, in line with previous studes[10,13]. An interesting observation in this group was the significant trismus decrease in the first postoperative day, which is similar to group B (oral route), fact which might be result of the higher concentration of dexamethasone obtained immediately at injury site. These results add more power to the concept that dexamethasone administered close to the surgical site is a valuable way to decrease edema and trismus[5,6,12,32].

Our results, regarding Levene and Shapiro-Wilks tests, have not shown statistically significant differences between groups with regard to postoperative pain, edema and trismus decrease after third molar extraction. This is in line with several authors who have observed the therapeutic efficacy of submucosal administration of corticosteroids in previous studies, shown that submucosal dexamethasone injection, as well as its oral administration, may be a feasible alternative for more invasive dental procedures[6,10,12,13]

CONCLUSION

Bolus administration of parenteral dexamethasone by submucosal injection, and oral administration with tablets have shown similar effects to decrease pain, edema and trismus after impacted third molar extractions.

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