Comparison of oral health-related quality of life after lower third molar extraction following preemptive administration of Traumeel S® vs dexamethasone

Comparaçoãoda qualidade de vida de pacientes submetidos à exodontia de terceiros molares inferiores após administração preemptiva de Traumeel S® vs dexametasona

Comparación de la calidad de vida en pacientes sometidos a extracción del tercer molar mandibular tras la administración preventiva de Traumeel S® frente a dexametasona

Abstract

Purpose: To compare the effect of intramuscular administration of dexamethasone versus Traumeel S® on patients’ oral health-related quality of life (OHRQoL) after surgical extraction of impacted lower third molars (3M). Patients and methods: A randomized, triple-blinded clinical trial was conducted. The sample was composed of 17 patients with asymptomatic bilateral lower 3M positioned as class IIB according to the Pell and Gregory classification. The patients were randomly assigned into 2 groups: intramuscular dexamethasone or Traumeel S®. The OHRQoL was assessed using the Oral Health Impact Profile (OHIP) version 14. It was considered patients’ perception regarding different quality of life dimensions, in the first seven postoperative days. Results: There was a significant OHRQoL improvement in the dexamethasone group when compared to Traumeel S® group. It was noted a significant decrease of psychological disability and psychological discomfort in patients receiving dexamethasone vs those receiving Traumeel S®. Conclusion: Intramuscular injection of dexamethasone showed a greater improvement of the OHRQoL following 3M surgeries when compared to Traumeel S® injection.

Keywords: Dexamethasone; Homeopathy; Oral surgery; Third molar; Arnica Montana.
1. Introduction

Quality of life (QoL) is a multidimensional concept that involves the patient ability to accomplish daily activities (Galvão et al., 2018; Sancho-Puchades et al., 2012). The QoL assessment consists of questionnaires aiming to measure the efficacy and efficiency of treatments. This measurement is based on physical, psychological, and social aspects in each individual’s life. Thus, health-related disabilities can change the QoL as well. On the other hand, it is a subjective analysis and thereby, the results of this evaluation may present differences depending on each individual perception (Sancho-Puchades et al., 2012).

Third molar surgical removal is a common procedure in dentistry because of its high impaction prevalence. This tooth extraction is indicated when there are pathologies associated with its presence such as caries (Falci et al., 2012), pericoronitis (Galvão et al., 2019), cysts, and tumors (Mello et al., 2019). Specifically, lower third molar (L3M) surgeries can lead to high postoperative inflammatory consequences such as pain, swelling, and trismus. These postoperative inflammatory parameters can disable the patients, compromising their quality of life in the early postoperative days (Alcântara et al., 2014; Duarte-Rodrigues et al., 2018).

Postoperative inflammation is mainly controlled through drug protocols, aiming to reduce the patients’ discomfort and morbidity. The pharmacological strategy consists of blocking the formation or inhibiting the effects of acute inflammation mediators through the administration of steroidal and non-steroidal anti-inflammatory drugs (NSAIDs) (Lima et al., 2018).

Dexamethasone is the most used anti-inflammatory drug in the prevention of pain after L3M surgeries (Fernandes et al., 2019). The effectiveness of this allopathic drug has been proven in previous studies (Alcântara et al., 2014; Lima et al., 2018; Falci et al., 2017; Bhargava et al., 2014). On the other hand, there are other drug classes used alternatively to the traditional ones for L3M surgery. Currently, the searching for alternative drugs over the allopathic ones is on the raise.
Traumeel S® is a homeopathic formulation (Biologische Heilmittel Heel GmbH, Baden Baden, Germany) resulted from a mixture of 12 botanical substances and two minerals (Scientifics Bio-Logics-Heel). It has anti-inflammatory properties and has already shown a good performance on third molar surgeries (de Souza et al., 2021). However, no studies have searched whether homeopathic medications improve QoL after L3M surgeries.

This study aimed to compare the impact of the preoperative injection of dexamethasone vs Traumeel S® on the QoL of patients following L3M surgeries, in a short-term follow up.

2. Methodology

This study is a randomized split-mouth triple blinded clinical trial. The Consolidated Standards of Reporting Trials (CONSORT) checklist for clinical trials was followed (Moher et al., 2010). This randomized clinical trial (RCT) is a branch of the same research already published, comparing Traumeel S® vs dexamethasone on postoperative pain, edema, and trismus (de Souza et al., 2021), and was registered in (https://www.clinicaltrials.gov), NCT03567369. The present study shows the QoL results of this comparison. The surgeries were performed on the authors’ university after ethical committee approval (2.341.947). A total of 34 patients underwent third molar surgery based on the results of a sample size calculation.

The following eligibility criteria were applied to patients’ selection. Inclusion: 1) health individuals, 2) older than 18 years, 3) patients who gave their writing consent to participate in the study, 4) patients with bilateral asymptomatic impacted or included L3M. Exclusion: 1) patients who have allergy to dexamethasone or Traumeel S®, 2) patients who have taken anti-inflammatory drugs within 15 days prior to surgery (washout period).

The randomization process was performed through sealed opaque envelopes. The randomization was performed to know which side the third molar would be extracted first (right or left) and which medication would be applied in the first surgery (protocol 1 or protocol 2). The other side was operated 45 days after the first surgery and the other drug protocol was applied. To assure the triple blind design (surgeon, patient, and evaluator), a fourth person who was not involved with the research, was responsible to manipulate and deliver the drugs. Thus, the patient acted as his/her own control. The drug in each protocol was revealed only at the end of all surgeries and after all the statistical analyzes were complete. The protocol 1 consisted in Traumeel S® 2.2mg/2mL and protocol 2 was dexamethasone 8mg/2mL. The route of administration was the intramuscular and the medication was injected into the masseter muscle.

Surgical procedure

All surgeries were performed under local anesthesia (2% lidocaine with epinephrine 1:100000) blocking the inferior alveolar, lingual, and buccal nerves. After anesthesia, according to the randomized process already described, the drugs were administered to the patient. The medications were injected in three different points of the masseter muscle (Messer and Keller, 1975).

All surgeries were performed by the same experienced oral and maxillofacial surgeon. The surgical technique was conducted in accordance with Hupp (Hupp et al., 2008). Osteotomy and tooth sectioning were performed, when necessary, always under irrigation with a 0.9% sterile saline solution. Stiches were performed with 4-0 silk suture. At the end of each surgery, patients received postoperative instructions and rescue medication (18 tablets of acetaminophen 500mg). They were informed to take one tablet, every four hours for up to three days in case of pain. They were also advised to avoid taking other medications that were not provided by the study protocol. Besides that, the patients should inform the researcher if they took any additional medication.

3
Data collection

The QoL was assessed using the Oral Health Impact Profile (OHIP) version 14, adapted and validated to the Portuguese language (Afonso et al., 2017). The questionnaire includes the following items related to the oral condition: 1) functional limitation, 2) physical pain, 3) psychological discomfort, 4) physical disability, 5) psychological disability, 6) social disability, and 7) social disadvantage. The scores for each condition ranged from 0 to 4, where zero corresponded to “never” and 4 to “always”. The questionnaire was applied preoperatively (baseline) and seven days postoperatively (test) in both surgeries, right and left sides.

Statistical analysis

Statistics were performed using the software Statistical Package for Social Science (SPSS), version 22.0. The mean of the OHIP scores given for each medication, at the baseline and the postoperative moment, was calculated. The higher the mean value the worse was the QoL. The normality test Shapiro-Wilk was used to check data distribution. Then, the association parametric or non-parametric tests were performed according to the normality test. To assess the difference between the means of the groups, the Wilcoxon test for paired samples was used when the data distribution was non-normal, and the paired t test was used for data with normal distribution. A value of p<0.005 was adopted for statistical significance. In case of loss of patient during follow-up, in the allocated groups, an intention-to-treat analysis was performed in order to preserve the random distribution.

3. Results

The descriptive analysis was the same reported in the previous published study by the same research group (de Souza et al., 2021). The similarity between the two groups can be proved by the results about surgery duration (p=0.19) and postoperative analgesic intake (p=0.15) (Table 1).

|                      | Traumeel S® (2.2mg) | Dexamethasone (8mg) | p-value |
|----------------------|---------------------|---------------------|---------|
| Surgery time (minutes) | 14.48 ± 7.33        | 16.56 ± 5.49        | 0.19    |
| Number of taken analgesics | 9.44 ± 5.73    | 6.88 ± 5.41         | 0.15    |

Source: Authors.

In the postoperative moment, the patients who had their third molar extracted and were treated with Traumeel S® (23.05±11.46) experienced worse QoL than baseline values (10.05±6.10), p<0.001. This worsening on QoL is attributed to functional limitation (2.41±1.69), physical pain (5.23±2.61), physical disability (3.64±2.62), psychological disability (3.05±2.24), and social disability (3.52±4.09). On the other hand, the patients who had their third molar extracted and were treated with dexamethasone showed the same postoperative QoL (total OHIP) than baseline, p=0.212. However, the functional limitation was worse in the dexamethasone group when comparing baseline to postoperative values (p=0.005). The direct comparison between Traumeel S® and dexamethasone showed better overall QoL in the dexamethasone group (p=0.02). This result can be attributed to psychological discomfort (p=0.007) and psychological disability (p=0.012) (Table 2).
Table 2. OHIP evaluation by each domain.

| Variable            | Preoperative | 7 days after | p-value | Preoperative | 7 days after | p-value | p-value |
|---------------------|--------------|--------------|---------|--------------|--------------|---------|---------|
|                     | Traumeel     | Traumeel     |         | Dexamethasone| Dexamethasone|         |         |
| OHIP total          | 10.058 (6.10)| 23.05 (11.46)| <0.001*| 11.87 (9.34) | 16.12 (10.17)| 0.212  | 0.020*  |
| Functional limitation| 0.352 (0.70)| 2.41 (1.69)  | <0.001*| 0.68 (1.07)  | 2.25 (1.80)  | 0.005* | 0.322   |
| Physical pain       | 2.94 (1.78)  | 5.23 (2.61)  | 0.023* | 3.06 (1.69)  | 4.06 (1.87)  | 0.138  | 0.114   |
| Psychological discomfort | 2.76 (1.88)| 3.05 (2.24)  | 0.64   | 3.12 (2.18)  | 1.83 (1.56)  | 0.053  | 0.007*  |
| Physical disability | 1.11 (1.40)  | 3.64 (2.62)  | 0.003* | 1.43 (1.45)  | 2.75 (2.54)  | 0.129  | 0.172   |
| Psychological disability | 1.83 (1.97)| 3.05 (2.24)  | 0.022* | 1.81 (1.90)  | 1.93 (1.56)  | 0.467  | 0.012*  |
| Social disability   | 0.64 (0.99)  | 3.52 (4.09)  | 0.003* | 1.18 (1.64)  | 1.93 (1.84)  | 0.127  | 0.234   |
| Handicap            | 0.41 (0.79)  | 1.17 (1.18)  | 0.086  | 0.56 (0.96)  | 1.31 (1.66)  | 0.082  | 0.943   |

Source: Authors.

4. Discussion

The aim of this study was to compare preemptive intramuscular injection of dexamethasone with intramuscular homeopathic preparation *Traumeel S®* in patients who underwent lower third molar surgery in respect of QoL at the seventh postoperative day. The main findings include: 1) There was a significant improvement of QoL following dexamethasone administration when compared to *Traumeel S®*; 2) There was no statistically significant difference between the two groups regarding the following outcomes: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, and social disability.

Dexamethasone acts differently from *Traumeel S®*. Thus, all the procedures and interventions in this study were standardized at a maximum level. In this way, the different results between the groups would only be addressed to the drugs’ effects.

The previous published article resulted from this same research (de Souza et al., 2021), showed no statistically significant differences in rescue analgesic intake. However, as a result of the randomization, dexamethasone was administered mostly in the second surgery for each patient. Therefore, it could be suggested that the mean analgesic consumption for the second surgery might have been decreased if patients had not used this drug to avoid the same pain experience of the first surgery. This directly impact the results on QoL, since rescue analgesic consumption is linked to postoperative pain, which is strictly associated with QoL.

Following the same idea, dexamethasone may have shown better results on postoperative QoL than *Traumeel S®* because of psychological influences. A previous experience with pain, discomfort, and disabilities may prepare the individual to similar experiences that are to come. Thus, individuals may react in a lighter way to bad feelings that are not new anymore (Scherer, 2009). Also, individuals can react differently to similar situations and that supports a floating characteristic of a quality-of-life evaluation.
Pain is one of the symptoms that most influence the QoL. In this way, following the results of this study, pain was higher in the Traumeel S® group in the 48-hour follow-up (de Souza et al., 2021). This is explained by the half-life of dexamethasone, which is probably longer than the Traumeel S® (de Souza et al., 2021; Al-Dajani, 2017; Troiano et al., 2018).

Thus, a lower impact on QoL is expected for those patients treated with dexamethasone.

Owing to the current literature, this is the first randomized clinical trial that compared effect of intramuscular injection of dexamethasone vs Traumeel S® after lower third molars surgery. Therefore, it was not possible to compare the recent findings to previous studies.

The limitations of the present study include the absence of a placebo control group to assess a real effect of both medications. On the other hand, the strengths of this study include: 1) all patients acted as his/her own control; 2) both surgeon, patients and assessor were blinded; 3) an intention-to-treat analysis was performed in order to preserve the random distribution. Further well-designed with larger sample size randomized clinical trials are suggested to compare and better elucidate the present results.

5. Conclusion

Preemptive intramussetric injection of dexamethasone was associated with better postoperative QoL than the homeopathic complex Traumeel S® after lower third molar surgeries at the 7th postoperative day.

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