



The Efficacy of Ketorolac Buccal Infiltration Following Surgical Removal of The Impacted Mandibular Third Molar on Postoperative Pain and Trismus

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Abstract

Surgical extraction of the mandibular third molars are widely carried out in dental practice. The procedure is associated with postoperative complications such as pain and trismus.

Objective: The study aimed to assess ketorolac's analgesic and anti-inflammatory efficacy after surgical extraction of the mandibular third molar.

Methods: The study was designed as a double-blinded, randomized prospective clinical study in which 44 patients who required surgical removal of an impacted mandibular third molar were included. They were randomly distributed into two groups (the study and the control/placebo groups), with 22 patients in each group. Immediately after the last stitch, the study group received 30mg/1 ml of ketorolac, while the control group received 1 ml of normal saline at the buccal mucosa near the extraction site of both groups. The mouth openings of the patients were recorded preoperatively, and on the 2nd and 7th postoperative days, a comparison between the two groups was made. The pain level was assessed postoperatively using the numeric rating scale.

Results: The comparison between the two groups by pain score showed that there was a statistically significant difference ($P = 0.001$) in postoperative pain between the study and control groups at all times after the operation. Regarding the trismus, there was no significant difference ($p > 0.05$) between both groups on the 2nd and 7th postoperative days.

Conclusion: Ketorolac buccal infiltration is effective for postoperative pain following third molar surgery but has no significant effect on trismus.

Introduction:

After the third molar surgery, typically, the patient experiences moderate to severe postoperative pain which lasts for at least 24 hours after the procedure (1). This type of pain is considered to be a common clinical model for studying acute pain as a result of these operations (2). It reaches its maximum intensity shortly after the end of the surgery, and, in most cases, patients require some type of pain management (3). Swelling, trismus, and moderate to severe discomfort also has been reported, even with simple extractions (4, 5). Controlling these post-operative sequelae may lead to a better recovery in terms of lifestyle and oral function (6). Trismus is caused by trauma to adjacent vital tissues, bone cutting, soft tissue retraction, and tissue handling, which causes inflammation and prostaglandin release, prolonged mouth opening during complicated extraction resulting in spasms in muscles, as well as the stripping of muscle fibers as a result of elevating the mucoperiosteal flap, which leads to masseter muscle myositis (7). The extraction difficulty shows direct relation to trismus post-operatively (8, 9). There are numerous methods for reducing or eliminating pain and trismus, including the use of biological factors like PRF (10), techniques for closing the flaps, flap designs (11), and medications like corticosteroids (12) and non-steroidal anti-inflammatory drugs (13). Ketorolac tromethamine is one of the non-steroidal anti-inflammatory drugs (NSAIDs) belonging to the acetic acid group and displays analgesic, anti-inflammatory, and antipyretic properties (14). At first, Ketorolac was developed as a parenteral nonsteroidal anti-inflammatory drug for the treatment of post-operative pain, and its analgesic effect is comparable to that of morphine and other NSAIDs (15). Also, the potency of ketorolac in reducing the pain of dentoalveolar origin has been reported in the literature (14). Currently, little clinical research has investigated the efficacy of submucosal administering of ketorolac, to manage pain and trismus resulting from lower third molar surgery. It was hypothesized that ketorolac has

clinical efficacy in reducing pain and trismus when administered submucosally in the buccal vestibule after mandibular third molar surgery.

This study aimed to evaluate the clinical efficacy of buccal infiltration of ketorolac in managing pain and trismus after lower third molar surgical extraction in adult patients.

Materials and Methods

Study Design and Sample

The study is designed as a double-blind, randomized, prospective, controlled clinical study. In which 44 patients were included in this study, the details of the procedure were explained, and informed consent was obtained from them. The Research Ethics Committee at the College of Dentistry, University of Baghdad, approved the protocol for this study (protocol reference number 921021). The extractions were performed at the Department of Oral and Maxillofacial Surgery of the specialized dental center in Al Najaf city, Iraq, from February 2022 to September 2022.

Inclusion criteria included patients who needed surgical extraction of a mandibular third molar that was either completely or partially covered by bone with mesioangular (according to Winter's classification of 1926), Class I or II, and position A or B (according to Pell and Gregory's classification of 1933), and who also had good oral hygiene and a surgical site free of active infection. On the other hand, the study excluded patients with any systemic disease, a recent history of head and neck radiotherapy, pregnancy, female patients taking oral contraceptives pills, patients that were not capable of coming back for the follow-up visit, cystic lesions or periapical pathology related to the impacted tooth, or any interference with the inferior alveolar nerve, smokers, and patients allergic to ketorolac therapy.

Blinding and allocation concealment

Patients were assigned randomly into 2 groups: the ketorolac group, and the placebo/control group. The patient and the researcher (the surgeon) were blinded to this type of interference (the medicines and groups). 44 Enrolled patients were distributed randomly into two groups, 22 patients for each group:

Group I (ketorolac tromethamine) received 1 mL of 30mg ketorolac in the buccal mucosa (the study group) Fig. (1). In group II (normal saline), the patients received 1 mL of normal saline in the buccal mucosa (placebo/control group).

The randomization code (either K for ketorolac or N for normal saline) was kept in an opaque, sealed envelope, this code was only accessible to the assistant investigator. On the day of surgery, the assistant investigator unsealed the envelope, holding the patient code and the drug to be administered; as a result, the drug was placed into a 1 mL insulin syringe. The double-blind study design was used in this investigation since all information about the treatment was kept hidden until the end of the study. In the datasheet, the assistant investigator noted all of the parameters (pre- and post-operative mouth openings, pain measurements at different intervals) that were measured by the surgeon to avoid observer bias.

Preoperative measurement

Mouth opening: the vertical distance between the incisal edges of the left upper and lower central incisors, measured by an electronic digital caliper in millimeters.

Extraction technique

All the patients underwent extraction of impacted mandibular third molars (IMTMs) by the same surgeon and an assistant under local anesthesia (2% lignocaine with 1:200,000 adrenaline) for blocking the inferior alveolar, lingual, and

long buccal nerves. The surgical field was prepared, and aseptic techniques were followed. An envelop flap was reflected with adequate bone removal using a low-speed surgical handpiece. This was associated with continuous irrigation with normal saline solution in copious amounts throughout the operation. The tooth was sectioned by a high-speed dental handpiece whenever needed and removed by elevator, followed by thorough socket toileting and debris removal. The suturing of the flap was done with (3-0) braided black silk as shown in Fig. (2), (3) and (4).

Medicament Injection Technique

After suturing was finished, injection of the medicines started immediately, each patient received a buccal infiltration by using an insulin syringe of 1 mL (ketorolac) or 1 mL (normal saline) based on their group (0.5 mL in the lower buccal vestibule near the surgical site and 0.5 mL in the retromolar area of the same side) (16) to ensure more effective distribution of the treatment around the extraction site, with slow injection for about 5 minutes and firm gauze pressure on the incision line to prevent material leakage Fig. (5).

The patients were instructed to take only the medications that had been prescribed for them, including Augmentin® tab 625 mg (amoxicillin 500 mg, clavulanic acid 125mg) every 8 hours. And in the case of penicillin allergy, patients were instructed to take Azithromycin Cap. 500 mg, 1 tab per day for 3 days; analgesic tablets were prescribed (paracetamol 500mg), three times per day for both groups; postoperative instructions were advised; an appointment for recalls was made on the 2nd and 7th postoperative days for checkups and measurements; and sutures were removed on the seventh day after good healing.

Postoperative Assessment

The mouth openings of the patients were recorded on the 2nd and 7th postoperative days, Fig. (6). Regarding pain measurement, the operator ensured that all

patients received self-assessment pain questionnaires in the form of a numerical rating scale (NRS) for pain, designed as a horizontal ascending graph segmented into a single 11-point numeric scale Fig. (7). The participants were educated to select the number that best reflected the intensity of their pain, where 0 represents no pain and 10 represents the worst imaginable pain. The time to use the pain chart was pre-determined at 6 hours, 12 hours, 24 hours, the 2nd day (48 hours), the 3rd day (72 hours), and the 7th-day intervals. The questionnaires contained six NRSs, one for each specific time from the 1st to the 7th day.

Statistical Analysis

The data were analyzed using Statistical Package for Social Sciences (SPSS) version 26. The data are presented as mean, standard deviation, and ranges. The significance of the difference between different percentages (qualitative data) was tested using the Pearson Chi-square test (χ^2 -test) with the application of Yate's correction or the Fisher Exact test whenever applicable. An independent-samples t-test was used to compare the variables accordingly. A P-value less than 0.05 was considered significant.

Result

Forty-four tooth extractions were performed on 44 patients (13 males and 9 females) in the study group and (14 males and 8 females) in the control group. The mean age in the study group was 23.95 (\pm SD 4.62) years versus 26.59 (\pm SD 5.33) years for the control group, ranging from 18 to 40 years. Concerning the side of the jaw, the left side was operated on in the highest proportion of the study group, 13 patients (59.1%), while the right side was operated on in 12 patients (54.5%) of the controls. Regarding the depth of IMTMs, position A was found commonly in both groups: 12 patients (54.5%) in the study group and 13 patients (59.1%) in the controls. Concerning class, class II was the highest class found in 15 patients (68.2%) and 12 patients (54.5%) of the study and

control groups, respectively. No significant difference ($P < 0.05$) was found between the two groups in terms of age, gender, side of jaw, depth, or class of the IMTMs.

Regarding trismus, the comparison of mean mouth openings before and after the surgical operation showed that mouth opening significantly decreased after 2 days and 7 days of operation compared to that preoperatively in the study and control groups. A significant increase was detected in the mouth opening on the 7th postoperative day compared to that on the 2nd postoperative day of both groups Table (1).

The percentage of limitation in mouth opening was not significantly different ($P < 0.05$) for both groups on the 2nd and 7th post-operative days Table (2). The comparison between the two groups by pain score at the postoperative 6 hours, 12 hours, day one (24 hours), day two (48 hours), day three (72 hours), and day seven showed that there was a significant difference ($P = 0.001$) in the postoperative pain between the study and control groups at all times after the operation Table (3). The time for surgical removal of IMTMs was 22.54 ± 3.8 minutes. in the study group and 21.91 ± 3.9 minutes. In the control, it was > 20 minutes for the highest proportion of the study group 16 (72.7%) and the control group 14 (63.6%). Pederson difficulty index was used to evaluate the extraction difficulty degree, which showed that the moderate difficulty of the surgical procedures was reported among 16 (72.7%) and 17 (77.3%) respectively of the research and control groups. It was clear that There was no discernible variation ($P \geq 0.05$) in the time and difficulty of surgical procedures involving the two groups Table (4).

Discussion

The mandibular third molar surgical extraction is often associated with post-operative pain and trismus that lead to loss of jaw function. Many complex factors contribute to these situations, but they

mostly originate from inflammation that is initiated by trauma from surgery (17). Patients undergoing these procedures can expect moderate to severe pain, which will typically require them to take an analgesic for at least 24 hours following the procedure (18). Third molar surgery is a common model for evaluating analgesic efficacy because it often causes a consistent level of pain and allows one to distinguish weak from strong analgesics based on their degree of intensity (15). This study revealed that the pain scores at different postoperative scheduled intervals were significantly different between the study and control groups at all times after the operation. While the mouth openings before and after the surgical operation were significantly not different for both groups on the 2nd and 7th postoperative days. These results are in agreement with Hasheminia, Faghihian (18) who showed that ketorolac was as effective as dexamethasone in decreasing pain severity after IMTM surgery when injected submucosally. Also, in agreement with (2) showed that the use of sublingual tablets of ketorolac is effective in controlling pain, and in agreement with several studies showed that ketorolac in a variety formulation, exhibited better pain control properties than a control group after impacted third molar surgeries, according to various studies that compared its effectiveness to other medications (19), tramadol (20), and sodium diclofenac (21). Regarding trismus, the findings of this study were in agreement with a study by (3). They mentioned that the limitation in mouth opening reaches the maximum intensity on the 2nd post-operative day, then the symptoms gradually improve and get better on the 7th post-operative day, and Bienstock, Dodson (22) According to their results, regaining normal activities is associated with a mean delay of less than two days after surgical removal. While disagreeing with (2) who showed that the use of sublingual tablets of ketorolac is effective in controlling trismus. All the IMTMs included in the study were mesioangular angulation (according to winter classification) in which the long axis of the impacted mandibular third molar inclined in a mesial direction to the

lower 2nd molar. Choosing this type of angulation was due to the high prevalence rate in comparison to other angulations of impactions (23-25). pain is an experience that is difficult to be evaluated and depends on individual variations like pain tolerance or anxiety (26). Numerical rating scale was utilized in this study to evaluate the intensity of pain felt after surgical removal of the wisdom teeth, as it is easy to understand by the patient, does not need language translation, data are interpreted and documented simply, as well as the parametric tests can be used for analyzing their results (27). The pain was measured from 6 hours of operation through 7 days. The reason is that the pain begins to increase during the fade of local anesthesia and reaches its intensity within 6–12 hours after surgical operation (28), and persists for about two to three days, then gradually decreases till the 7th postoperative day (29). The time for the surgical operation of IMTMs elapsed from the first incision till the accomplishment of last suture was > 20 minutes for the highest proportion of both groups. The reason for this may be because the impacted teeth were selected in the same angulation, mesioangular, and they all underwent surgery with the same surgeon. According to Pederson difficulty index the present study showed that moderately difficult extractions was the commonest in both groups. This is in agreement with (30), however, (31) stated that Among 762 extractions (71.1%) were not difficult, (16.3%), were moderately difficult and (12.6%) were very difficult. (32) revealed that patient related factors like age, gender and surgical difficulty had no effect on severity of post-operative pain and trismus after IMTMs surgery. A local analgesic administration in the mucosa has certain advantages. It is simple, noninvasive, and cost-effective. It also avoids passing through the gastrointestinal tract and metabolizing drugs in the liver, where some medications are metabolized (33). Also, some patients prefer local drug administration over oral, intramuscular, or intravenous administration (2). After the last suture, the medicine should be injected immediately to prevent the removal of a large amount of the medication after the flap is elevated in the

adjacent tissue as well as irrigation during the surgical procedure. When the medication is injected prior to flap elevation, a large amount of the medication will be removed (18). The dental pain is predominantly inflammatory, Ultimately, ketorolac inhibits cyclooxygenase, resulting in prostaglandin production being inhibited (18), with a plasma half-life (2-6 hours) and the duration of action (6-8 hours) (34), made it suitable for pain reduction, since the maximum pain after IMTM surgeries appear 6–8 h postoperatively (35). Limitations in mouth opening after the surgical extraction of IMTM may occur as a result of injuring muscles during the surgery, which will result in impaired function of the muscles of mastication (36). The insignificant reduction in the trismus between the two groups may be attributed to the single dose of 30 mg ketorolac that has been injected locally in the buccal vestibule after the surgical extraction which may cause little effect when compared with studies that used different routes of administration and multiple doses per day. Besides that, the one-sided flap design used in this study may result in more tension on mucosa and muscles around the extraction site during flap retraction and reflection (7).

Thus, the hypothesis that has been proposed (ketorolac has clinical efficacy in reducing pain when administered submucosally in the buccal vestibule after mandibular third molar surgery) was confirmed, while the hypothesis concerning the trismus reduction by ketorolac has been rejected. The present study was limited by the effect of individual characteristics and differences on pain perception, as individuals in different groups may display varying pain perception and thresholds. Future studies should consider wash-out periods and split-mouth designs to resolve this issue

Conclusions

The results from this study showed that ketorolac provided effective pain management after the surgical removal of the mandibular third molar. Regarding trismus, ketorolac has no significant effect on the limitation of mouth opening compared to that of the control group.

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Conflicts of Interest Statement: No conflicts of interest



Figure (1) ketorolac ampule 30mg/1ml



Figure (2) The surgical set for the impaction procedure.



Figure (3) Extraction kit.

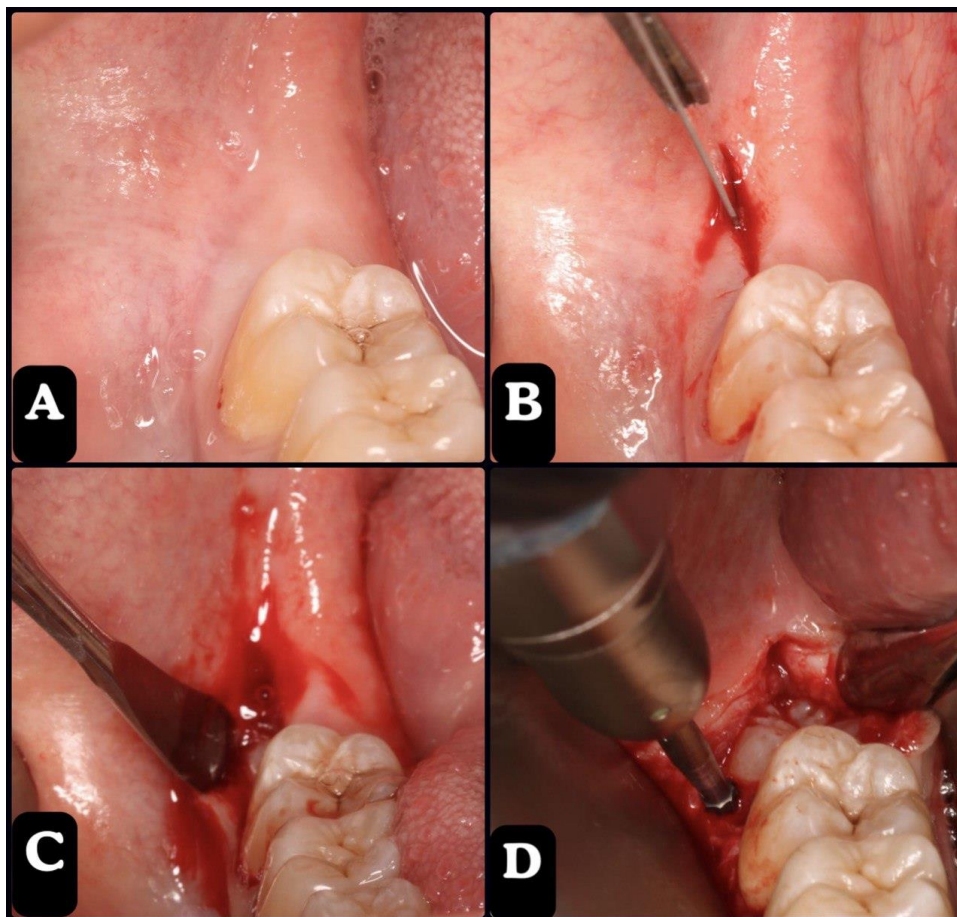


Figure (4): (A) preoperative, (B) incision of the flap (C) reflection of flap and tooth exposure (D) bone removal.

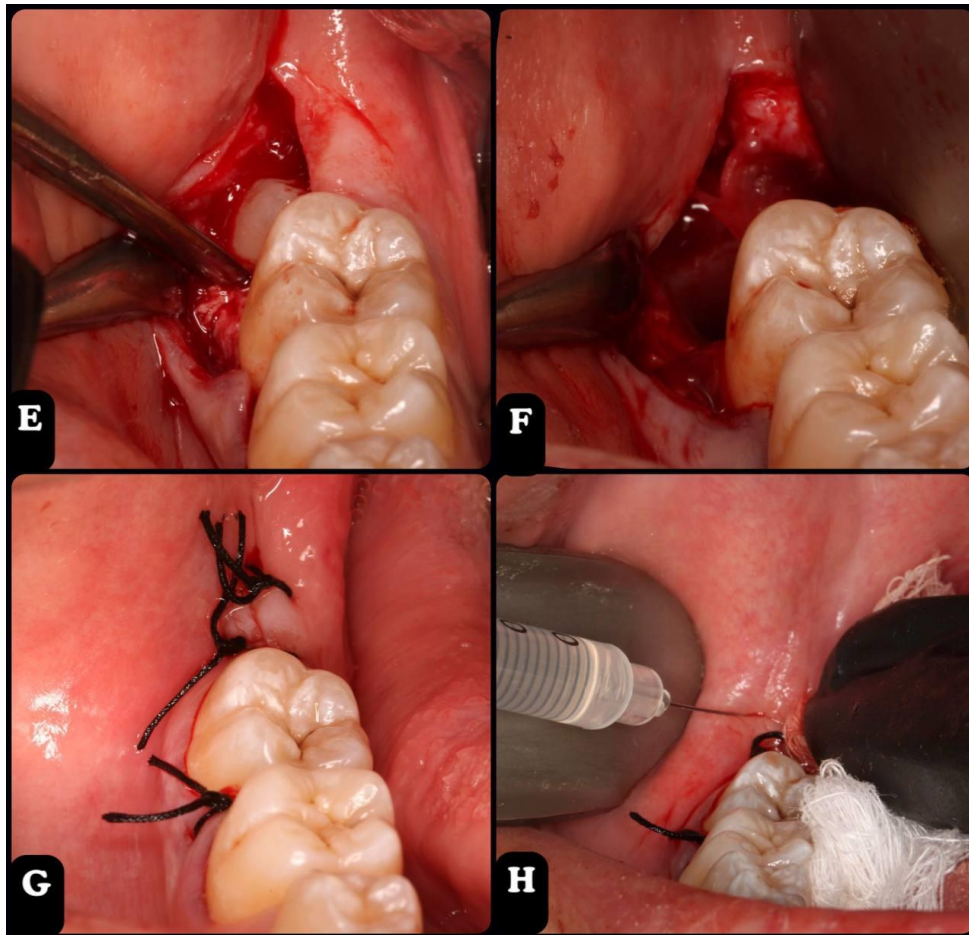


Figure (5): (E) tooth removal, (F) socket cleaning and sharp bone removal (G) flap suturing (H) ketorolac injection.

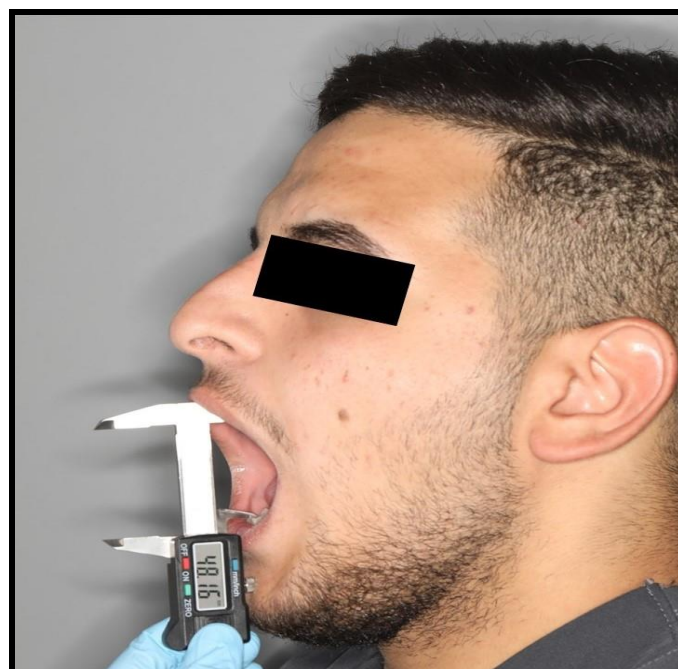


Figure (6) Measurement of mouth opening

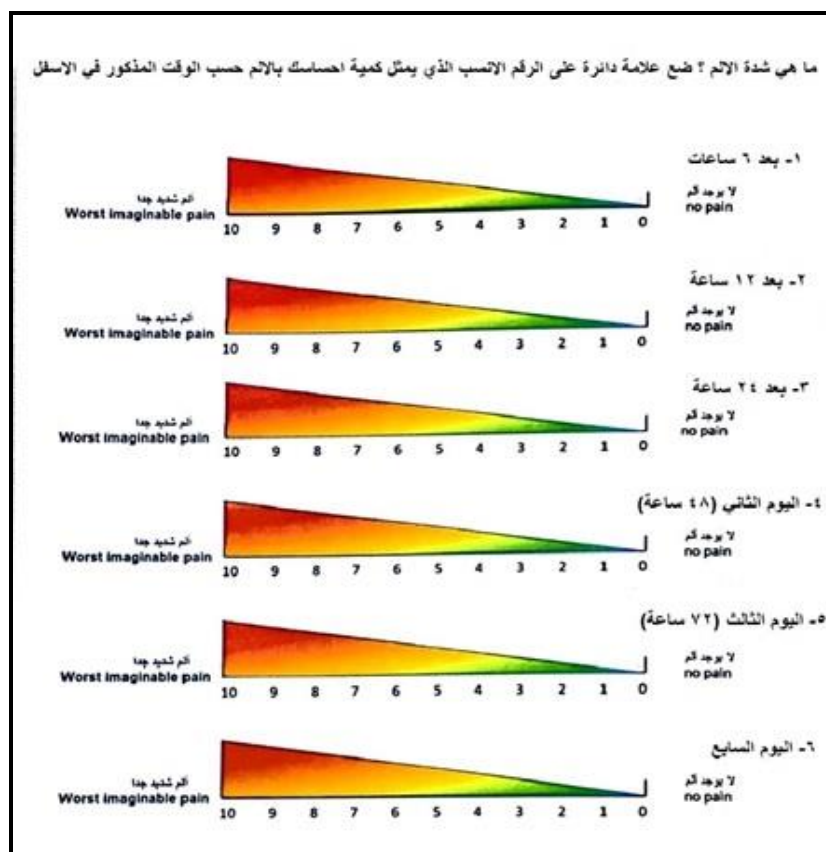


Figure (7): NRS for pain assessment at different intervals

Table (1) Comparison of mouth opening of both groups before and after extractions

Time intervals measurements	Groups		P Value*
	Study Group Mean ± SD	Control Group Mean ± SD	
Preoperatively	48.31 ± 7.08	50.86 ± 6.19	0.221
2 nd Day Postoperatively	35.83 ± 9.74	37.01 ± 8.25	0.668
7 th Day Postoperatively	41.70 ± 9.28	44.28 ± 6.01	0.281

Table (2) Comparison between the groups by the percentage of limitation in mouth opening on the 2nd and 7th postoperative days in relation to the baseline (preoperative)

Time intervals measurements	Groups		P Value*
	Study Group Mean ± SD	Control Group Mean ± SD	
2 Days Postoperatively	-26.12 ± 15.43	-27.18 ± 13.88	0.812
7 Days Postoperatively	-14.04 ± 12.02	-12.62 ± 9.07	0.661

Table (3) Comparison of the postoperative pain score between the two groups

Postoperative Pain	Groups		P Value*
	study Group Mean ± SD	Control Group Mean ± SD	
6 hrs.	3.45 ± 1.99	6.86 ± 1.24	0.001
12 hrs.	2.50 ± 1.73	5.32 ± 1.42	0.001
Day One	2.05 ± 1.43	4.18 ± 1.91	0.001
Day Two	1.23 ± 1.19	3.14 ± 2.12	0.001
Day Three	0.59 ± 0.73	2.23 ± 1.54	0.001
Day Seven	0.05 ± 0.21	1.14 ± 1.20	0.001

Table (4) Time and difficulty of extraction distributions for the two groups

Time and Difficulty	Groups		P- Value
	Study n= 22	Control n= 22	
Extraction Time (Min.)			
≤ 20	6 (27.3)	8 (36.4)	0.517
> 20	16 (72.7)	14 (63.6)	
Extraction Difficulty			
Slight	6 (27.3)	5 (22.7)	0.728
Moderate	16 (72.7)	17 (77.3)	

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