Original Article

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Efficacy of intraosseous saline injection for pain management during surgical removal of impacted mandibular third molars: a randomized double-blinded clinical trial

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Background: Surgical extraction of impacted mandibular third molars is the most common procedure performed by oral surgeons. The procedure cannot be performed effectively without achieving profound anesthesia. During this procedure, patients may feel pain during surgical bone removal (at the cancellous level) or during splitting and luxation of the tooth, despite administration of routine nerve blocks. Administration of intraosseous (IO) lignocaine injections during third molar surgeries to provide effective anesthesia for pain alleviation has been documented. However, whether the anesthetic effect of lignocaine is the only reason for pain alleviation when administered intraosseously remains unclear. This conundrum motivated us to assess the efficacy of IO normal saline versus lignocaine injections during surgical removal of impacted mandibular third molars. The aim of this study was to assess the efficacy of IO normal saline as a viable alternative or adjunct to lignocaine for alleviation of intraoperative pain during surgical removal of impacted mandibular third molars.

Methods: This randomized, double-blind, interventional study included 160 patients who underwent surgical extraction of impacted mandibular third molars and experienced pain during surgical removal of the buccal bone or sectioning and luxation of the tooth. The participants were divided into two groups: the study group, which included patients who would receive IO saline injections, and the control group, which included patients who would receive IO lignocaine injections. Patients were asked to complete a visual analog pain scale (VAPS) at baseline and after receiving the IO injections.

Results: Of the 160 patients included in this study, 80 received IO lignocaine (control group), whereas 80 received IO saline (study group) following randomization. The baseline VAPS score of the patients and controls was 5.71 ± 1.33 and 5.68 ± 1.21, respectively. The difference between the baseline VAPS scores of the two groups was not statistically significant ($P > 0.05$). The difference between the numbers of patients who experienced pain relief following administration of IO lignocaine (n=74) versus saline (n=69) was not statistically significant ($P > 0.05$). The difference between VAPS scores measured after IO injection in both groups was not statistically significant ($P > 0.05$) (1.05 ± 1.20 for the control group vs. 1.72 ± 1.56 for the study group)

Conclusion: The study demonstrates that IO injection of normal saline is as effective as lignocaine in alleviating pain during surgical removal of impacted mandibular third molars and can be used as an effective adjunct to conventional lignocaine injection.

Keywords: Impacted Tooth; Intraosseous Injections; Local Anesthesia; Normal Saline; Placebos; Surgical Removal.

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INTRODUCTION

Pain management is an essential component of surgical practice [1]. Local anesthesia is the mainstay of pain management during all oral surgical procedures. There is a plethora of documented and clinically tested local anesthetic techniques for all dental procedures, depending on the surgical site [2].

Surgical extraction of impacted mandibular third molars is the most common procedure performed by oral surgeons. This procedure cannot be performed effectively without achieving profound anesthesia. Failure to achieve adequate local anesthesia can be operator-dependent or patient-dependent [3]. Operator-dependent failures could be due to use of improper techniques or defective anesthetic solutions. Patient-dependent failures may be caused by anatomical, pathological, or psychological factors.

During surgical extraction of impacted mandibular third molars, an inferior alveolar nerve block (IANB) along with lingual and long buccal nerve blocks are administered prior to making an incision, elevating a periosteal flap, and surgically removing bone, with or without sectioning and removing the tooth [4]. During this procedure, the patient may feel pain during surgical removal of the buccal bone (at a cancellous level) or during sectioning and luxation of the tooth, despite the administration of routine nerve blocks. In this situation, additional nerve blocks, supraperiosteal infiltrations, or intraosseous injections (IO) are administered to achieve profound anesthesia. Administering IO lignocaine injections during third molar surgeries to provide effective anesthesia for pain alleviation has been documented [5]. However, whether the anesthetic effect of lignocaine is the only reason for pain alleviation when administered intraosseously remains unclear. This conundrum was our primary motive for assessing the efficacy of IO saline versus lignocaine injections during surgical removal of impacted mandibular third molars. Hence, the objective of this study was to compare the efficacy of IO lignocaine (control group) and saline injections (study group) for pain management during surgical removal of impacted mandibular third molars. In this study, we named the IO saline injection technique the saline-assisted local anesthetic technique (SALT). Patients who received IO saline injections administered using the SALT were included in the study group.

METHODS

This double-blind randomized controlled trial was performed at the outpatient department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences, Sri Ramachandra Institute of Higher Education and Research (SRIHER). We designed this study to compare the effectiveness of the SALT with that of lignocaine injections in relieving intraoperative pain during third molar surgeries.

This study was approved by the Institutional Ethics Committee of Sri Ramachandra Institute of Higher Education and Research, Chennai, India (reference number: IEC/19/NOV/155/75), and registered at the Clinical Trial Registry of India on 07/06/2021 (http://www.ctri.nic.in/) (reference number: CTRI/2021/06/034039). The study was conducted in accordance with the guidelines of the Declaration of Helsinki. In addition, as this was a randomized controlled trial, the CONSORT guidelines were followed while conducting the study. The CONSORT flowchart is presented in Fig. 1.

1. Study population and sample size

The study population comprised patients who reported to the Department of Oral and Maxillofacial Surgery at SRIHER for surgical extraction of impacted mandibular third molars. A sample size of 160 patients was needed to achieve 95% confidence interval and 90% power. This was initially planned as a crossover trial, but it didn't happen in the study; hence, the study didn't follow a crossover trial.

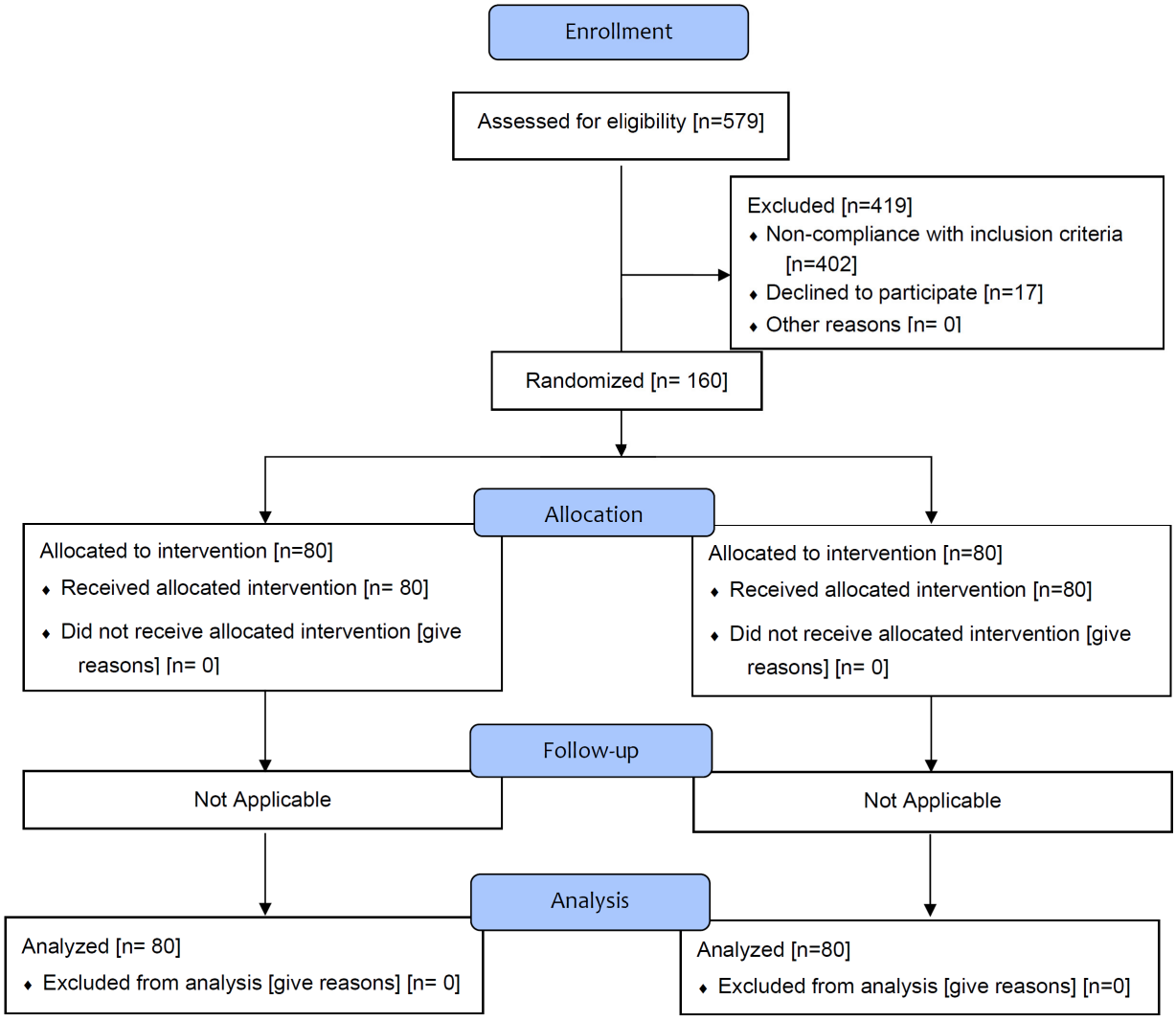

Fig. 1. CONSORT flow diagram and study strategy. CONSORT, consolidated standards of reporting trials.

2. Inclusion criteria

Patients older than 19 years of age who required surgical removal of impacted mandibular third molars and reported feeling pain during surgical removal of bone at a cancellous level during the procedure and/or while the tooth was sectioned (odentectomy) and/or luxated, and understood and were willing to follow all study protocols were included in the study.

3. Exclusion criteria

Patients younger than 19 years of age, patients with severe infection, patients who did not report pain during surgical removal of bone at the cancellous level or during sectioning and luxation of the tooth, and patients with known allergies to local anesthetics (amides and esters) were excluded from the study. Patients with systemic and debilitating diseases and pregnant and lactating women were excluded as well.

4. Study duration

The study period was from June 2021 to November 2021 (six months).

5. Data collection

The 160 study participants were equally divided into

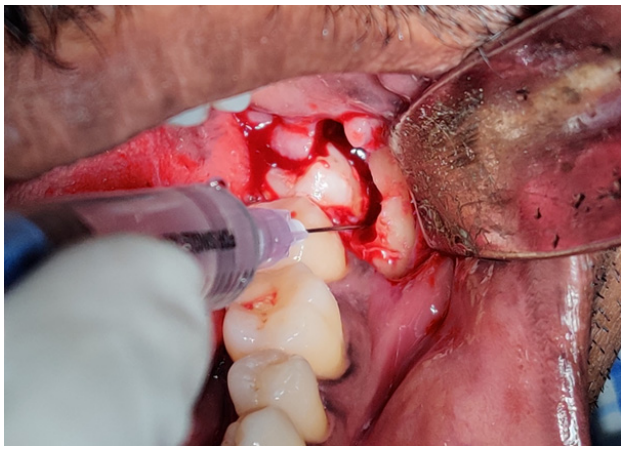

Fig. 2. Blinded intraosseous lignocaine/saline injection administered using a 26-gauge needle

Table 1. Demographic data of the study participants (age distribution)

Demographic Data					
	Study group [SALT]		Control group [Lignocaine]		P-Value
	No.of patients	Mean	No.of patients	Mean	
Age	80	26	80	25	0.288

No., number; SALT, saline-assisted local anesthetic technique.

Table 2. Demographic data of the study participants (sex distribution)

Demographic Data					
	Study group [SALT]		Control group [Lignocaine]		P-Value
	Female	Male	Female	Male	
Sex	31 [38.8%]	49 [61.3%]	34 [42.5%]	46 [57.5%]	0.62

SALT, saline-assisted local anesthetic technique.

the study group, which included patients who would receive IO saline injections (SALT group), and the control group, which included patients who would receive IO lignocaine injections. Patients were randomized into either the study group or control group using the block randomization method, with a block size of eight. Double blinding was performed; that is, the patients and the primary investigator were not aware of the drugs administered and the group allocations.

6. Surgical technique

Each patient underwent surgical removal of an impacted mandibular third molar under local anesthesia. Local anesthesia was achieved by administering 2% lignocaine hydrochloride with epinephrine (1:200000) for inferior alveolar, lingual, and long buccal nerve blocks. Subjective and objective symptoms were checked 4-5 minutes after administration of the abovementioned nerve blocks. The Moore-Gilby collar technique for bone removal was used for all procedures. Surgical removal of bone and tooth sectioning were performed using a No.702 bur and a slow-speed straight handpiece. Patients who experienced pain during bone removal at a cancellous level or during sectioning and luxation of the tooth were included in the study. A chart containing the 0-10 visual analog pain scale (VAPS) scoring criteria was used to assess the pain levels of the patients before administering IO injections [6]. After recording the VAPS score, IO saline or lignocaine injection was administered using a 26-gauge needle depending on the patient's group (Fig. 2). The choice of drug for IO injection was concealed and was opened and interpreted by a skilled assistant who was aware of the name of the drug and the randomized group allocation. The patient and the primary investigator were blinded to the type of IO injection administered. The procedure was continued after the IO injection. If the patient was asymptomatic, the VAPS protocol was repeated and the patient's score was noted. The use of IO lignocaine or saline was limited to 2 ml. If the patient did not feel pain relief with 2 ml of the blinded IO injection, the patient's details were noted, and additional lignocaine nerve blocks were administered or the Gow-Gates technique was performed to successfully complete the procedure without pain. Patients who reported pain after the IO injections were categorized as having pain despite the IO injection. After a successful tooth extraction, the surgical site was closed using 3-0 silk sutures.

7. Statistical analysis

VAPS data and the significance of differences between groups were analyzed using the chi-square test and independent t-test. Statistical analyses were performed using the SPSS software, version 16.0. The statistical tests were performed with a confidence interval of 95%. Statistical significance was set at $P < 0.05$.

Table 3. Distribution of impacted teeth in the study population based on Winters classification

Impacted tooth based on Winter's Classification			
	Study group [SALT]	Control group [Lignocaine]	P-Value
Impacted tooth	No. of Patients	No. of Patients	
Mesio-angular	22 [27.5%]	27 [33.8%]	0.23
Disto-angular	20 [25%]	26 [32.5%]	
Horizontal	26 [32.5%]	15 [18.8%]	
Vertical	12 [15%]	12 [15%]	

SALT, saline-assisted local anesthetic technique.

Table 4. VAPS score differences in the study groups before and after intraosseous injections

VAPS Scores						
	VAPS before IO Injection		VAPS after IO Injection			
	Study group [SALT]	Control group [Lignocaine]	Study group [SALT]		Control group [Lignocaine]	
			With Pain	Without Pain	With Pain	Without Pain
No.of Patients	80	80	11	69	6	74
Mean VAPS	5.71	5.68	5.64	1.72	5.5	1.05
SD	1.33	1.21	1.21	1.56	0.55	1.20
P-value	0.852		< 0.001		< 0.001	

IO,intraosseous; SALT, saline-assisted local anesthetic technique; SD, standard deviation; VAPS, visual analog pain scale.

Table 5. Comparing the Pain reduction scores in study and control group

	Study Group [SALT]	Control Group [Lignocaine]	P-Value
VAPS score before IO Injections	5.71 +/- 1.33	5.68 +/- 1.209	0.852
VAPS score after IO Injections	2.26 +/- 2.03	1.39 +/- 1.66	0.003
Mean reduction in pain	3.45 +/- 1.94	4.29 +/- 1.88	0.006

IO, intraosseous; SALT, saline-assisted local anesthetic technique; VAPS, visual analog pain scale.

RESULTS

1. Demographic details

During the study period, 579 patients who required surgical removal of impacted third molars were assessed. Of these, 419 patients who did not meet the inclusion criteria (n=402) and those who declined to participate (n=17) were excluded. Thus, 160 patients were included in this study. The mean age of the patients in the study and control groups was 26 and 25 years, respectively (Table 1). The study group consisted of 31 females and 49 males, whereas the control group consisted of 34 females and 46 males (Table 2). The differences between the age and sex distributions of the two groups were not statistically significant ($P > 0.05$). The impacted third molars were categorized according to the Winter's classification and the results showed that we examined 22 mesioangular, 20 distoangular, 26 horizontal, and 12 vertically impacted teeth in the study group and 27 mesioangular, 26 distoangular, 15 horizontal, and 12 vertically impacted teeth in the control group (Table 3). The distribution of impacted teeth in the two groups were not significantly different ($P > 0.05$)

2. Absence of pain and VAPS score assessment

The baseline VAPS score of the patients in the control and study groups prior to IO injections was 5.68 ±1.21 and 5.71±1.33, respectively. Of 80 patients in the control group who received IO lignocaine for pain management, 74 (92.5%) felt no pain after injection of the local anesthetic solution and reported a mean VAPS score of 1.05 ± 1.20. In the study group, 69 patients (86.2%) experienced no pain after IO administration of normal

Table 6. Distribution of patients without pain in the study groups after intraosseous injections

Comparison of patients without pain after IO Injections		
	Study group [SALT] Without Pain	Control group [Lignocaine] Without Pain
No.of Patients	69 [86.3%]	74 [92.5%]
P-Value	0.2	

IO, intraosseous; No., number; SALT, saline-assisted local anesthetic technique.

saline and reported a mean VAPS score of 1.72 ± 1.56. The differences between the numbers and VAPS scores of patients who experienced pain relief in the two groups was not statistically significant (P > 0.05) (Tables 4, 5, and 6). No complications such as inadvertent injury of the inferior alveolar neurovascular bundle, which can cause profuse bleeding or needle breakage, were noted intraoperatively after administration of the IO injections.

DISCUSSION

Effective pain management is one of the most important aspects of a successful dental extraction. Failure of mandibular anesthesia is common and related to the thickness of the cortical plate in the adult mandible [7,8]. Studies that involved the use of radiography and ultrasonography to locate the inferior alveolar nerve bundle or mandibular foramen have revealed that an accurate location does not guarantee successful pain management [9-12]. The basis of this problem can be explained by the central core theory [13,14].

Difficulty in achieving profound mandibular nerve blocks for third molar surgeries has led to the development of alternative techniques to the traditional Halsted approach and IANB. These include the Gow-Gates technique, Akinosi-Vazirani technique, periodontal ligament (PDL/intraligamentary) injection, IO injection, intraseptal injection, and use of buffered local anesthetics [15-19]

IO injections involve the deposition of a local anesthetic solution into the cancellous bone, which supports the teeth and surrounding structures. Conventionally, PDL and intraseptal anesthesia are described as variations of IO anesthesia. While surgically removing the buccal bone during third molar surgery, IO injections are recommended if the patient still complains of pain. IO local anesthetic injections are administered by stabilizing the syringe and directing it along the long axis of the tooth to be anesthetized. In this procedure, the syringe bevel faces the tooth and the needle is advanced apically until bony resistance is achieved. A minimum of 0.2 ml local anesthetic solution is deposited for 20 s [20]. It has been reported that anesthetic success is significantly greater with 2% IO lignocaine injections [18]. In the present study, we assessed the efficacy of IO saline injection as an alternate or adjunct for IO lignocaine injection. To our knowledge, no study has been conducted to compare the effectiveness of IO saline injections with that of local anesthetics. We named this IO saline injection technique the SALT. Hence, the present study is the first of its kind.

While analyzing the results, we were surprised to observe an IANB failure rate of approximately 30% in our department. Further analysis revealed that the IANB failures were not as pronounced in other minor oral surgeries. Notably, surgical extraction of mandibular third molars constituted only a fifth of all the procedures. The reason for the failure of anesthesia was that after administering IANB, patients generally do not feel any pain/discomfort when the incision is, during flap reflection, or during initial bone removal. However, during cancellous bone removal or sectioning and luxation of the tooth, it is natural for the operating surgeon to reassure and counsel the patient when there is mild discomfort or pressure. To ensure that these concerns were not taken lightly, we also included patients who experienced these minimal symptoms (low VAPS scores, 1–3) as described above. This led to an excessive number of patients being included in the study, which reflected as a high IANB failure rate. Notably, following the administration of IO injections, even patients with minimal symptoms were comfortable during the procedure, thus proving that it is a simple and effective

adjuvant technique following partially ineffective nerve blocks.

The results of the present study revealed a considerable rate of IANB failure during bone removal at the cancellous level, which highlights the need for IO injections for successful completion of third molar surgeries. In the present study, patients in the IO saline and lignocaine groups who complained of pain during surgical bone removal had similar VAPS scores. However, after administering IO injections, 74 of 80 patients in the lignocaine group experienced significant pain relief, whereas 69 of 80 patients in the saline group experienced pain relief. The difference between the numbers of patients the saline and lignocaine groups who experienced pain relief following IO administration of saline or lignocaine was not statistically significant, proving that both lignocaine and saline were equally effective when administered intraosseously. Moreover, the VAPS scores of the patients in the two groups were not significantly different, indicating that saline produced the same amount of pain relief as lignocaine.

Considering this evidence, whether the anesthetic effect of lignocaine is the sole reason for the alleviation of pain after IO lignocaine injection remains unclear. In addition, how IO saline injection produces a similar effect even though an anesthetic effect is not a documented pharmacodynamic characteristic of saline needs to be explored. This gray area was the primary motive behind our use of saline and analysis of its efficacy versus that of IO lignocaine injection during surgical extraction of impacted mandibular third molars. As saline is the most common placebo used in clinical trials, we chose 0.9% normal saline over other IO injections.

The authors of various studies have concluded that intracutaneous and subcutaneous injections of normal saline or sterile water in the lumbosacral region in pregnant women can reduce the intensity of back and shoulder pain during labor [21,22]. In 2017, Bar-Or et al. concluded that intra-articular saline injections effectively reduce pain compared with no injections [23]. The clinical benefit of intra-articular saline for pain relief in patients with knee osteoarthritis has been studied by various authors. A systematic review indicated that pain relief is achieved with intra-articular saline injections [24]. In addition, a study demonstrated that ultrasound-guided physiological saline injections can effectively reduce myofunctional pain [25].

We hypothesized that pain reduction following IO saline injection could possibly be the result of increase in pressure inside the cancellous portion of the mandible created by the IO injection, which could lead pain relief as explained by the gate control theory. However, the effect of normal saline on pain reduction remains unclear.

In conclusion, we compared the efficacy of IO saline and lignocaine injections during surgical removal of impacted mandibular third molars. The results of this study prove that the IO saline injection technique (SALT) can be used as an adjunct or supplement for IO local anesthesia and additional nerve blocks to alleviate intraoperative pain during surgical bone removal or sectioning and luxation of the tooth. The advantages associated with the use of saline instead of lignocaine could result in a reduction of the lignocaine doses used, and the consequent toxicity associated with higher doses. Moreover, the use of saline will reduce the systemic load of lignocaine, which could otherwise cause or precipitate adverse cardiac effects in patients with cardiovascular disease.

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Jawahar Babu. S: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Visualization, Writing - original draft
Naveen Kumar Jayakumar: Conceptualization, Methodology, Project administration, Supervision, Writing - review & editing
Pearlcid Siroraj: Conceptualization, Data curation, Investigation, Methodology, Project administration, Validation, Writing - original draft

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REFERENCES

1. Brennan F, Carr DB, Cousins M. Pain management: a fundamental human right. Anesth Analg 2007; 105: 205-21.
2. Khoury J, Townsend G. Neural blockade anaesthesia of the mandibular nerve and its terminal branches: rationale for different anaesthetic techniques including their advantages and disadvantages. Anesthesiol Res Pract 2011; 2011: 307423.
3. Meechan JG. How to overcome failed local anaesthesia. Br Dent J 1999; 186: 15-20.
4. Khalil H. A basic review on the inferior alveolar nerve block techniques. Anesth Essays Res 2014; 8: 3-8.
5. Leonard MS. The efficacy of an intraosseous injection system of delivering local anesthetic. J Am Dent Assoc 1995; 126: 81-6.
6. Kahl C, Cleland JA. Visual analogue scale, numeric pain rating scale and the McGill pain Questionnaire: an overview of psychometric properties, Phys Ther Rev 2005: 10:2: 123-8.
7. Oulis CJ, Vadiakas GP, Vasilopoulou A. The effectiveness of mandibular infiltration compared to mandibular block anesthesia in treating primary molars in children. Pediatr Dent 1996; 18: 301-5.
8. Sharaf AA. Evaluation of mandibular infiltration versus block anesthesia in pediatric dentistry. ASDC J Dent Child 1997; 64: 276-81.
9. Hannan L, Reader A, Nist R, Beck M, Meyers WJ. The use of ultrasound for guiding needle placement for inferior alveolar nerve blocks. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1999; 87: 658-65.
10. Berns JM, Sadove MS. Mandibular block injection: a method of study using. an injected radiopaque material. J Am Dent Assoc 1962; 65: 735-45.
11. Galbreath JC. Tracing the course of the mandibular block injection. Oral Surg Oral Med Oral Pathol 1970; 30: 571-82.
12. Reader A, American association of Endodontics: Taking the pain out of restorative dentistry and endodontics: current thoughts and treatment options to help patients achieve. profound anasethesia, Endodontics: Colleagues for excellence. Winter 2009
13. Delong R.H: Local anesthetics, St Louis,1994, pp110-111.
14. Strichartz G. Molecular mechanisms of nerve block by local anesthetics. Anesthesiology 1976; 45: 421-41.
15. Gow-Gates GA. Mandibular conduction anesthesia: a new technique using extraoral landmarks. Oral Surg Oral Med Oral Pathol 1973; 36: 321-8.
16. Akinosi JO. A new approach to the mandibular nerve block. Br J Oral Surg 1977; 15: 83-7.
17. Malamed SF. The periodontal ligament (PDL) injection: an alternative to inferior alveolar nerve block. Oral Surg Oral Med Oral Pathol 1982; 53: 117-21.
18. Coggins R, Reader A, Nist R, Beck M, Meyers WJ. Anesthetic efficacy of the intraosseous injection in maxillary and mandibular teeth. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1996; 81: 634-41.
19. Whitcomb M, Drum M, Reader A, Nusstein J, Beck M. A prospective, randomized, double-blind study of the anesthetic efficacy of sodium bicarbonate buffered 2% lidocaine with 1:100,000 epinephrine in inferior alveolar nerve blocks. Anesth Prog 2010; 57: 59-66.
20. Malamed SF. Local anaesthetic considerations in dental specialty. In: Handbook of local anesthesia. 6th ed. St Louis, Elsevier Inc. 2004.
21. Derry S, Straube S, Moore RA, Hancock H, Collins SL. Intracutaneous or subcutaneous sterile water injection compared with blinded controls for pain management in labour. Cochrane Database Syst Rev 2012; 18; 1: CD009107.
22. Faied SM, Abdalla AM, Youssef AYM. Intradermal sterile water injection versus epidural bupivacaine in painless first stage of labor. Egypt J Hosp Med 2019; 77: 5589-96.

23. Bar-Or D, Rael LT, Brody EN. Use of saline as a placebo in intra-articular injections in osteoarthritis: potential contributions to nociceptive pain relief. Open Rheumatol J 2017; 31: 11: 16-22.
24. Altman RD, Devji T, Bhandari M, Fierlinger A, Niazi F, Christensen R. Clinical benefit of intra-articular saline as a comparator in clinical trials of knee osteoarthritis treatments: a systematic review and meta-analysis of randomized trials. Semin Arthritis Rheum 2016; 46: 151-9.
25. Kongsagul S, Vitoonpong T, Kitisomprayoonkul W, Tantisiriwat N. Ultrasound-guided physiological saline injection for patients with myofascial pain. J Med Ultrasound 2019; 28: 99-103.