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Comparative Efficacy of MadaJet®XL and Conventional Injection Technique for Primary Maxillary Molar Local Anesthesia: A Randomized Clinical Trial

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A B S T R A C T

Objectives: This study aimed to compare the efficacy of a needle-free system (MadaJet®XL) and the conventional injection technique for primary maxillary molar local anesthesia before restorative procedures in 6 to 12-year-old patients.

Materials and Methods: This cross-over randomized clinical trial was conducted on 30 children requiring restoration of at least two primary maxillary molars. The two molars requiring restoration in each patient were randomized using quaternary random blocks to receive either local anesthesia with MadaJet®XL or the conventional injection technique. To assess the efficacy of the techniques, pain score during injection was recorded using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale, and the number of patients with failed local anesthesia after MadaJet®XL administration was reported. The Wilcoxon Signed Ranks test was employed for data analysis (alpha=0.05).

Results: The highest score was reported with the conventional injection technique (FLACC score=9). The mean pain score was 4.1±2.6 in the conventional group and 2.3±1.3 in the MadaJet®XL group. The Wilcoxon Signed Ranks test showed significantly higher pain score in the conventional injection technique than the MadaJet®XL (P<0.001). Re-injection was performed for 19 patients (63.3%) due to their discomfort during dental procedure when MadaJet®XL was used.

Conclusion: Despite the lower level of pain and discomfort experienced during local anesthesia administration by MadaJet®XL, this device is not suitable for restorative procedures of primary maxillary molars, due to failure to achieve complete anesthesia.

Keywords: Anesthesia, Local; Pediatric Dentistry; Injections, Jet

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INTRODUCTION

Controlling the patients' pain and anxiety is a fundamental skill for dental clinicians. Local anesthesia is among the essential steps for pain control. However, needle insertion into the tissue for local anesthesia causes anxiety in the majority of patients. The injection itself is painful for some patients. Paradoxically, the procedure that is designed to reduce pain may itself result in receiving painful dental injections [1]. Also, there is a relation between pain and anxiety. Patients' pain threshold reduces during anxiety; meanwhile, a painful situation increases the level of anxiety [2,3]. This statement highlights the significance of pain and anxiety control during anesthetic injection.

Several strategies have been developed to administer painless anesthesia and address this problem, such as topical anesthetic gels, injection site pre-cooling, using vibration or pressure at the injection site, using slower injections with computer-controlled anesthesia delivery systems, and needleless injection techniques [4]. Jet injectors are needleless injection systems that work with the principle of applying an anesthetic solution with high pressure to penetrate tissues. The main goal of jet injections is to deliver local anesthesia without imposing needle insertion on patients who have problems with needles, which is known as needle-phobia or blenophobia [5-7]. Successful application of jet injection systems has been reported during curettage and scaling, gingivectomy, biopsy, abscess drainage, and restorations [5,8-10]. Nevertheless, there is no consensus over preference among different jet injection devices and acceptance of jet injections over the conventional method in pediatric patients [11, 12].

Therefore, the aim of this study was to compare the efficacy of a needle-free system (MadaJet®XL) and conventional injection technique for primary maxillary molar local anesthesia before restorative procedures in 6 to 12-year-old patients.

MATERIALS AND METHODS

Study design

This cross-over randomized clinical trial was conducted at the School of Dentistry of Tehran University of Medical Sciences during one month (March–April 2022). The ethical approval was obtained from the Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.DENTISTRY.REC.1398.085), and the study protocol was registered in the Iranian Registry of Clinical Trials (IRCT20191015045116N1). Written informed consent was obtained from all participants prior to inclusion in this study. The criteria used to report the results were derived from the Consolidated Standards of Reporting Trials.

Participants

The inclusion criteria were as follows: 1) age range of 6-12 years, 2) having at least two carious primary maxillary molars requiring classic amalgam class I or II restoration, 3) having a score of 3 (positive) or 4 (completely positive) according to the Frankl's behavioral criteria [13]. The exclusion criteria were: 1) any systemic diseases, 2) any local or systemic infection, and 3) any sign or symptom of pulp involvement.

Randomization and blinding

Randomization was performed using quaternary random blocks. The injection operator and assistant who evaluated the pain level during injection were not blinded due to the appearance of local anesthetic equipment. Although participants did not see the injection equipment during the procedure, because of the differences in these two instruments, they could not be blinded. Parents and statistician were blinded to the anesthetic technique. The postgraduate student who performed all the restorative procedures was also blinded.

Intervention

Patients who met the eligibility criteria were asked to participate in this study. The study objectives were described to the children's guardians prior to their enrollment and their written informed consent was obtained.

The application of both injection techniques was carried out in two different appointments in each individual with an interval of one week by the same pediatric dentist in all the participants. The administration sequence for the injection techniques was randomly assigned to each individual, using quaternary random blocks. For the conventional injection technique, a short 27-gauge needle (Feizteb Co., Iran) was used. Lidocaine (2%) with 1:80,000 epinephrine (EXIR Pharmaceutical Co., Iran) was injected at the apical area (0.6 cc over 20 seconds) based on the supra-periosteal injection technique [13,14]. The sterilizable MadaJet®XL (Mada Medical Products, New Jersey, USA) was used for needleless anesthesia. MadaJet®XL sprays the anesthetic agent over the attached gingiva. Three apical points in the mesiobuccal, distobuccal, and palatal were chosen for full anesthesia. At each point, 0.1 mL of the anesthetic agent (2% lidocaine with 1:80,000 epinephrine) was sprayed.

To assess the efficacy of the two techniques, pain score during injection was recorded using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale [15,16], and the number of patients with failed local anesthesia was reported. The FLACC score was recorded by only one assistant. This scale consists of five parts including facial expression, leg activities, bodily activities, crying, and consolability. The possible score of each part is 0 to 2, yielding a total score of 0 to 10 (Table 1). Higher scores show stronger reaction to pain. Then, a postgraduate student performed the restorative procedures. The patients with failed local anesthesia during the restorative procedure were re-injected using the conventional technique. Constant complaints of pain during dentin removal were considered as failure of local anesthesia. In other words, lack of pain was defined as the successful anesthesia ensuring patient comfort.

Outcome measure

Pain during injection with MadaJet®XL and the conventional injection technique was the main outcome measure.

Sample size calculation

The sample size was calculated to be 27 patients in each group assuming alpha=0.05, study power of 80%, difference of 35% in the outcome between the two groups, and 50% chance of success in each group using the Power and Sample Size Calculation software version 3.0.43. Considering the possibility of loss to follow-up, at least 30 patients must be enrolled.

Statistical analysis

The normality of data distribution was assessed by the Kolmogorov-Smirnov test. Pain as a quantitative variable was presented as mean ± standard deviation. The Wilcoxon Signed Ranks test was used to compare the pain scores between the MadaJet®XL and the conventional injection techniques. All analyses were performed using SPSS statistics software for windows, version 20.0 (SPSS, Inc., Chicago, IL, USA). P values < 0.05 were defined as statistically significant.

RESULTS

Thirty subjects participated in this study and none of them were harmed during this research. Figure 1 describes the study process based on the CONSORT flow diagram. The Wilcoxon Signed Ranks test showed that the pain score associated with the conventional injection technique was significantly higher than that with MadaJet®XL (P<0.001, Table 2).

Re-injection was performed for 19 patients (63.3%) due to failure of local anesthesia during dental procedures when MadaJet®XL was used.

DISCUSSION

The aim of this study was to compare the efficacy of MadaJet®XL and the conventional injection technique for primary maxillary molar local anesthesia before restorative procedures in 6 to 12-year-old patients.

MadaJet®XL is an autoclavable jet injection device that delivers the local anesthetic solution with high pressure using a mechanical system. This device consists of 1) a head assembly with glass fill chambers holding

Table 1. Face, Legs, Activity, Cry, Consolability scale

Categories	Scores		
	0	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown; withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or sleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs; frequent complaint
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort

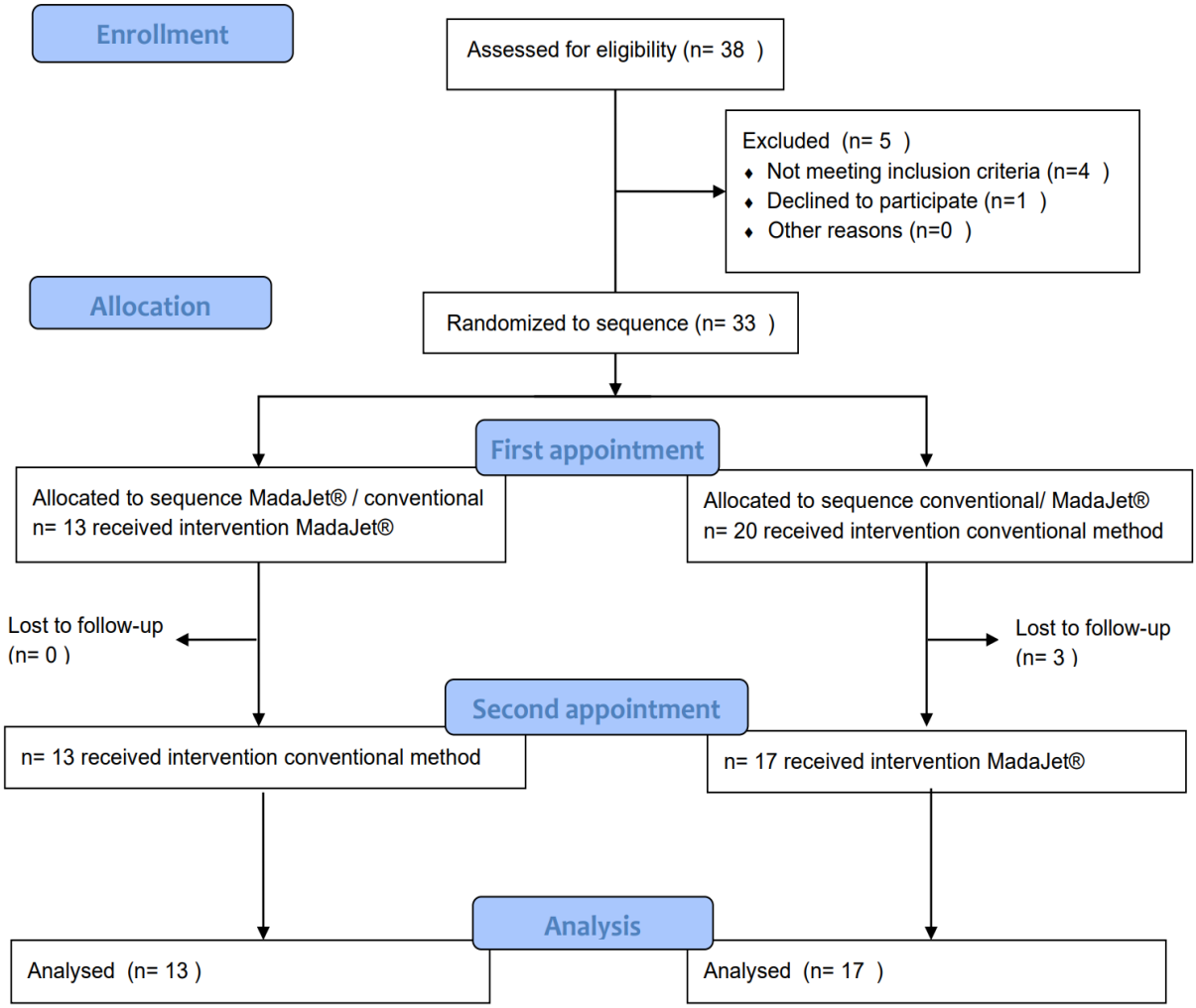

Fig 1. CONSORT flow diagram of the study

Table 2. Minimum, maximum, mean, and standard deviation of the FLACC score in the two groups (n = 30)

Intervention	Mean± SD	Minimum	Maximum	P value
conventional	4.1± 2.6	0	9	<0.001
MadaJet®XL	2.3± 1.3	0	6	

Wilcoxon Signed Ranks test: SD: Standard deviation

up to 4 mL of local anesthetic solution, 2) a body with cocking lever and discharge button, and 3) an extended-tip and sheath which can be changed between each patient and allows for pinpoint accuracy at the injection site. Each injection of MadaJet®XL sprays 0.1 cc of anesthetic solution at a depth of 2–2.5 mm below the epithelium. High pressure during anesthetic solution insertion forms tiny droplets of the drug which can be taken up by the nerves' myelin sheath immediately [5]. Therefore, speed and volume for each injection cannot be affected by operators. It is worthy to mention that in several studies about the conventional method (injection with the needle), it has been shown that lower speed and/or lower volume during injection result in lower pain perception [17-19]. These findings cannot be generalized to jet injection devices, as there has not been any research about the effect of speed and volume on pain perception in jet injectors until now. Besides,

there is a higher speed but lower volume in jet injection devices compared to the conventional method; hence, the difference in pain perception between the two methods cannot be directly attributed to these two parameters. Further studies are required to concentrate on this issue.

The main findings of the present study showed that children experienced significantly less pain with MadaJet®XL during injection than the conventional method in line with previous studies [5,20]. The following studies used other jet injectors. Ocak et al. [21] compared INJEX® (Rösch AG Medizintechnik, Germany) with the conventional injection method in 12 to 18-year-old patients and reported that INJEX® was less painful. On the contrary, Arapostathis et al. [1] concluded that the conventional method was preferred to INJEX® in 6 to 11-year-old participants. The main cause may be attributed to the design of jet injectors. In all jet injection devices, the anesthetic delivery segment forms a 45-degree angle with the main body of the device. However, INJEX® forms a 90-degree angle. The 45-degree angle design allows for better positioning relative to the gingiva, leading to less pressure and discomfort during anesthesia administration and less leakage of anesthetic solution, which results in less experience of bad taste [1]. Therefore, INJEX® causes significant discomfort in younger children and is less tolerable by them [22]. The Comfort-in system (Mika Medical; Busan, Korea) is another needleless device. One study reported less pain with Comfort-in [8]; while, another study found no significant difference in pain perception [12]. Inconsistencies in the results of the aforementioned studies show insufficient research on children and lack of a systemic investigation on jet injection devices.

In the present study, after anesthetic administration, a blind dentist did all the restorative procedures. Re-injection was performed for 19 patients (63.3%) due to failure of local anesthesia during dental procedures when MadaJet®XL was used. This shows the inability of this jet injector to achieve successful anesthesia, frequently resulting in a need for an additional conventional infiltration technique. This finding was in line with previous studies [1,8,11,21]. However, other studies on adult patients reported needleless devices as successful [9,10,20]. Differences in the success of local anesthesia with jet injection devices might be due to shorter duration of anesthesia in jet injectors [8,11], different dental procedures [1,8,23,24], tooth position in dental arch (jet injection is more effective in anterior teeth [1]), and heterogeneity in the age range of the study populations.

It should be mentioned that pain perception is affected by physical, psychological, and mental factors. Also, children's reaction to dental procedures is complex. Their response is influenced by the child's age, temperament, level of anxiety, parental anxiety, and previous dental experiences [25-27]. Further studies considering these factors are recommended.

Limitation

This study was not without limitations. First, confounding factors such as child's temperament that can affect pain perception were not considered; although the effect of this confounder was reduced by the cross-over study design. Second, the assistant who evaluated pain was not blinded to the group allocations. Therefore, further research is recommended to address these shortcomings.

CONCLUSION

Despite the lower level of pain and discomfort experienced during local anesthesia administration by MadaJet®XL, this device is not suitable for restorative procedures of primary maxillary molars, due to failure to achieve complete anesthesia.

CONFLICT OF INTEREST STATEMENT

None declared.

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