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Evaluating Child Behavior and Preference Toward NumBee and Traditional Syringe (a Randomized Clinical Trial)

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Abstract

BACKGROUND: Local anesthetics are the gold standard for pain control in dentistry. Most patients still view the "needle" as a source of anxiety and disruptive behavior rather than relief. The patient's cooperation and comfort level will increase with the administration of painless local anesthetic injection using appropriate technique. The purpose of this study was to assess the patient cooperation and behavior after receiving local anesthesia injection and to compare patients' acceptance and preference of needleless NumBee anesthetic delivery device to conventional dental syringe.

MATERIALS AND METHODS: 30 non-fearful 6-8-year-olds who had never been to the dentist were selected for the study using a split-mouth design. They underwent a simple class I restoration on both mandibular permanent first molar teeth in two separated dental visits. The Frankl behavior rating scale was used to assess patient behavior following injection. Patients expressed their preference and acceptance of the used syringes by answering a questionnaire.

RESULTS: After injection by either method, 25 patients had Frankl behavior rating score of 4. Patients that had a negative response with the traditional method, showed a score of 2, following NumBee injection (p=0.035).

CONCLUSION: Patients accepted both methods, and NumBee may induce less fear, with minimum stinging and unpleasant taste.

KEYWORDS: Syringes; Anesthesia; Local; Mental health; Child Behavior; NumBee

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Introduction

Numerous pediatric dental services require the administration of local anesthetic, which acts to decrease the sympathetic activation brought on by the dental operation. Local anesthetics are regarded as the foundation of pain control in children that need to undergo dental treatments such as extractions, pulpotomies, or pulpectomies [1].

The most distressing part of the dental anesthesia experience is the use of a needle, which is referred to as "needle phobia" or blenophobia and may be the reason for delaying dental treatments [1-3].

Therefore, the dental practitioner aims to perform treatments with minimum of pain and discomfort [4].

Feeling anxiety may also lead to more severe and prolonged discomfort during dental treatments [5,6].

There are some risks, particularly when administering inferior alveolar nerve blocks [7-10]. To minimize risks and discomfort, dental syringes have

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been redesigned to make dental injections easier and less painful.

One of the redesigned systems is a device named as NumBee (BioDent, Simi Valley, CA). The manufacturer of this device claims to deliver local anesthetics painlessly and without the need for a hypodermic needle. It comprises a tiny metal cannula that is covered in a silicone-like material and utilized for intraligamentary injections that do not penetrate the periodontal ligament. For pediatric patients, this could be an enormous gain over the standard syringe [11].

The aim of this work was to study on an intraligamentary needleless syringe (NumBee) in order to evaluate patients' behavior, preferences, and acceptance of the intraligamentary device for dental anesthesia.

Material and Methods

Sample collection

About 800 primary schools aged children were surveyed after approval from Al-Karkh Health Directorate, and approximately 450 children had no previous dental experience. The clinical phase was held at the primary health care center in Baghdad. A visual intraoral examination was completed for all the 450 children.

Children included in this study were healthy with no cognitive impairment who never been in the dentist and with "positive" or "definitely positive" behavioral rating according to the Frankl behavior classification scale [12]. We selected children that had bilateral class I carious lesion on their mandibular permanent first molars with initial or moderate caries according to ADA caries classification 2015 (ICIDAS scores 2/3/4) [13]. All the details of the study and the address of the dental center where the restorative procedure would be performed were explained in detail to the school headmaster, and the phone number of the investigator was given to allow interested parents to have direct contact with the investigators. Parents/guardians who showed initial interest were then contacted privately and provided written informed consent after a comprehensive explanation of the study's objectives. Information about the participant's overall health and an assessment of the likely adherence to the study guidelines were obtained. A date and time for the dentist appointment were then scheduled accordingly.

Calculation of sample size and randomization

To determine sample size, G power 3.1.9.7 (University of Düsseldorf, Germany) with partial eta square ŋ2 =0.06 (medium effect size) was utilized. The correlation between measures (sides and treatments) used was 0.5, and the effect size of F for two devices and two sides under these conditions used was 0.2526, producing a sample size of 27 subjects plus 10% as an error rate [14], resulting in a sample size of 30. The impact size distribution of partial eta squares varies between small (0.01-0.059), moderate (0.06-0.139), and big (>=0.14 13-16 d) [15-18].

A single-blinded design was employed for this study to identify which method was utilized (NumBee or a conventional syringe). Using the Random Number Generator (RNG) tool in Microsoft Excel, participants and interventions were randomized also for the allocation of the injection site and the order of anesthetic method was conducted using a block design.

Intervention

At the waiting room, the dentist monitored the patient's general behavior in accordance to Frankl Behavior Scale (scale 3/4).

Administration of local anesthesia with 2% lidocaine and 1:80,000 epinephrine was employed. Regarding the standard injector for inferior alveolar nerve block, a long needle with a 27-gauge was employed. When local anesthetic administration was carried out with NumBee, the dentist used a plastic tip which is particularly purchased from the manufacturer (Figure 1). Before administering the injection, there was no topical anesthesia used at the injection site.

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Figure 1. *The intraligamentary needle-free (NumBee)*

While using NumBee, the manufacturer's instructions were followed. They recommend injecting four sites opposite to the mandibular permanent first molar roots, which will administer 0.48 mL of anesthetic fluid over 80 seconds. After 40 seconds the anesthesia can take full effect [11]. The inferior alveolar nerve block involves diffusion of 1.5 ml of anesthetic solution over the course of 60 seconds [19], with waiting for five minutes before starting the restorative session [20].

After the patient received the anesthesia, a questionnaire regarding their own preference and the degree of their acceptance of both methods was filled out. The questionnaire consisted of two parts: one was about the symptoms and fear they had during injection and the second included some of the observations that were recorded by the dentist by asking parents about any problems endure postoperatively by contacting them via telephone [21].

A. Symptoms during anesthesia:

1. Annoyance or pain during administration of anesthesia.
   NO□ YES □

2. Fear during administration.
   NO□ YES □

B. Symptoms immediately after anesthesia :

1. Bleeding of the mucosa.
   NO□ YES □

2. Pain. NO□ YES □

3. Stinging. NO□ YES □

4. Bad taste. NO□ YES □

5. Annoyance or discomfort after recovery from anesthesia.
   NO□ YES □

Children underwent class I restoration on their mandibular permanent first molar teeth in two separate but consecutive sessions. A tooth-colored restorative material was used for cavity filling. Following this, the dentist assessed the patient behavior and determines a score based on the Frankl behavior rating scale.

At the end of both visits, patients were interviewed and asked to give their own opinion of the most scared and most favorable method, what method to choose for the next dental session to numb their teeth.

Statistical analysis

Data analysis was performed by using Statistical Package for Social Science (SPSS version -22, Chicago, Illinois, USA). Frequency, mean rank, and inferential statistics (marginal homogeneity test and Mc Nemare's test) were determined. The level of significance was 0.05.

Results

On comparing both modalities of injection of Frankl behavior rating scale by using the marginal homogeneity test, Frankl behavior rating scale score 4 was the most prevalent score among the participants after receiving the injection using either method (25 patients) as shown in (Table 1), however, Frankl behavior rating scale score 3 was reported in both methods but was more frequent after inferior alveolar nerve block injection. Patients showed a score of less cooperative status (score 2) on Frankl behavior rating scale for both methods but it was higher in NumBee injection (p value=0.035).

Regarding the questions asked for the participants to express their acceptance and preference of both modalities, the McNemar's test showed that the NumBee injection induced less fear in participants, a less unpleasant state after injection with a lesser number of participants who experienced a stinging sensation in comparison with inferior alveolar nerve block method, however; with statistically non-significant difference (Table 2).

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Table 1: Distribution of Frankl behavior scale scores among techniques and time.

Technique	Time	Score	Sex		
			M	F	Total
			N.	N.	N.
NumBee	Baseline	4	13	17	30
	After	2	0	2	2
		3	2	1	3
		4	11	14	25
Block	Baseline	3	0	1	1
		4	13	16	29
	After	2	0	1	1
		3	1	3	4
		4	12	13	25

FRNb-FRBB (pre for both methods): p value=1, FRN1-FRBL1(after injection for both methods): p value=0.451, FRBL0-FRBL1(pre – post for IANB): p value=0.059, FRN0-FRN1, p value=0.035

Table 2: Acceptance and preference of children for both techniques.

Sex	Variable	NumBee	Inferior alveolar nerve block	McNemar's test p-value
		N.	N.	
Boys	Pain during injection	8	6	0.625
	Fear during injection	6	5	1.000
	Bleeding after injection	7	6	1.000
	Pain after injection	2	1	1.000
	Stinging after injection	3	3	1.000
	Bad taste after injection	9	8	0.453
	Annoyance post-op.	2	1	1.000
Girls	Pain during injection	10	8	0.727
	Fear during injection	9	11	0.688
	Bleeding after injection	7	6	1.000
	Pain after injection	2	1	1.000
	Stinging after injection	4	7	0.453
	Bad taste after injection	13	10	1.000
	Annoyance post-op	5	5	1.000
Total	Pain during injection	18	14	0.388
	Fear during injection	15	16	1.000
	Bleeding after injection	14	12	0.791
	Pain after injection	4	2	0.688
	Stinging after injection	7	10	0.508
	Bad taste after injection	22	18	0.424
	Annoyance post-op.	7	6	1.000

Regarding the interview made at the end of the dental sessions, most children favored NumBee (N=27), chose NumBee when asked about the method they would choose to anaesthetize their tooth in the future

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(N=25), and stated the conventional syringe frightened them the most (N=26).

Discussion

Being able to guide children pleasantly through their dental experiences and promote a positive dental attitude in order to improve their oral health is one of the cornerstones of the pediatric dentistry practice [22].

Dental needle injections have long been a source of worry and anxiety for individuals needing to face the dentist [23].

As a logical consequence, it was strongly recommended that an anesthetic delivery system be created with a less frightening appearance and with a low level of anxiety arousal [24].

NumBee was selected for this study because of its needle-free design as an attempt to reduce the painful injection as it eliminates the damage from a needle stick which in turn would improve the pediatric patients' attitude in the dental clinic [11].

After a thorough reviewing for the published scientific literatures, it was found that delivering local anesthetic to pediatric patients with NumBee has not been studied.

The design of the split-mouth offered the possibility of a savings costs. This design eliminates any aspects of the treatment comparisons that are related to differences between subjects being tested, which leads to a reduction in the amount of error variance, and, as a consequence, a more accurate assessment.

Participants of 6 to 8 years of age were selected, as this age group are easier to deal with during treatment in comparison to younger children. Moreover, this age group has the capacity to comprehend logical concepts such as discomfort and anxiety and express themselves properly [25].

No topical anesthetic was used to ane sthetize the injection sites and this was to ensure that the topical anesthesia would not affect the children's reactions or behavior and the patient would express their actual feeling. The reason for completing the dental procedures in two sessions rather than one was because the procedure would be time-consuming and could hinder the child's ability to participate owing to fatigue and exhaustion, resulting in false positive responses.

Children who have previously received dental treatment may retain memories of anxiety and pain, which can increase their likelihood of experiencing anxiety and fear during future visits. This may also lead to more disruptive behavior. Additionally, the presence of a positive treatment history can also impact the results of the study. Therefore, it was imperative to select children with lack of history of dental visits.

A double-blinded design was not possible, as the operator would always be aware of the significant difference between the methods concept for local anesthesia administration, in addition to apparatus design that was obviously different.

In the present study, the researcher chose to treat the mandibular dentition because the mandible's higher bone density in contrast to the maxilla, which hopefully allowed for a more accurate evaluation of the intraligamentary anesthetic efficacy of the NumBee [26,27].

As behavior evaluation is the most essential tool in the pediatric dentistry to enable the dentist to execute the required treatment plan in the most effective manner, promoting a positive attitude toward dental care. The Frankl's behavior rating scale is a tool used to evaluate the patient's behavior and considered to be the most reliable tool established for rating children's behavior in a dental setting [28].

In the present study, the level of positive behavior for the participants who anesthetized with NumBee was reduced ($p=0.035$), and this could be attributed to a lesser degree of the profound anesthesia anticipated from NumBee, as anesthesia is infused into the epithelium and connective tissue that lies between the gingival sulcus's

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base and the PDL according to the manufacturer [29,30]. This means, as compared to the conventional needle injection, that less local anesthetic is defused to the marrow spaces of the bone around the teeth, giving less chance to provide deep sensation of tooth numbness. This gave rise to lesser negative behavior in Frankl behavior score towards NumBee injection compared to the inferior alveolar nerve block.

Patients in this study disclosed their acceptance and preference equally for both methods; however, less fear was induced in patient who were injected by NumBee. This was also clear when N participants declared conventional syringe frightened them during the interview.

Conclusion

The patient's preference and the acceptance regarding both methods were equivalent; however, patients who are phobic of needles may benefit from NumBee as a lower number experience fear while receiving local anesthesia, less stinging sensation, and they had a minimum unpleasant taste.

Ethical consideration

All procedures were performed according to the Declaration of Helsinki's ethical guidelines and approved by the Central Committee of Ethics of the College of Dentistry, University of Baghdad (no. 576322, dated 02.06.2022). Furthermore, scientific approval has obtained from the scientific committee in the department of Pediatric and Preventive Dentistry in the College of Dentistry at the University of Baghdad. Besides that, ClinicalTrials.gov has registered this study and assigned it a registration code of (NCT05899296).

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