



A Comparison of Pain Perception and Efficiency in NumBee versus Conventional Injection

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Article Type	ABSTRACT
Research Paper	Background and Objective: The pain and anxiety caused by ordinary dental syringes in children has led to the invention of needle-free injection, which can affect the attitude of young patients towards dentistry. The aim of this study is to compare the needle-free syringe (NumBee) and the conventional one in terms of anesthesia efficiency and pain perception during anesthetic injection and tooth cavity preparation. Methods: In this cross-sectional study, 30 patients aged 6-8 who had no experience of visiting a dentist and all of them needed Class I tooth restoration for their mandibular 1st permanent teeth, were selected. They received local anesthetic by NumBee for one side and a conventional dental syringe for the other in two randomized sequential dental treatments. Wong Baker Faces pain scale was used to assess pain perception during local anesthetic injection and cavity preparation. Efficiency was evaluated by reported symptoms during cavity preparation and the need for rescue anesthesia. Findings: NumBee injections induced less pain than cavity preparation for 12 out of 17 girls ($p=0.019$). However, when the children were anesthetized with NumBee, cavity preparation was significantly more painful than with inferior alveolar nerve block ($p=0.013$). Conclusion: According to the results of this study, NumBee injection was less painful than inferior dental nerve block. However, NumBee supplies less anesthesia than the inferior alveolar nerve block. Keywords: Anesthetic Efficiency, Needleless Anesthesia, Numbee, Pain Perception, Pediatric Dentistry.

Received:

Apr 4th 2023

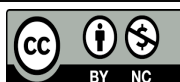
Revised:

May 23rd 2023

Accepted:

Jul 11st 2023

Cite this article: Kamal Naji D, Juma Jafar Z, Ahmed Yas B. A Comparison of Pain Perception and Efficiency in NumBee versus Conventional Injection. *Journal of Babol University of Medical Sciences*. 2024; 26: e13.



Introduction

Pain is a sensory and emotional experience that is impacted by a variety of factors, including physiologic, sensory, affective, cognitive, socio-cultural, and behavioral elements (1). In addition, pain is considered as the primary reason why a patient seeks dental treatment. On the contrary, according to Rajeev et al, dentophobia typically causes individuals to postpone receiving necessary dental treatment, which can lead to serious health issues in the future (2). In pediatric dentistry, preventing or minimizing discomfort helps children improve trust, enhance cooperation, and enjoy subsequent dental visits (3). Dental caries affects people of all ages, particularly young children (4), and restorative dental care can cause dental anxiety in children due to its many uncomfortable stimuli. However, the unpleasant sensory experience of local anesthetic injection preoccupies most of the patient's mind (5-7).

Local anesthetic is the foundation of dental pain treatment. Restorative and surgical pediatric dental procedures require it (8). The objective fear of the child during the administration of local anesthesia, which spans from the sight of the needle to the pain associated with needle injection, increases the patient's anxiety and leads to future fear of receiving local anesthesia (9). The child's psychological and emotional state, previous pain experiences, anxiety level, and awareness of the treatment can all affect their pain perception (10). The amount and the type of anesthetic solution, the speed of injection, the dental practitioner's skill, the injection site, the use of topical anesthesia, and the injection technique all affect injection pain (11) and needle puncture (12).

Various injection devices had been released in order to alleviate the children's pain during local anesthetic injection, which include computer-controlled local anesthetic delivery (CCLAD), vibrotactile devices, computer-assisted intraosseous anesthesia (CAIO), the Quick sleeper, and the needleless intraligamentary syringe (3). The NumBee (BioDent, Simi Valley, CA) is a unique device that delivers local anesthetic atraumatically without a hypodermic needle (12) (Figure 1). It is a tiny silicone-encased metal cannula for intraligamentary injections without periodontal ligament penetration.



Figure 1. The NumBee (BioDent, Simi Valley, CA)

The NumBee concept involves sealing the NumBee tip to the PDL by advancing it to the gingival sulcus. Local anesthetic is infused into the tissue by slowly pressing the syringe (13). There was an urgent need to investigate NumBee and assess its performance on the pediatric dentistry; so, the present study was designed to evaluate the level of pain experienced during the administration of local anesthetic using NumBee, as well as the pain associated with cavity preparation during the restoration of mandibular permanent first molars. Furthermore, this study was conducted to compare these outcomes with those of the inferior alveolar nerve block (IANB) and to evaluate the efficacy of both methods of anesthesia.

Methods

This clinical trial followed the ethical criteria of the institutional and national research committee and the 1964 Helsinki Declaration. The scientific approval for the present study was obtained from the scientific committee in the department of Pediatric and Preventive Dentistry, College of the Dentistry/University of Baghdad; additionally, the ethical approval (no. 576322) for the study was obtained on (2.6.2022) from the Central Committee of ethics in the College of Dentistry/University of Baghdad.

In this split-mouth randomized clinical trial, thirty randomly selected school children who had to meet the inclusion criteria, no systemic disease history, aged 6-8 years, negative visit to dental clinics, were indicated for bilateral class I on their mandibular permanent 1st molars, had only initial or moderate caries based on the American Dental Association Dental Caries Classification System 2015 (ACIDAS scores 2/3/4), and rated as a 3 or 4 on the Frankl behavior rating scale. Patients were excluded if they were mentally and medically compromised, having history of allergy to local anesthesia (LA), uncooperative children, badly carious mandibular permanent 1st molar, and being on orthodontic treatment. This study was single-blinded to the employed technique (NumBee or traditional syringe). Between June and August 2022, several Baghdad elementary schools were surveyed. Addresses and class lists were sent to nominated students. Parents were contacted via school "WhatsApp" groups. Those who initially consented were asked to provide further information about their children's health. To enhance participant cooperation, the restorative procedure was conducted in dental clinic located near the surveyed primary schools. Informed consent was obtained from all individual participants included in the study.

The calculation of the sample size was performed using G power 3.1.9.7 (university of Dusseldorf, Germany) with partial eta square $\eta^2=0.06$ (medium effect size) (14), power of study=80%, alpha error of probability=0.05, the correlation between measures (sides and treatments) was 0.5, and effect size of F was 0.2526; two devices and two sides (two arches) with all these conditions were considered and the definite effect size was 27 subjects, and 10% was added as an error rate (15). So, the sample size included 30 subjects. The Partial eta square effect size range from small (0.01-0.059), to medium (0.06-0.139), to large ≥ 0.14 (14, 16-18).

A random allocation of sides and treatments and the order of anesthetic technique were generated using Microsoft Excel (Random Number Generation [RNG]) using a block design. All rights and welfare of the children were respected. Before any procedure relevant to the study, the parents gave their approval by signing an informed consent form, and they were given a comprehensive explanation of the purpose of the study and how it would be performed. Measures were taken to ensure the privacy and confidentiality of the patients involved in the study, including the elimination of any identifiable data collected prior to and during dental sessions including the patient's phone number and any photo of the patient.

The intervention was started with 1 local anesthetic injection of 2% lidocaine with 1:80,000 epinephrine. Children underwent class I restoration on their mandibular permanent first molar teeth after receiving an IANB on one side and NumBee on the other in two separate sessions. In the IANB, a 27-gauge needle with a standard dental anesthetic syringe was used while a plastic tip, which was supplied specifically by the manufacturer, was used with NumBee (Figure 2). Topical anesthesia hadn't been used prior to injection.

For the NumBee injection, each squeeze of the syringe delivers 0.06 mL of the anesthetic solution to the injection site. Two squeezes of NumBee are enough for each injection site. The manufacturer recommends injecting 4 dots on the mandibular permanent 1st molar (one for each root); this will administer 0.48 mL of anesthetic solution over a duration of 80 seconds (13). Immediately after each injection, the children were subjected to rate the pain experienced during injection using Wong-Baker Faces Pain Scale on a preprinted form (Figure 3).

The children's feelings were demonstrated as faces from a smile expression to a crying expression that are described vocally as ("No Hurt" to "Hurts Worst") and the child was asked to choose the face that expresses his / her feeling; the pain scale was well explained to the child prior to utilizing the scale to understand numeric ranking from "0" to "10" scales (19).



Figure 2. Injection with NumBee in the lingual sulcus of mandibular left permanent first molar



Figure 3. The Wong-Baker Face Pain Scale (20)

Successful anesthesia with NumBee can be anticipated after about 40 seconds (21), while for the IANB technique, 1.5 ml of anesthetic solution was deposited over the course of 60 seconds (22). The IANB requires a five-minute waiting period before the dentist can initiate treatment (23).

The local anesthesia efficiency was checked by a qualitative statement to see if it was profound enough for the subject to experience sufficient analgesia during the restorative procedure. If discomfort was experienced by the subject during the restorative procedure, a rescue anesthesia was administered by any method necessary to facilitate completion of the restorative procedure, and the anesthesia was considered as a failure (13).

Data analysis was performed by using Statistical Package for Social Science (SPSS version-22, Chicago, Illinois, USA), and frequency, percentage, and mean rank, inferential statistics were analyzed using Wilcoxon sign rank tests and Mc Nemare's test. The measure for statistical significance has been defined at a p-value level of less than 0.05.

Results

The results show that there were no differences in pain between the two techniques during injections, while there were more children who felt pain during cavity preparation when they were injected by NumBee

than children who were anesthetized by IANB with a statistically significant difference ($p=0.013$). In addition to that, there were more girls injected by NumBee who were affected by pain during the cavity preparation than during injection with a significant difference ($p=0.019$), as shown in table 1. Regarding the pain response after injection (Figure 3) and during cavity preparation (Figure 4), the results show that there was a non-significant difference between the two techniques (NumBee and IANB).

Table 1. Descriptive and statistical test Wang Baker pain between techniques and steps of treatment

Gender	N	Rank	Injection	Statistics			Technique	N	Rank	Mean rank inj-cav	Z	p-value
				N	Rank	Cavity						
Boys	2	NR ^a	5.75	3	NR ^a	3	Numbee	4	NR ^c	5.13	0.732	0.464
	7	PR ^b	4.79	5	PR ^b	5.4		6	PR ^d	5.75		
		Z=1.350			Z=1.294		IANB	4	NR ^c	5	0.832	0.405
		p=0.177			p=0.196			6	PR ^d	5.83		
Girls	4	NR ^a	4.5	4	NR ^a	4.5	Numbee	12	NR ^c	7.38	2.336	0.019*
	4	PR ^b	4.5	8	PR ^b	7.5		2	PR ^d	8.25		
		Z=0			Z=1.705		IANB	5	NR ^c	4.70	0.719	0.429
		p=1			p=0.088			3	PR ^d	4.17		
Total	6	NR ^a	8.92	7	NR ^a	7	Numbee	16	NR ^c	12	1.240	0.215
	11	PR ^b	9.05	13	PR ^b	12.38		8	PR ^d	13.5		
		Z=1.166			Z=2.163		IANB	9	NR ^c	9.61	0.046	0.963
		p=0.243			p=0.013*			9	PR ^d	9.31		

PR=Positive rank, NR=Negative rank, a=Numbee<IANB, b=Numbee>IANB, c=injection<cavity, d=injection > cavity

*Means it was significant.

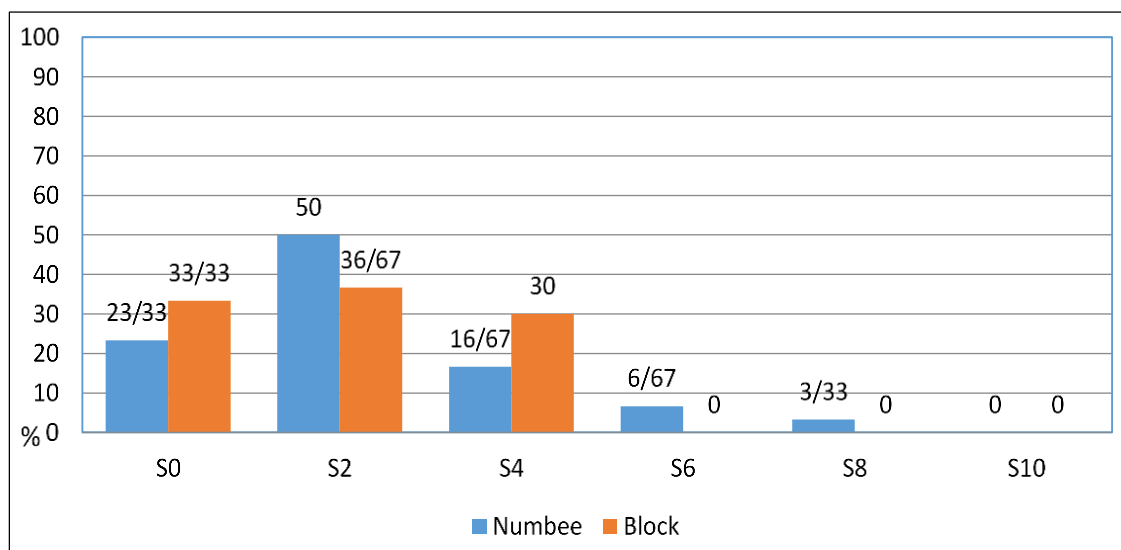


Figure 3. Distribution of Wang Baker pain scale scores during injection

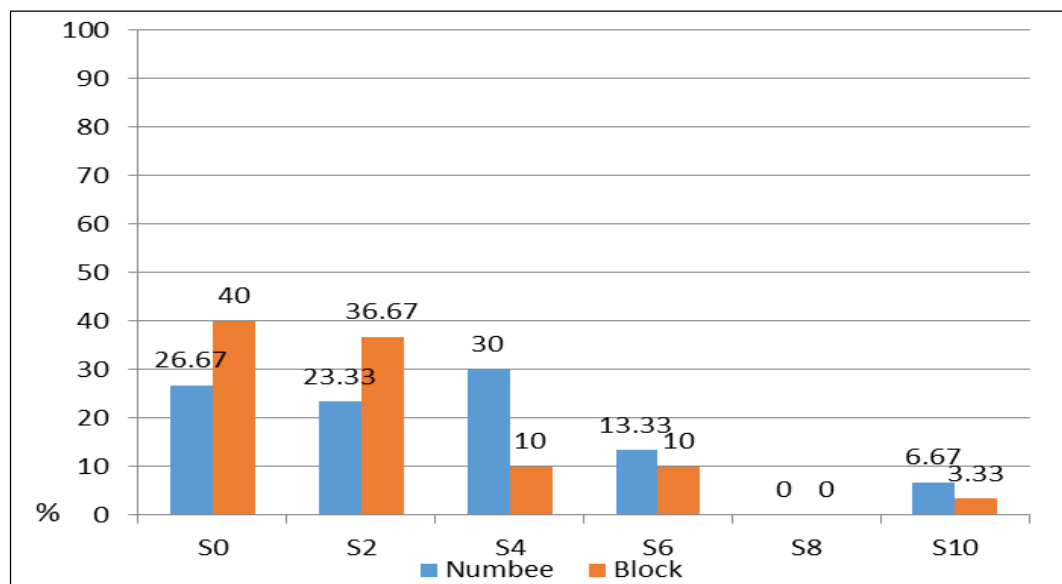


Figure 4. Distribution of Wang Baker pain scale scores during cavity preparation

By applying Mc Nemare's test of pain during drilling for cavity preparation, there was a non-significant difference between the two techniques. Additionally, the number of children who needed rescue anesthesia showed a non-significant difference in both techniques (Table 2).

Table 2. Descriptive and statistical test of anesthesia efficiency between the two techniques

Gender	vars.	NumBee (n=30) Number(%)	IANB (n=30) Number(%)	Mc Nemare's test
Boys	Pain in drilling	2(15.38)	3(23.08)	1
	Rescue anesthesia	1(7.69)	2(15.38)	1
Girls	Pain in drilling	9(52.94)	7(41.18)	0.625
	Rescue anesthesia	8(47.06)	5(29.41)	0.375
Total	Pain in drilling	11(36.67)	10(33.33)	1
	Rescue anesthesia	9(30.00)	7(23.33)	0.688

Discussion

Despite the fact that girls are more likely to be nervous about anesthesia injections, this study revealed that girls who were anesthetized by NumBee reported significantly less pain during injection. The aforementioned observation indicates that the needle-free tip may have been better received by children due to its less intimidating appearance and greater suitability for pediatric use. Additionally, the NumBee tip's provision of an anesthetic injection with minimal pain perception may have contributed to its ability to render injections more tolerable than the conventional dental syringe needle.

On the other hand, the majority of the children who were chosen for the study reported that IANB caused them more pain than NumBee did during injection. However, when the children were anesthetized with NumBee, the pain experienced during cavity preparation was significantly higher than those anesthetized with IANB.

Although classified as an intraligamentary type of injection, the NumBee is not advanced into the PDL because its tip is only inserted to the base of the gingival sulcus according to the manufacturer's instructions (13). This can make it less likely for the anesthetic solution to be diffused thoroughly on the marrow spaces of the bone and the surrounding tissue, which explains why NumBee provided a lower level of pulpal anesthetic depth and why children felt more pain during the restorative procedure when compared to IANB which provided more effective anesthesia while also reducing the amount of pain experienced during cavity preparation.

The reason for choosing NumBee in this study was the needle-free design in a try to lessen the patient's feelings of fear when they see the needle, especially in the pediatric patients. It also provides single tooth anesthesia without the need to anesthetize the whole nerve branch while eliminating the self-inflicted post-operative injury and give a reasonable duration of operative anesthesia (13).

The electric pulp tester (EPT) was not used in this study for checking the depth of anesthesia due to ethical issues concerning its use among children; furthermore, children may get anxious and give the wrong reaction to EPT. Instead, the pulpal anesthetic efficiency was determined by reporting whether or not the child experienced any discomfort during the drilling of carious lesions and whether or not rescue anesthesia was administered to alleviate that discomfort.

Topical anesthesia was not used to topically anesthetize the sites receiving the injections, so the children will not miss-assess the pain experienced based on Wang-Baker Face pain scale. The purpose of performing the dental procedures in two separate visits rather than one visit is that the procedure may take a long time and might affect the child's ability to cooperate, as children get tired quickly, which may lead to incorrect responses.

In this study, the Wong-Baker Faces Pain scale was selected because it's helpful for assessing pain and is considered as one of the most preferred scales by children (24). Its application is widespread, and its validity is widely accepted, with users preferring cartoon-like depictions. Regardless of their resemblance to a "real" human face, these scales appear to work well across gender and race/ethnicity. Their success may be in part due to their neutrality (20).

Based on the results of the present study, NumBee's pen-like design and the needless tip could make injections less painful for pediatric patients, and the device was less intimidating to them than a conventional syringe. On the other hand, children anesthetized with IANB reported a more satisfying operative experience.

Conflict of interest: Authors have no conflict of interest.

Acknowledgment

The author expresses his gratitude to clinic staff and co-authors for their valuable contributions in the preparation of the manuscript.

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