Original Article

Pain Perception and Effectiveness of Palatal Approach Anterior Superior Alveolar Block Anesthesia using Single Tooth Anesthesia in Children: A Randomized Controlled Trial

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Abstract

Background: Restoring multiple anterior teeth in children using conventional infiltration is challenging due to the need of multiple injections, a considerable amount of anesthetic solution, and lip numbness. The palatal approach anterior superior alveolar block injection (P-ASA) using the Wand single tooth anesthesia (STA) provides an alternative and innovative technique that overcomes several challenges and should be furtherly tested. **Aim:** The aim of this study was to compare the pain perception and the effectiveness of P-ASA injection using STA (Milestone Scientific, Inc.) and a 30 G × 0.5 inch needle, to the regular multiple maxillary infiltration local anesthetic technique (MIT) in restoring primary anterior maxillary teeth. **Design:** This study was designed as a randomized controlled clinical trial in which 64 healthy children who need restoration and/or pulp treatment on primary maxillary anterior teeth were assigned to either receiving P-ASA block injection or regular (MIT). Children's behavior was assessed during anesthesia administration objectively using face, legs, activity, cry, and consolability behavioral pain assessment scale (FLACC). Children's self-reported pain was evaluated subjectively at two different time points (directly after injection of anesthesia and after full dental treatment) using the Wong–Baker FACES pain rating scale (WBFPRS). Data were statistically analyzed using SPSS version 13.0 and statistical significance was determined as $P \leq 0.05$. **Results:** Children receiving the P-ASA reported less pain both during and after anesthesia administration ($P = 0.0001$)**.** Similar results of pain were reported after treatment completion using both techniques ($P = 0.464$). **Conclusion:** P-ASA can be considered as an excellent alternative to administer deep, fast, effective, and less painful anesthesia of the upper primary anterior teeth and related gingival tissues compared to MIT.

Keywords: *Maxillary infiltration anesthesia, palatal approach anterior superior alveolar block anesthesia, single tooth anesthesia and pain perception*

Introduction

The treatment of carious primary maxillary incisors particularly in the case of children affected by early childhood caries remains one of the main challenges in the field of pediatric dentistry.[1] The difficulty of the challenge is further intensified with the necessity of placing esthetic restorations or crowns under compromised conditions such as in the cases of very young, precooperative children.[2] To maximize the quality of the treatment and ensure optimal conditions during the operative procedures and restoration placement, the use of general anesthesia is often deemed necessary.[3] However, the increase in dental care costs in addition to the adverse health and psychological risks imposed by the use of general anesthesia urged the exploration of more conservative and less traumatic approaches for the treatment of children.[4] Injection of local anesthesia is by far the most common used technique for pain control in dentistry. Nevertheless, this technique might be in itself painful to pediatric patients and is often distressing not only to patients but also to dentists who often find it stressful to perform.[5]

Subsequently, different approaches employing painless techniques were developed to facilitate the delivery of local anesthetic as the use of topical anesthetic, the application of pressure and stretching mucosa at the injection site, syringe concealment, distraction, and slower injection rate.[5] Despite these efforts, fear of injection has continued to afflict the dental profession.[6]

A convenient, traditional, safe, and effective method to anesthetize maxillary

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teeth and associated tissues is the conventional infiltration technique (IT). In this technique, anesthesia is administrated in the mucobuccal supraperiosteal fold in close proximity to the apices of teeth to be anesthetized.[7] However, it requires multiple injections to cover multiple anterior teeth and causes anesthesia of the associated facial musculature and lip area.[8] This may lead to additional stress and apprehension, especially in precooperative children. Consequently, an alternative technique was introduced in 1999 by Friedman and Hochman, which is the palatal approach anterior superior alveolar nerve block (P-ASA). This approach enables anesthesia of multiple teeth in the maxilla, up to six anterior teeth, as well as the palatine anterior one-third and labial gingiva through one palatal injection while avoiding any collateral anesthesia of nearby tissues of the face as the lips or other muscles of facial expression.[9]

About two decades ago, the Wand (Milestone Scientific, Livingston, NJ) was introduced. The Wand is a computer-controlled local anesthesia delivery device. This device delivers the anesthetic solution at a slow constant rate using a microprocessor and an electronically controlled motor activated by a foot pedal. The anesthetic solution then passes through a thin, light-weight handpiece, with a needle held in a pen-like grasp, under controlled pressure and volume ratios, independent of the tissue resistance.[10] This eliminates the variation in pressure due to the thumb-operated plunger as in a traditional syringe. In addition, the device allows rotation of the needle during insertion, consequently enabling precise injections without deflection. This system has two flow speeds with adjustable flow rates, a slow one (ControlFlo) and a fast one (RapidFlo).[10]

To the best of our knowledge, there are no recent studies in the literature discussing the quality of the P-ASA block injection anesthesia using the Wand single tooth anesthesia (STA) system, in comparison to the traditional maxillary infiltration local anesthetic technique (MIT) in children. This study aimed to compare the pain perception and effectiveness of the P-ASA block injection using a computer-controlled local anesthetic delivery (CCLAD) system The Wand STA, Milestone Scientific Pvt. Ltd., Livingston, USA using a 30 G × 0.5 inch needle on one hand, with the traditional MIT using the traditional dental syringe in restoring primary anterior maxillary teeth on the other hand.

Methods

Ethical considerations

This study was ethically approved by the Institutional Review Board at Beirut Arab University (IRB code: 2016H-0036-D-R-0151) and a consent form was signed by patients' guardians

Study population

This study was designed as a randomized controlled clinical trial in which 64 healthy children (29 boys and 35 girls) aged between 4 and 6 years were equally assigned to either receiving a P-ASA using The Wand STA using a 30 G × 0.5 inch needle or the regular multiple MIT using a traditional syringe. Sample size was calculated using www.sealedenvelope.com, where 58 patients were required to have an 80% chance of detecting an increase in the outcome, at the 5% level of significance, and six more patients were added for more convenience.

Inclusion and exclusion criteria

Children who required restoration with or without pulp treatment on multiple maxillary anterior teeth were included in the study. The teeth were required to be on opposite sides of the midline. An included child had to have a medical history that does not entail any allergies to medications, local anesthesia, mental limitations, previous dental treatment, previous experience with intraoral injections, previous experience of treatment under conscious sedation, or any sort of medication known to alter or modify the child's perception of pain. As part of the inclusion criteria, each child's behavior was assessed using Frankl Behavior Rating Scale, a widely used scale in which the child's reaction to dental procedure is rated on a four-point scale ranging from definitely negative to definitely positive.[11] Only children with positive and definitely positive behavior were included in the study. Participants' guardians were required to sign an informed consent form after receiving detailed explanation about the procedure.

Randomization

The subjects were randomly assigned by an independent dental assistant using a toss of a coin to the two groups of this trial:

- Group A (32 children): Receiving P-ASA block injection using the Wand STA using a 30 G × 0.5 Inch needle
- Group B (32 children): Receiving regular MIT using traditional syringe.

For participants in both groups, the whole procedure was explained to the child in age-suitable lay language. After seating the child on the dental chair, 2% lignocaine with 1:100,000 epinephrine was administered using 0.5 inch 30-gauge needle. This was done after drying the injection site using cotton and applying a topical anesthetic gel for 30 (s). A distraction technique of nose rubbing during injection was employed. For patients in Group A, administration of anesthesia was done according to the manufacture's instruction. A cotton swab was pressed firmly against the typical palatal injection site lateral to the incisive papilla. The needle bevel was placed flat against the palatal mucosa and the flow of anesthetic solution was initiated with the STA mode (1 cc per 207 s) until

one-fourth of cartridge was delivered. After achieving mild anesthesia, the tissue was penetrated with the needle and injection was maintained to allow diffusion of anesthetic solution ahead of the needle tip. When blanching was observed, the needle was further advanced deeper into the nasopalatine canal [Figure 1]. Meanwhile, the injection was sustained using the normal mode (1 cc per 35 s) until the reminder of anesthetic solution in the cartridge was deposited. It is worth noting that, although the standard 1.8-ml cartridges were used with the Wand STA which is similar to the regular handheld syringe, 1.4 ml is, in fact, the maximum amount of local anesthetic solution delivered by the Wand STA with a standard cartridge.[12] This is because 0.2 ml remain unused in the cartridge and microtubing while another 0.2 ml is usually spent through purging of air from the tubing before injection.[12] For patients in Group B, each received multiple maxillary infiltration injections slowly at approximately 1 ml/min using a regular handheld aspirating syringe (Septodont, France). All injections were administrated by one operator to avoid interoperator variability.

Child behavior was assessed objectively during administration of the anesthesia using face, legs, activity, cry, and consolability (FLACC) by a dentist standing at 1.5 m away from the dental chair. The FLACC scale is an objective tool used to quantify and evaluate the pain behaviors of children who are aged between 2 months and 7 years old and characterized by their potential inability to verbally express the presence of pain or accurately report its severity. The FLACC Scale is widely known for its validity and reliability.[13] It encompasses five categories (i.e., FLACC) with each scored on a 0–2 scale resulting in a total score ranging from 0 to 10, with 0 representing the absence of pain.

The Wong–Baker FACES pain rating scale (WBFPRS) is a horizontal subjective scale used to assess self-reported pain of the child. It can be used in children aged 3–17 years. It consists of 6 hand-drawn faces, scored between 0 and 10, and ranging from a smiling "no hurt" face on the far left to a crying "hurts worst" face on the far right.[14,15]

On the other hand, child's self-reported pain was assessed subjectively twice; once immediately after injection and another time after the full treatment procedure using WBFPRS [Figure 2 and Table 1].[13-15]

Statistical analysis

A nonparametric Mann–Whitney U-statistical test was used to measure statistical differences in FLACC and WBFPRS results with the dependent variable being the anesthesia technique used (P-ASA versus MIT). Wilcoxon Signed Ranks test was applied to test for statistical difference in WBFPRS scores between the two different time points of assessment (i.e., right after anesthesia and after full treatment) with regard to the anesthesia technique. Statistical significance was determined as $P \leq 0.05$. Data were statistically analyzed using SPSS version 13.0. The obtained results from the FLACC assessment were reported based on the four pain categories, also known as FLACC behavioral degrees, generally used for the interpretation of the FLACC scores [Table 2]. Similarly, WBFPRS core was presented based on its six ordinal pain categories [Table 2].

Results

The sample included 64 healthy children (29 boys and 35 girls) aged 4–6 years and requiring restoration of primary maxillary anterior teeth with or without pulp treatment. All children were with positive or definitely positive behavioral reactions according to Frankl behavior scale. Cases were divided into two equal groups according to anesthesia technique (P-ASA technique and MIT technique) [Tables 3 and 4].

Results showed that, during anesthesia administration, the majority of children who received anesthesia using P-ASA technique felt mild pain (56.3%). Meanwhile, the majority of children in the MIT group felt moderate pain (81.3%) according to the FLACC assessment [Table 5]. Statistical

Figure 1: P-ASA block injection using STA

Table 1: The Face, Legs, Activity, Cry, Consolability scale

Criteria	Score 0	Score 1	Score 2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
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 asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

analysis revealed a significantly lower pain level experienced in children receiving the P-ASA technique compared to those who underwent the MIT technique.

As for the WBFPRS assessment, the majority of the children who received anesthesia using the P-ASA technique reported that the technique does not hurt (59.4%) directly after injection of anesthesia compared to 62.5% among those of MIT group who reported that it "hurts little more." After treatment completion, the majority of the children reported that there was no hurt regardless of the anesthesia technique used with 65.6% for the P-ASA group and 56.3% for the MIT group. A difference in pain perception in the MIT group was noted between its assessment using WBFPRS directly after the injection and that after treatment completion, where after full treatment, the majority reported that the technique does not hurt (56.3%) compared to "hurts little more" directly after injection (62.5%) [Table 6]. Statistical analysis using Mann-Whitney U-test assessing the differences in WBFPRS scores measured directly after anesthesia administration, and after treatment completion revealed that, among children in the P-ASA group, there is no significant difference in pain scores measured at the two different assessment times (P = 0.464), with a mean rank of 2.0 recorded in both time stages. Among children in the MIT group, a significant difference in FACES scores measured directly after anesthesia and after full treatment was detected where scores after full treatment were significantly lower than those assessed directly after anesthesia injection (P = 0.0001) [Table 7].

Table 2: Studied outcome variables

FLACC	
FLACC score	**FLACC behavioral degree**
0	Relaxed and comfortable
1-3	Mild pain
4-6	Moderate pain
7-10	Severe discomfort or pain or both
WBFPRS	
WBFPRS score	**WBFPRS pain category**
0	No hurt
2	Hurts little bit
4	Hurts little more
6	Hurts even more
8	Hurts hole lot
10	Worst

FLACC: Face, Legs, Activity, Cry, Consolability, WBFPRS: Wong-Baker FACES pain rating scale

Table 3: Randomization of eligible pediatric patients according to anesthesia, stratified by gender

Anesthesia technique	*n* (%)		
	Male	Female	Total
P-ASA technique	15 (46.9)	17 (53.1)	32 (100)
MIT technique	14 (43.8)	18 (56.3)	32 (100)
Total	29 (45.3)	35 (54.7)	64 (100)

P-ASA: Palatal approach anterior superior alveolar block injection, MIT: Maxillary infiltration local anesthetic technique

Discussion

Profound anesthesia is crucial for any successful dental procedure. Painless anesthesia is critical to achieve child cooperation and enhance the trust between the child patient and the dentist. Injection of local anesthesia may be equally stressful to both patients and dentists.[5] Thus, there is a need to explore approaches that aim to provide a pain-free injection while simultaneously achieving the desired level of anesthesia. This need is further underlined by the fact that children who experience psychological suffering due to the use of general anesthesia or conventional traumatic dental care approach often avoid seeking dental care during adulthood.[11]

Dental fear and anxiety can emerge as a result of various reasons including previous experiences of pain and discomfort while seeking dental care which often impacts individuals' behavior toward dental health.[16] Anxiety and fear related to dental anesthesia injections might be due to mechanical trauma as a result of needle insertion, rapid discharge of anesthetic solution, or sudden distension of the oral tissues.[17] Thus, computer-controlled injection delivery devices were introduced to offer constant pressure/volume ratios of an anesthetic agent regardless of tissue resistance variations, enabling an effective and comfortable injection and eliminating the thumb-operated plunger variability of the traditional syringe.

Several studies in literature have compared injections using the Wand to those using the traditional technique through regular syringes to evaluate difference in terms of reaction to pain, reporting pain, and patient behavior.[18] However, data specific to pediatric patients remain scarce. The only existing study so far on the use of P-ASA nerve block in children to anesthetize the primary anterior maxillary teeth

Table 4: Minimum, maximum, average, and standard deviation of children's age (years) according to anesthesia technique

Variable	Anesthesia technique	Number of children	Minimum	Maximum	Average	SD
Age (years)	P-ASA technique	32	4	6	5.1	0.7
	MIT technique	32	4	6	4.9	0.7
	Total	64	4	6	5.0	0.7

P-ASA: Palatal approach anterior superior alveolar block injection, MIT: Maxillary infiltration local anesthetic technique, SD: Standard deviation

was that done by Klein *et al*. in 2005.[12] The study showed that anesthesia with the CompuDent (Second generation Wand) system caused significantly less disruptive behavior during injecting the anesthetic solution than the traditional supraperiosteal injections. Nevertheless, both techniques seemed to provide similar anesthetic quality for the primary maxillary anterior teeth within quarter of an hour from anesthetic solution deposition.

Figure 2: The Wong–Baker FACES pain rating scale

Table 5: Results of Face, Legs, Activity, Cry, Consolability assessment stratified by anesthesia technique used

FLACC behavioral degree	Anesthesia technique	
	P-ASA technique, *n* (%)	MIT technique, *n* (%)
Relaxed and comfortable	8 (25.0)	0
Mild pain	18 (56.3)	6 (18.8)
Moderate pain	6 (18.8)	26 (81.3)
Severe discomfort or pain or both	0	0
Total	32 (100)	32 (100)

P-ASA: Palatal approach anterior superior alveolar block injection, MIT: Maxillary infiltration local anesthetic technique, FLACC: Face, Legs, Activity, Cry, Consolability

In 2008, the third and latest generation, the Wand STA System, Milestone Scientific, Inc., Livingston, NJ, was launched, with the dynamic pressure sensing (DPS) technology. DPS was specifically fabricated for dental applications which added a feature that was not available in the previous second-generation Wand Plus (CompuDent). The instrument allows continuous monitoring of real-time pressure during the whole injection procedure and can minimize the pressure used. Meanwhile, it can detect any loss of pressure due to leakage during the injection.[19]

The present study was performed to assess and compare the effectiveness of a single injection of P-ASA using the described new System; Wand STA to the traditional MIT in restoring multiple maxillary primary anterior teeth in children through assessing pain perception both objectively and subjectively.

Only cooperative children, having "positive" or "definitely positive" behavioral ratings according to Frankl scale[20] were included in this study. As children with negative and definitely negative behavior might report more pain, distress and show more pain associated behavior during local anesthesia injection due to their anxiety.[21]

Extraction procedure was not selected in this study as it is considered to be the most painful procedure for children and require both buccal and palatal infiltration injection where palatal infiltration injection is among the most painful dental injections due to the characteristic of the palatal tissue and is considered by many dentists to be one of the most traumatic techniques used in dentistry[22] and thus will add to the challenge during MIT.

Table 6: Results of Wong-Baker FACES pain rating scale assessment stratified by anesthesia technique used and time of assessment

WBFPRS pain categories	Directly after injection of anesthesia		After full treatment	
	P-ASA technique, *n* (%)	MIT technique *n* (%)	P-ASA technique, *n* (%)	MIT technique, *n* (%)
No hurt	19 (59.4)	0	21 (65.6)	18 (56.3)
Hurts little bit	13 (40.6)	9 (28.1)	10 (31.3)	13 (40.6)
Hurts little more	0	20 (62.5)	1 (3.1)	1 (3.1)
Hurts even more	0	3 (9.4)	0	0
Hurts hole lot	0	0	0	0
Worst	0	0	0	0
Total	32 (100)	32 (100)	32 (100)	32 (100)

WBFPRS: Wong-Baker FACES pain rating scale, P-ASA: Palatal approach anterior superior alveolar block injection, MIT: Maxillary infiltration local anesthetic technique

Table 7: Results of Mann-Whitney U-test

Studied variable	Studied stage	*n*		Mean rank		*U*	*P*	Significant difference?
		P-ASA	MIT	P-ASA	MIT			
WBFPRS scores	After anesthesia	32	32	18.33	46.67	58.5	0.0001	Yes
	After full treatment	32	32	31.05	33.95	465.5	0.464	No

P value<0.05. WBFPRS: Wong-Baker FACES pain rating scale, P-ASA: Palatal approach anterior superior alveolar block injection, MIT: Maxillary infiltration local anesthetic technique, U: Results of Mann-Whitney U-test, *n*: number

Children with previous intraoral injections or any dental experience that might influence the results were excluded from the study. This was done to overcome the influence of patient's expectation, as patients with high pain expectations will significantly perceived dental injection as being more painful than others.[23]

The WBFPRS was utilized for subjective evaluation of pain as it is considered to be a valid, reliable, and simple scale for pain assessment in young children. This was done twice. Once immediately after anesthesia administration to asses self-experience of pain during injection technique and another time after the whole treatment procedure (anesthesia and restoration) to assess the effectiveness of anesthesia and the overall self-experience of pain. This was done to evaluate pain from the child's own point of view.

As child's pain threshold can influence the subjective evaluation of pain, FLACC behavioral pain scale was used during anesthesia administration as an objective method that observes motor reactions to provide more consistent information about the child experience concerning pain since accurate pain assessment in children is more challenging to assess. The FLACC pain assessment tool is based on nonverbal communication that incorporates observing five categories of pain behaviors: facial expression, leg movement, activity, cry, and consolability and changing them into numerical record. Lower numerical score denotes less pain. The FLACC scale is considered a reliable and valid scale that can quantify pain-related behavior, especially in young children who are not able to verbally report their actual pain.[13]

It is worth mentioning that neither the operator nor subjects were blind to the mode of local anesthetic delivery. However, an independent observer was assigned to evaluate patient behavior in an attempt to overcome any bias.

Results of this study indicated that the P-ASA technique using the Wand STA might be a more efficient anesthesia technique than the traditional MIT in pediatric patients. This was highly underlined by the finding that children who received the P-ASA technique were significantly more comfortable than those receiving the MIT in reference to the objective FLACC assessment tool. Even when children self-reported their pain, P-ASA anesthesia technique appeared to be statistically less painful than MIT directly after injection. Allen *et al*.,[24] Ashkenazi *et al*.,[25] and Mittal *et al*.[26] reported similar findings highlighting that the use of computer-controlled local anesthetic delivery injection system (CCLAD) was significantly less likely to cause the child to cry and to exhibit disruptive body movements.

This can be attributed to the fact that P-ASA using the Wand STA as a CCLAD created an improved pressure gradient for the diffusion of solution even with different tissue resistances. This, in turn, maintained an optimal flow rate of anesthetic solution with the pressure variance, while the conventional syringe injection system directly relates the flow rate to the pressure of local anesthesia injected.[27]

Although superior effectiveness of P-ASA perceived after treatment completion was noted, it was not proven statistically in this study. This indicated that the P-ASA anesthesia technique proved to be statistically less painful than MIT directly after injection, yet both techniques were to some extend efficient in reducing self-perceived pain during treatment. This highlights the need for investing additional effort to investigate the effectiveness of P-ASA compared to the traditional MIT after the completion of dental treatment.

Video recording the dental injection procedure and permitting another evaluator to observe it could have further improved the reliability of the results and this could be a limitation of this study. Moreover, heart rate measurement is not subject to observer bias and can be more valid measure that aid to direct observation, since it is a physiological parameter used for objective pain evaluation and can assess pain and anxiety indirectly.

Conclusion

P-ASA can be considered as an excellent alternative to administer deep, fast, effective, and less painful anesthesia of the upper primary anterior teeth and related gingival tissues compared to MIT.

Recommendation

Pediatric dentists should consider the use of P-ASA using STA instead of the multiple MIT technique in restoring multiple anterior teeth in young questionably cooperative children, as it is a more comfortable, single injection technique that eliminate collateral numbness of circumoral tissues

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Conflicts of interest

There are no conflicts of interest.

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