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COMPARISON OF PAIN PERCEPTION FOR NERVE BLOCK AND INFILTRATION INJECTION USING THE CONVENTIONAL METHOD AND COMPUTERIZED CONTROL SYSTEM: RANDOMIZED CONTROL TRIAL

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ABSTRACT

Aim: This clinical study evaluated and compared pain perception of the inferior alveolar nerve block and buccal infiltration techniques in children using Conventional syringe and STA Wand® device.

Material and Method: This clinical research involved 80 children between five and eight years of age, exhibiting positive or definitely positive behavior patterns according to the Frank behavior rating scale (FBRS), who required simple extraction or restoration. Children were randomly divided into two main groups (n=40), Conventional Syringe (control group) and STA Wand® device study group. Then, each main group was subdivided into two equal subgroups (n=20) based on the type of injection techniques buccal infiltration (BI) or inferior alveolar nerve block (IANB). To evaluate pain during administration of Mepivacaine anesthetic solution, children were asked to complete the Wong-Baker FACES Pain Rating Scale (WBFS) and the provider-filled Sound, Eye, and Motor (SEM) scale. Data was collected and statistically analyzed.

Results: There was a statistically significant difference according to the SEM scale between the studied groups (P≤0.05). Sound, Eye & Motor scale, the mean score was statistically significantly higher in the Conventional group as compared to the STA group, for each subscale and total SEM. Additionally, significant differences were observed in WBFS scores among device types (P=0.026). For BI and IANB, no significant differences in pain experiences were found according to the WBFS. However, significant differences (P≤0.05) in SEM pain scores were observed between groups, depending on the injection techniques employed.

Conclusion: STA Wand® computer control device leads to lower pain scores compared to the conventional syringe method.

KEY WORDS: Pine perception, Computer control local anesthesia, STA, CCLAD, children.

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INTRODUCTION

Pain management is essential to dental care, particularly for pediatric patients.[1] The administration of a local anesthetic injection is the primary cause of fear and anxiety in dentistry, particularly among children, due to its association with discomfort and pain. Therefore, the main goal of a dental practitioner is to achieve dental procedures with minor pain and discomfort for the patient.[2]

Noncompliance with dental care is often caused by dental anxiety and fear of local anesthetic administration. Pain related to local anesthetic injection has been linked to mucosal needle penetration and solution injection. So, it is essential to administer local anesthesia in a pain-free manner to reduce stress during dental treatments.[3]

Although many patients can tolerate needle penetration, the pain caused by the injection during administration can be a barrier for others to receive dental injections and necessary treatment during future visits, as it can be painful.[4] Thus, it is important to explore techniques that can alleviate or minimize pain in patients, as this can lead to greater satisfaction with their treatment and prevent patients from avoiding dental treatment.[5,6]

There has been discussion on the effectiveness of several complementary techniques in lowering the pain response, brought on by the delivery of local anesthetic drugs. Topical analgesics, distraction strategies, warming the anesthetic agents, modifying the rate of infiltration, buffering the local anesthetic, and utilizing a slower injection rate are some of these procedures.[7,8]

While traditional syringes remain the predominant method for administering local anesthetics, "computer-controlled local anesthetic delivery systems" (CCLAD) have developed since the mid-1990s. These systems allow for the control of the solution flow rate through the needle. The majority of CCLAD devices have the capability to diminish injection flow and maintain a steady speed, taking into account the anatomical properties of the tissues.[9]

According to most available studies, CCLAD systems appears to provide superior pain control, particularly for palatal injections, compared to the traditional technique.[10,11] "Painless anesthetic devices" are introduced as a variety of devices designed to administer local anesthetic at a controlled and predetermined speed. These devices are categorized as "computer-controlled local anesthetic delivery" (CCLAD) devices.[12]

This study was performed to compare the pain perception experienced during the administration of inferior alveolar nerve block (IANB) and buccal infiltration (BI) anesthesia in children. The comparison includes the use of the conventional method and the Single Tooth Anesthesia (STA) Wand® device.

MATERIALS AND METHODS

This study was performed after gaining approval from the ethical committee of the Faculty of Dentistry, Mansoura University code No**. (A0108023PP).** Also, this study was registered at ***ClinicalTrails.gov*** under registration ID: **NCT06129162.**

The sample size was determined using G*Power 3.1.9.4 software with an α level (significance level) of 0.05 (equivalent to a 95% confidence level), an effect size of 1.44, and a power of 0.95. This configuration leads to a type II error rate (β level) of 0.05, employing a two-tailed significance test and an allocation ratio of 1:1 at the endpoint, based on the findings of a previously published study by Berrendero et al.[13], who compared differences in perceived pain between conventional and computerized anesthesia. The results revealed that 14 children were enough in each group to evaluate the pain perception between the conventional method and the STA Wand® computerized device.

However, this number was increased to 20 children to compensate for any potential bias and to increase the power of results.

Eighty children aged five to eight years were selected from the clinic of the Pediatric Dentistry Department at Mansoura University based on the following inclusion and exclusion criteria: They were healthy children without systemic diseases or anesthetic allergies requiring local anesthesia for simple dental extraction or restoration. Understanding of pain assessment was a prerequisite for cooperative children who scored positive or definitely positive on the Frankel Behavior Rating Scale and whose parents signed a consent form to participate in the study. Children who failed to meet these criteria were excluded from the study.

The eighty children were randomly divided into two main groups (n=40): The conventional Syringe (control group) and the STA device group. The randomization was performed using a computerized randomization website (https://www.graphpad.com/). The participating children were given sequential numbers from 1 to 80 and then randomly assigned to one of the four study subgroups (20 in each) based on the injection technique used—either inferior alveolar nerve block (IANB) or upper buccal infiltration (BI). Each subgroup received a distinct method of administering local anesthesia.

The allocation concealment was ensured by using the sequentially numbered, opaque, sealed envelopes (SNOSE) technique[14], made by an independent person before starting the study. The sequence generation table was kept sealed and secured till the end of the study.

For the blinding of the study, the children were unaware of the approach used to reduce pain from local anesthetic injections (single-blinded study). To uphold blinding, both the conventional syringe and the handpiece of the STA device were kept out of the children's view.

After a complete dental and medical history assessment, the child was advised to sit comfortably in the dental chair. The Tell Show Do (TSD) behavior management technique was used for all children and a straightforward explanation of the process of administering local anesthesia was provided to them.

The local anesthetic components were introduced using the metaphor of a 'sleepy pen,' which included the conventional syringe barrel and the disposable handpiece of the STA device. The child was allowed to touch the used piece to gain confidence. The 'sleepy juice', referring to the anesthetic solution, was described as the substance that would make the tooth go to sleep.

After introducing the used method, each child was informed what he/she might experience a minor sensation of a prick or pressure-like feeling. This was demonstrated in a friendly manner by touching the palm of the child's hand during the explanation. Then anesthetic solution was administered according to the type of injection technique.

For Buccal Infiltration Sub-Groups; the child was positioned in a supine posture, and the cheek was gently pulled sideways to create space in the muco-buccal fold while keeping the mucosa firm. Then, a sterile gauze was used to dry the tissue, and a small amount of topical anesthetic gel (DMG America, Englewood, NJ, USA) was applied to the injection site for at least one minute. The anesthetic syringe was positioned below the child's line of sight and placed into the mouth, holding it in a manner that positioned the needle bevel towards the bone.[15]

Subsequently, the needle was inserted parallel to the long axis of the tooth, reaching the height of the muco-buccal fold over the target tooth. It was advanced a few millimetres until the bevel of the needle was at or above the apical region of the tooth.[15] Then aspiration was performed and at that stage, the mepivacaine hydrochloride with epinephrine 1:100,000 anesthetic solution was administered gradually.

For Inferior Alveolar Nerve Block Sub-Groups; in the same supine or semi-supine position, the child was directed to widen his/her mouth and open it as wide as possible. Then, a sterile gauze was used to dry the tissue, and a small amount of the same topical anesthetic gel was applied to the injection site for at least one minute. Meanwhile, the operator positioned the ball of his thumb on the coronoid notch of the anterior border of the ramus to pull the tissues, ensuring they remained taut. The rest of the fingers were placed on the posterior border of the ramus.[15]

The syringe barrel and the handpieces of the STA device are positioned, away from the child's sight, over the two primary mandibular molars on the opposite side of the arch, aligned parallel to the occlusal surface. The needle tip is inserted below the occlusal plane, between the internal oblique ridge and the pterygomandibular raphe. Aspiration was performed before administration of mepivacaine.[16] Then, mepivacaine hydrochloride with epinephrine 1:100,000 anesthetic solution was administered according to the equipment used.

For the Conventional group, the IANB injection was performed using a 27-gauge needle, while the BI injection was performed using a 30-gauge needle. On the other hand, in the STA Device Group, the IANB injection was performed using a disposable handpiece (1.25 inch 27 gauge), while the BI injection was performed using a disposable handpiece (1 inch 30 gauge).

The pain perception in all groups was evaluated using a subjective Wong-Baker FACES pain rating scale **(WBFS)**, and an objective Sound, eye, and motor **(SEM)** scale. Both were used to measure pain felt during the administration of anesthesia. The Wong-Baker FACES Pain Rating scale (Figure 1) consists of six cartoon faces depicting varying facial expressions, ranging from very happy face to very sad one. The child was briefly explained about each face, before the procedure started, and then asked to select the face that best described their feelings during the administration of local anesthesia after finishing it.

The second scale is the SEM scale, employed as an objective method for pain assessment, where the patient's sound, eye, and motor responses are observed. These responses are categorized on a scale ranging from 0-3 categories comfort, mild discomfort, moderately painful, and painful (Table 1). The administration of local anesthesia was documented by video recording to be assessed by two different trained examiners (not including the principal investigator) using the SEM scale.

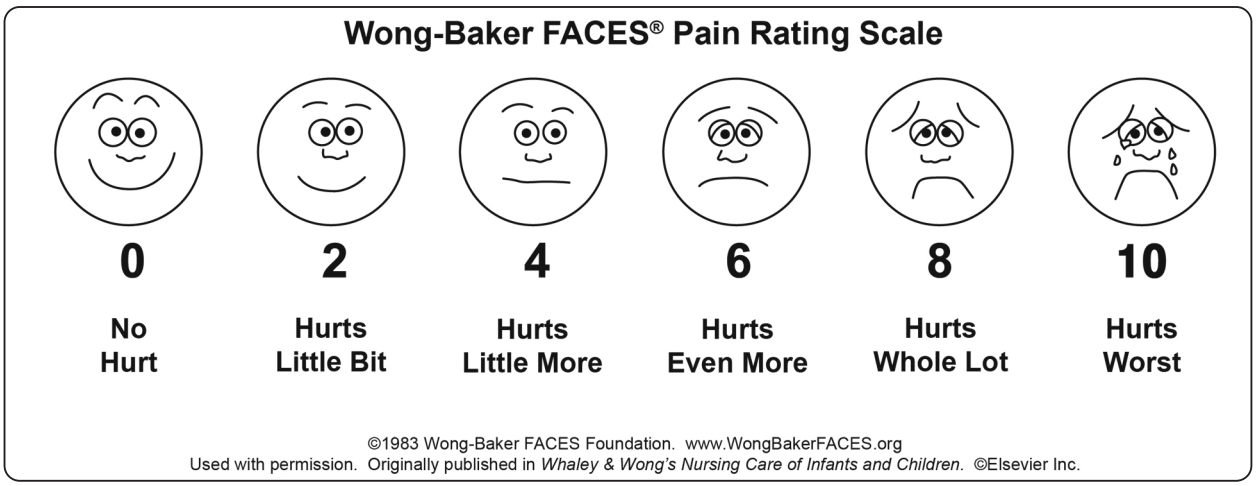

Fig. (1) The Wong-Baker FACES Pain Rating scale.

TABLE (1) Sound, Eyes and Motor (SEM) Scores:

Score	Designation	sounds	Eyes	motor
0	Comfort	No sounds indicating pain	No eye signs of discomfort	Hands relaxed, no apparent body tenseness
1	Mild discomfort	Nonspecific possible pain indication	Eyes wide show of concern, no tears	Hands show some tension
2	Moderately painful	Specific verbal complaint	Watery eyes	Random movement of arms/ body grimace, twitch
3	Painful	Verbal complaint indicates intense pain	Crying, tears running down the face	Movement of hands to make aggressive physical contact, pulling head away punching

This was to enhance the consistency and accuracy of pain assessment.

Statistical analysis:

Data were analyzed using the Statistical Package of Social Science (SPSS) program for Windows (Standard version 24). The normality of data was first tested with one-sample Kolmogorov-Smirnov test.

Qualitative data were described using numbers and percentages. Association between categorical variables was tested using the Chi-square test while the Fischer exact test was used when the expected cell counts less than 5. Continuous variables were presented as median (Min-Max) for non-normally distributed data. The two groups were compared by Mann Whitney test. Spearman correlation was used to correlate continuous data.

For all above mentioned statistical tests done, the threshold of significance is fixed at 5% level (p-value). The results were considered significant when the $p \leq 0.05$. The smaller the p-value obtained, the more significant are the results.

RESULTS

As shown in (Table 2), children who reported negative experiences (Hurt worst) were significantly higher in the Conventional group, accounted for 15% as compared to 0% in the STA group, p-value ≤ 0.05. There is no statistically significant difference regarding experiences (No hurt, Hurt, Hurt little more and Hurt even more) among the studied groups. Experiences (No Hurt) were reported in 57.5% of the STA group and 37.5% in the Conventional group. Negative experiences (Hurt little more and Hurt even more) were reported in 15%, and 5% in Conventional group while 5% & 0% in STA group, respectively.

For the conventional technique, the most common experience was (No Hurt) with a percentage of 37.5% followed by (Hurt) with a percentage of 27.5% and (Hurt little more and Hurt worst) with a percentage of 15% for each. Only 2 children experienced (Hurt even more) with a percentage of 5.0%. For the STA group, the most common experience was (No Hurt) with a percentage of 57.5% followed by (Hurt) with a percentage of 37.5% and only 2 children experienced (Hurt little more) with a percentage of 5.0%. No children experienced other negative scores.

Among the BI technique subgroups, there is no statistically significant difference regarding experiences (No hurt, Hurt, Hurt little more, Hurt even more, and Hurt worst). For the conventional technique group, the most common experience was (Hurt)with a percentage of 40% followed by (No Hurt) with a percentage of 25% and 10% for both (Hurt little more and Hurt even more).

Three children experienced (Hurt worst) with a percentage of 15.0%, as shown in (Table 3).

For the STA group, the most common experience was (No Hurt) with a percentage of 50% followed by (Hurt)with a percentage of 40% and only 2 children experienced (Hurt little more) with a percentage of 10%. No children experienced other negative scores.

Also, among IANB subgroups, there is no statistically significant difference regarding experiences (No hurt, Hurt, Hurt little more, Hurt even more and Hurt worst). For the conventional technique, the most common experience was (No Hurt) with a percentage of 50% followed by (Hurt little more) with a percentage of 20% and 15% for both (Hurt and Hurt worst). No children experienced Hurt even more.

For the STA group, the most common experience was (No Hurt) with a percentage of 65% followed by (Hurt) with a percentage of 35%. No children experienced other negative scores, as shown in (Table 4).

TABLE (2) Comparison of pain score based on Wong-Baker scale between the studied main groups.

WBFS	Conventional (n=40)(%)	STA (n=40) (%)	Test of significance	p value
No hurt	15 (37.5%)	23 (57.5%)	χ^2 =3.21	0.073
Hurt	11 (27.5%)	15 (37.5%)	χ^2 =0.912	0.340
Hurt little more	6 (15.0%)	2 (5.0%)	FET	0.263
Hurt even more	2 (5.0%)	0 (0%)	FET	0.494
Hurt worst	6 (15.0%)	0 (0%)	FET	0.026*

χ^2: Chi-square test, FET: Fisher exact test,*significant p≤0.05

TABLE (3) Comparison of pain score based on Wong-Baker scale among BI subgroups.

WBFS (BI)	Conventional (n=20) (%)	STA (n=20) (%)	Test of significance	p value
No hurt	5 (25.0%)	10 (50.0%)	2.67	0.102
Hurt	8 (40.0%)	8 (40.0 %)	0.0	1.0
Hurt little more	2 (10.0 %)	2 (10.0%)	FET	1.0
Hurt even more	2 (10.0%)	0 (0%)	FET	0.487
Hurt worst	3 (15.0%)	0 (0%)	FET	0.231

FET: Fisher exact test

TABLE (4) Comparison of pain score based on Wong-Baker scale among IANB subgroups.

WBFS (IANB)	Conventional (n=20) (%)	STA (n=20) (%)	Test of significance	p value
No hurt	10 (50.0%)	13 (65.0%)	χ^2 =0.921	0.337
Hurt	3 (15.0 %)	7 (35.0%)	2.13	0.144
Hurt little more	4 (20.0 %)	0 (0%)	FET	0.106
Hurt even more	0 (0%)	0 (0%)	-	-
Hurt worst	3 (15.0%)	0 (0%)	FET	0.231

χ^2: Chi-square test, FET: Fisher exact test

According to the SEM scale, there was a statistically significant difference between the main studied groups (P≤0.05) as shown in (Table 5). In the sound, eye & motor scale, mean score was statistically significantly higher in the Conventional group as compared to the STA group, for each subscale and total SEM.

There was a statistically significant difference according to sound, eye and total SEM score among buccal infiltration technique subgroups (P≤0.05) as shown in Table (6). Mean sound, eye and total SEM score was statistically significantly higher in Conventional group as compared to STA group, while no difference was observed regarding the Motor subscale.

For IANB subgroups, there was a statistically significant difference according to the SEM scale (P≤0.05). In the sound, eye & motor scale, mean score was statistically significantly higher in Conventional group as compared to STA group, for each subscale and total SEM as shown in Table (7).

TABLE (5) Comparison of Sound, eye and motor scale among the studied main groups

	Conventional (n=40)	STA (n=40)	Test of significance	P value
Sound				
Mean ± SD	0.98±1.29	0.10±0.30	Z=3.39	**0.001***
Median (Min-Max)	0 (0-3)	0 (0-1)		
Eye				
Mean ± SD	1.45±1.11	0.35±0.48	Z=4.82	**≤0.001***
Median (Min-Max)	1 (0- 3)	0 (0- 1)		
Motor				
Mean ± SD	1.23±1.05	0.55±0.50	Z=2.95	**0.003***
Median (Min-Max)	1 (0- 3)	1 (0- 1)		
SEM				
Mean ± SD	3.65±3.21	1.00±1.06	Z=3.90	**≤0.001***
Median (Min-Max)	2 (0- 9)	1 (0- 3)		

Z: Mann Whitney test, *significant p≤0.05

TABLE (6) Comparison of Sound, eye and motor scale among BI technique subgroups.

SEM (BI)	Conventional (n=20)	STA (n=20)	Test of significance	P value
Sound				
Mean ± SD	1.10±1.33	0.15±0.36	Z=2.41	**0.016***
Median (Min-Max)	0 (0-3)	0 (0-1)		
Eye				
Mean ± SD	1.55±1.14	0.45±0.51	Z=3.18	**0.001***
Median (Min-Max)	1 (0- 3)	0 (0- 1)		
Motor				
Mean ± SD	1.25±1.11	0.60±0.50	Z=1.84	0.065
Median (Min-Max)	1 (0- 3)	1 (0- 1)		
SEM				
Mean ± SD	3.90±3.43	1.20±1.15	Z=2.38	**0.017***
Median (Min-Max)	2 (0- 9)	1 (0- 3)		

Z: Mann Whitney test, *significant p≤0.05

TABLE (7) Comparison of sound, eye and motor scale among IANB subgroups.

SEM (IANB)	Conventional (n=20)	STA (n=20)	Test of significance	P value
Sound				
Mean ± SD	0.85±1.26	0.05±0.22	Z=2.44	**0.015***
Median (Min-Max)	0 (0-3)	0 (0-1)		
Eye				
Mean ± SD	1.35±1.08	0.25±0.44	Z=3.69	**≤0.001***
Median (Min-Max)	1 (0- 3)	0 (0- 1)		
Motor				
Mean ± SD	1.20±1.00	0.50±0.51	Z=2.32	**0.02***
Median (Min-Max)	1 (0- 3)	0.50 (0- 1)		
SEM				
Mean ± SD	3.40±3.05	0.80±0.95	Z=3.13	**0.002***
Median (Min-Max)	2 (0- 9)	0.50 (0- 3)		

Z: Mann Whitney test, *significant p≤0.05

DISCUSSION

The administration of local anesthesia is one of the most distressing dental procedures for children. The pain associated with dental injections can trigger fear and anxiety, negatively impacting the child's overall dental experience. This can potentially lead to appointment avoidance or even cancellation.[17]

Given the need to find less painful methods of anesthesia, various approaches have been explored to reduce discomfort during dental injections. In this pursuit, a computerized local anesthetic delivery system has been introduced to reduce or virtually eliminate the pain associated with dental injections. This system delivers the anesthetic at a constant slow rate and controlled pressure, regardless of tissue resistance.[18]

Also, this computerized system decreases pain perception, increased patient comfort, improves efficiency and improve children's cooperation and alleviate their anxiety during the anesthetic procedure. These benefits ultimately enhance the overall experience for children. Additionally, the incorporation of safety features and streamlined processes contributes to better treatment outcomes and positive oral health experiences.[8]

This study compared and assessed the effectiveness of the STA device against the conventional syringe method, during the administration of anesthesia using the inferior alveolar nerve blocks and buccal infiltration injections techniques, in children aged five to eight years old of both genders.

The inclusion of children in this age range is consistent with a previous trial conducted by **Smolarek et al.** in which their cognitive abilities are compatible with their chronological age and are in a crucial developmental stage where they are more capable of expressing their pain experiences and understanding instructions provided by healthcare providers.[19]

The children were chosen based on the criteria of **Badr and Bacho** [20], **Mittal et al.**[21] and **Yılmaz et al.**[22] , and exhibiting positive or definitely positive behaviors according to the Frankl scale. On the other hand, the children displaying negative or definitely negative behaviors were excluded from the study. Because the children are more apprehensive, which can affect the accuracy of the pain scores.[23]

Regarding the CCLAD used in the study, the STA device is one of the most popular devices in the market.[24] It automatically controls and regulates flow rates and pressure during the injection by "Dynamic Pressure Sensing Technology". This dynamic pressure sensing monitors the exit pressure of the anesthetic for the optimal needle position during the administration process. Visual and audible feedback from the unit aids in identifying the correct location for injection.

Mepivacaine hydrochloride with epinephrine 1:100,000 was selected based on the findings of a meta-analysis conducted by **Su et al.**[25] and the guidelines provided by the American Academy of Pediatric Dentistry (AAPD) in 2023 to ensure safety and effectiveness for pediatric patients.

In this study, pain perception was assessed using two separate scales: the Sound, Eye, and Motor (SEM) scale, which is a behavioral or objective measure, and the Wong-Baker Face Pain Scale (WBFS), which is a self-report or subjective measure. The WBFS is specifically designed for children aged three and above, providing a valuable tool for describing their pain experiences.[26]

Additionally, this scale allows children to express their pain evaluation without relying on verbal communication.[27] The decision to use the Wong-Baker FACES scale for pain assessment during anesthesia was based on multiple studies[28–30], particularly in children, supporting its reliability.

Given the subjective nature of pain perception and the individual variability in patient responses to painful stimuli, there is a need for additional assessment scales to effectively observe and evaluate changes in patient behavior during treatment. These scales can include observations of facial expressions, crying, complaints, and body movements. Incorporating such scales is crucial in enhancing pain evaluation methods and ensuring a comprehensive understanding of patients' pain experiences.[31]

For that, the Sound, Eye and Motor (SEM) behavioral scale was selected based on **Mittal et al.**[21]**, Helmy et al.**[32] and **Abou Chedid et al.**[33] studies. In order to enhance the reliability of the pain assessment and avoid potential biases associated with the SEM scale, the administration of local anesthesia was recorded via videos. Subsequently, two independent examiners carefully reviewed the assigned scores. This process aimed to improve the consistency and accuracy of the evaluations.

The result of this study revealed that pain scores of WBFS and SEM with STA during anesthesia was lower compared to the conventional needle method. These findings highlight the beneficial effect of CCLAD on pain perception and indicate their efficacy in improving child comfort and satisfaction. This result comes in accordance with that of **Jälevik** and **Klingberg**[34], **Perugia et al.**[35], **Deepak et al.**[36] as well as **Dempsy Chengappa and Prashanth**[30].

In contrast, multiple studies indicated that there is no substantial difference in pain reduction when comparing the use of the CCLAD system to the conventional syringe for administering anesthetic solutions, as observed in the research conducted by **Queiroz et al.**[37] due to differences in age group, and by **El Hachem et al.**[29] due to the employment of a split-mouth design, which may influence the outcome negatively.

The WBFS results within BI technique did not yield any significant difference in pain scores among the two groups, and this comes in agreement with results of **Chavhan et al.**[38], but with a difference in the self-reported scale used. However, these results disagreed with that of **Garret-Bernardin et al.**[10] which may be attributed to differences in the age of children between this study and Garret-Bernardin et al. study.

Also, the results of WBFS within IANB techniques did not yield any significant difference in pain perception among the study groups, and this result was consistent with that of **Ram & Peretz**[39] and **Bataineh and Alwarafi**.[40] These findings

suggest that the implementation of these techniques did not impact the perception of pain during anesthesia administration, as measured by WBFS.

In contrast to WBFS, the results of the SEM pain scale suggested that using the STA device for BI during local anesthesia administration significantly reduced SEM pain scores compared to the conventional method, indicating improved comfort and reduced pain experienced by pediatric patients. These results come in agreement with those of **Feda et al.**[41] and **Mittal et al.**[21].

Additionally, the results of the SEM scale for the STA device while utilizing the IANB technique demonstrated superior pain management compared to the conventional method, specifically in the Sound, Eye and overall SEM categories, which came in consistent with the results of **Anil and Keskin**.[42] However, in the Motor category, although there was a slightly improved in pain scores with the STA device, the difference was not statistically significant.

In terms of the order of effectiveness among the two methods (Conventional and STA device), significant differences were observed between the traditional method and STA device WBFS and the total SEM scores across the two groups.

LIMITATIONS

Due to the complexity of pain, which includes sensory, affective, and cognitive aspects, using only self-assessment and behavioral scales may not capture all dimensions of pain. The STA device raises issues regarding the anesthetic solution wasted in the single-use handpiece tube and the expense of the subsequent consumables.

CONCLUSION

Based on the findings of the present study, it could be concluded that the utilization of computer-controlled local anesthetic delivery (STA device), leads to lower pain scores compared to the conventional syringe method.

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