Comparison of Patient Comfort During the First Stage of Conventional Versus Modified Two-Stage Inferior Alveolar Nerve Blocks in Pediatric Patients

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Our aim was to compare the comfort of pediatric patients during the first stage of the conventional 2-stage inferior alveolar nerve block (IANB) versus the modified 2-stage IANB. This was a parallel group, single-blinded, randomized controlled trial. Pediatric patients meeting the inclusion criteria were randomly allocated to 1 of the 2 groups receiving IANB, group 1 (31 subjects) utilized a conventional 2-stage technique, and group 2 (33 subjects) utilized a modified 2-stage approach. Patient comfort was assessed indirectly by 2 observers using the Face, Legs, Activity, Cry, Consolability (FLACC) scale during the first stage of the injections. FLACC score data between the 2 groups were analyzed using the chi-square test, and interobserver reliability was measured using kappa statistics. During the first stage of the injections, lower FLACC scores of 0 indicating a relaxed/comfortable patient experience were found in 57.6% of group 2 subjects compared with only 25.8% group 1 subjects, which was a statistically significant difference (p -value .013). Interobserver reliability assessed using kappa coefficients ($\kappa = 0.812$) indicated excellent agreement. FLACC scores for the pediatric patients during the first stage of the modified 2-stage IANB technique were significantly lower than during the first stage of the conventional 2-stage IANB technique.

Key Words: Local anesthesia; Children; Pain; Injections; Two-stage technique; Inferior alveolar nerve block.

Administration of local anesthesia in pediatric patients is often a challenging procedure. This is especially true with the inferior alveolar nerve block (IANB). The IANB is the most frequent technique used to obtain local anesthesia in both mandibular primary and permanent dentition.¹ But, it has been associated with pain and discomfort.^{2,3} An unpleasant experience can negatively impact children's behavior for subsequent dental visits and treatment.⁴ Various strategies have previously been used to help minimize discomfort associated with the administration of local anesthetic, such as the application of topical anesthetics, warming of the injectable anesthetic solution, decreasing the rate of anesthetic injection, reducing the needle diameter,

and use of a computerized local anesthesia delivery system.^{2,3,5,6} But these strategies have not helped children completely cope with the pain related to injections.^{2,6,7,8}

The conventional 2-stage injection technique has been suggested by various authors to decrease the pain of the local anesthetic.^{3,9} With this approach, the local anesthetic solution is administered in 2 separate stages. The first stage involves initial deposition of the solution just under the mucosal surface to obtain regional anesthesia. In the second stage, which is performed several minutes later, the remaining local anesthetic solution is deposited at the target site. This technique of injecting in 2 stages helps the clinician make a more painless needle entry into the preanesthetized submucosa. Thus, the 2-stage technique can be considered as a practical alternative to all conventional intraoral injections, including the IANB.^{3,9}

The drawback of the 2-stage technique, especially in children, is its deficiency to address the pain associated with needle insertion and initial deposition of the local

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anesthetic solution in the “first stage” of the injection. A modified 2-stage technique was proposed to address this shortcoming.^{10,11} In this modified technique, a disposable U 40 insulin syringe with an ultrashort 30-gauge needle was used in the first stage to reduce the pain associated with needle penetration and local anesthetic deposition.^{10,11} The present study compared the comfort levels of pediatric patients during the first stage of the conventional and modified 2-stage IANB techniques.

The null hypothesis was “there is no significant difference in the pain reaction during the first stage of the modified 2-stage IANB technique compared with the first stage of the conventional 2-stage IANB technique.”

METHODS

The study was a parallel group, single-blinded (patient), randomized controlled trial conducted in the Department of Paedodontics and Preventive Dentistry, Manipal College of Dental Sciences, Mangalore, Manipal Academy of Higher Education, Manipal, after obtaining ethical clearance from the institutional ethics committee. Parents of the patients were informed about the study using a patient information sheet, following which their informed consent to participate was obtained.

Inclusion and Exclusion Criteria

Pediatric patients between 6 and 10 years of age in whom an IANB was indicated for any dental procedure were included in the study. The subjects selected for inclusion in this study all had no previous experiences receiving an intraoral local anesthetic injection. Exclusion criteria for this study were patients exhibiting uncooperative behavior (Frankel's Scale 1 and 2), existing orofacial edema, infection, or abscess, systemic comorbidities requiring special dental treatment considerations, the use of any central nervous system depressants or any analgesic medications within 8 hours prior to treatment, or any report of severe dental pain.⁹

Sample Size and the Study Groups

An a priori power analysis was performed utilizing the results of Wong-Baker FACES® Pain Rating Scale (FPS) scores for IANB blocks as per the previous study by Sandeep et al⁹ to establish the effect size. The study demonstrated the mean difference between the conventional and the 2-stage technique as 1.3 FPS units (4.4 for conventional and 3.1 for the 2-stage technique, with a

standard deviation of 0.8 and 1.1 FPS units, respectively). With an average standard deviation of 0.95, an alpha error of 5% and power of 80%, using a clinically relevant difference of 0.9 FPS units, a calculated sample size of 54 subjects total, 28 subjects per group, was determined.

A total of 64 pediatric patients meeting the inclusion criteria were randomly assigned to 1 of the 2 study groups. The control group, group 1, utilized a conventional 2-stage IANB technique and had 31 subjects. The experimental group, group 2, utilized a modified 2-stage IANB technique and had 33 subjects. Assignment was performed by a person not otherwise involved in the study with the use of a computer-generated table of random numbers. Group allocation was concealed with the use of sealed envelopes, which were opened just before the commencement of the procedure.

Procedure

The recommended injection protocol for use with pediatric patients was followed for both groups. This included basic behavior management techniques such as euphemisms, tell-show-do, positive verbal reinforcement, and distraction.¹² The patient's buccal mucosa was dried with gauze and a flavored topical anesthetic (Precaine® topical anesthetic gel, Pascal International, Inc, Bellevue, WA) was applied to the area of needle insertion for 5 minutes using disposable sterilized cotton swabs. The local anesthetic solution used was 2% lidocaine with 1:200,000 epinephrine (Xylocaine® 2% with 1:200,000 epinephrine; AstraZeneca Pharma India Ltd, India). All injections administered in the study were performed by a single operator.

Conventional Two-Stage IANB Technique.^{3,9} A 2-mL disposable syringe with a 26-gauge $\times$ 1½ inch needle (Unolok, Hindustan Syringes and Medical Devices Ltd, India) was used. In the first stage, the needle was inserted slowly to a depth of 2 mm, and a drop of the local anesthetic solution was deposited. After 2 to 3 seconds, the needle was advanced further into the mucosa and another drop of anesthetic solution was deposited. This cycle of injecting small amounts of the anesthetic solution was continued until approximately 6 mm of the needle had been inserted into the mucosa, after which 0.3 mL of additional local anesthetic was injected gently after confirmation of negative aspiration. The first stage of the injection was completed in 60 seconds, and the total volume of anesthetic solution deposited at this stage was 0.5 mL. The needle was withdrawn, and the patient was observed for 5 minutes. After that observation period, the second stage began. The same

Table 1. Face, Legs, Activity, Cry, Consolability (FLACC) Scale^{9*}

Categories	Score 0	Score 1	Score 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	Arched, rigid or jerking
Cry	No cry	Moans/whimpers	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

* Interpretation: Scores were summed and categorized as follows: 0 = relaxed/comfortable; 1–3 = mild discomfort; 4–6 = moderate pain; 7–10 = severe discomfort/pain/both.

needle and syringe was reinserted and advanced toward the target site until the needle contacted the medial aspect of the mandibular ramus. An additional volume of 1 mL of local anesthetic solution was deposited over 1 minute after confirming negative aspiration during the second stage. The total volume of local anesthetic administered using the conventional 2-stage IANB technique was 1.5 mL.

Modified 2-Stage IANB Technique.^{10,11} Two different syringe/needle combinations were used in this technique. A 1-mL insulin syringe with a 30-gauge, ultrashort 8-mm needle (U-40 insulin syringe, Dispo van, Hindustan Syringes and Medical Devices Ltd, India) was used in the first stage. A conventional 2-mL disposable syringe with a 26-gauge $\times$ 1½ inch needle (Unolok, Hindustan Syringes and Medical Devices Ltd) was used for the second stage. In the first stage, the needle was positioned in contact with the mucosa, with the syringe positioned on the same side as the site of needle insertion. The buccal mucosa was then stretched over the needle so that approximately 2 mm of the needle was inserted into the mucosa. Approximately 0.5 units (the insulin syringe has 40 units per 1 mL) of the anesthetic solution was deposited. After 2 to 3 seconds, the needle was advanced further into the mucosa and another 0.5 units of local anesthetic was deposited. This cycle of injecting small amounts of the anesthetic solution was continued until approximately the entire length (almost 6 mm) of the ultrashort needle had been inserted into the mucosa, after which the remaining local anesthetic was deposited slowly following confirmation of negative aspiration. The time taken for the first stage of the injection was about 60 seconds, and the total volume of anesthetic solution deposited at this stage was 0.5 mL. The needle was withdrawn, and the patient observed for 5 minutes. After that observation period, the second stage began. An additional 1 mL of local anesthetic solution was deposited, using the 26 gauge/2 mL disposable needle/syringe combination, via the same approach discussed

previously for the second stage of the conventional 2-stage IANB technique. The total volume of local anesthetic administered using the modified 2-stage IANB technique was 1.5 mL.

Two observers (para clinical personnel), who were not otherwise involved in the study, objectively evaluated the reaction of subjects in groups A and B during the first stage of the injections using the Face, Legs, Activity, Cry, Consolability (FLACC) scale (Table 1).¹³ The observers were previously calibrated with the FLACC assessment. The observers stood outside the direct vision of the subjects but were close enough to enable accurate observations. The interobserver reliability was calculated to assess the consistency in the FLACC scoring assessments.

Statistical Analysis

IBM SPSS 20.0 software was used for statistical analysis. Assessment of the correlation between age or gender with the FLACC scores during the first stage injections between the 2 groups was done using the chi-square test. Intergroup and interobserver comparisons were assessed using the chi-square test and kappa statistics, respectively.

RESULTS

Tables 2 and 3 demonstrate the composition and comparison of the 2 study groups with respect to study subject age and gender. The chi-square tests showed no significant statistical differences between groups 1 and 2 with respect to age or gender (p -value of .112 and .451, respectively for age and gender).

Table 4 shows the cross tabulations assessing the FLACC scores during the first stage injections between the control (group 1) and the experimental (group 2)

Table 2. Group—Age Cross Tabulation*

Age	Study Group		Total
	Group 1	Group 2	
6			
Count	8	6	14
% within group	25.8%	18.2%	21.9%
7			
Count	4	9	13
% within group	12.9%	27.3%	20.3%
8			
Count	3	9	12
% within group	9.7%	27.3%	18.8%
9			
Count	8	6	14
% within group	25.8%	18.2%	21.9%
10			
Count	8	3	11
% within group	25.8%	9.1%	17.2%
Total			
Count	31	33	64
% within group	100.0%	100.0%	100.0%

* Chi-square value of 7.500 and *p*-value of .112.

groups using the chi-square test. In group 1, 8 subjects (25.8%) received a FLACC score of 0 (relaxed/comfortable) and 23 children (74.2%) received a FLACC score of 1 to 3 (mild discomfort). In group 2, 19 subjects (57.6%) received a FLACC score of 0 (relaxed/comfortable) and 14 subjects (42.4%) received a FLACC score of 1 to 3 (mild discomfort) during the injections (the Figure). The difference between groups 1 and 2 was statistically significant (*p*-value .013). For both groups 1 and 2, 100% of the subjects received FLACC score totals indicating either relaxed/comfortable or mild discomfort during the local anesthetic injections.

The scores given by both observers were compared using kappa statistics to assess interobserver reliability. Out of the 64 children who were evaluated, there was agreement on the scoring in 58 of the cases (90.6%) with a kappa coefficient of 0.812 indicating excellent agreement between FLACC scoring observers.

DISCUSSION

Fear of dental injections is undoubtedly ranked the highest among the hierarchy of quoted reasons for which pediatric patients avoid dentistry. Thus, a comfortable or painless intraoral local anesthetic injection experience may help reduce dental fear and anxiety, which can significantly help improve a pediatric patient's behavior in the dental operatory.¹⁴

According to the study conducted by Sandeep et al⁹ comparing conventional 1-stage and 2-stage injection

Table 3. Group—Gender Cross Tabulation*

Sex	Study Group		Total
	Group 1	Group 2	
Male			
Count	16	13	29
% within group	51.6%	39.4%	45.3%
Female			
Count	15	20	35
% within group	48.4%	68.6%	54.7%
Total			
Count	31	33	64
% within group	100.0%	100.0%	100.0%

* Chi-square value of 0.963 and *p*-value of .451.

techniques, the 2-stage technique significantly reduced the pain of injection in children. Another study by Rao et al¹⁰ compared the 1-stage IANB technique with the same modified 2-stage IANB technique utilized in this study, which concluded that the modified 2-stage IANB technique was less painful and better received by children. However, the study made the comparison with the conventional single stage IANB. This study is a direct comparison between the first stages of the conventional 2-stage and the modified 2-stage techniques when utilized in pediatric patients.

The FLACC scale was used in this study because of its objective evaluation parameters and excellent validity and reliability of pain assessment in young children.¹³ The parallel study design was selected to overcome potential bias that may arise with a crossover study design in local anesthetic trials involving pediatric patients. In a crossover design, an unpleasant first injection experience could cause objective fear leading to false-negative results during the second injection.

In the present study, lower FLACC scores indicating increased patient comfort during local anesthetic delivery were associated with the use of the modified 2-step IANB technique. One potential factor may be the difference in equipment used, as the design of an

Table 4. Group—Face, Legs, Activity, Cry, Consolability (FLACC) Score Cross Tabulation*

FLACC Score	Study Group		Total
	Group 1	Group 2	
0 (Relaxed/comfortable)			
Count	8	19	27
% within group	25.8%	57.6%	42.2%
1–3 (Mild discomfort)			
Count	23	14	37
% within group	74.2%	42.4%	57.8%
Total			
Count	31	33	64
% within group	100.0%	100.0%	100.0%

* Chi-square value of 6.615 and *p*-value of .013.

Comparison of Face, Legs, Activity, Cry, Consolability (FLACC) scores for groups 1 and 2 (p -value .013).

injection device has been found to contribute to the pain perception.¹⁵ In this context the insulin syringe with an ultrashort needle may appear less intimidating to pediatric patients compared with the conventional syringe design. Furthermore, according to Rao et al,¹⁰ the reduced pain reaction during needle insertion and deposition is related to the inherent properties of the insulin syringe, such as its ultrashort 8-mm needle length as well as the smaller diameter of the barrel and the plunger.¹¹ The curvature or deviation of the needles due to the resistance of tissues during insertion is termed needle deflection.¹⁶ The ultrashort length can potentially cause less needle deflection and consequently less tissue injury during the injection process thus contributing to increased patient comfort. The smaller barrel and plunger enable the delivery of very small volumes of anesthetic solution resulting in less expansion of soft tissue. According to Quaba et al,¹⁷ the rapid expansion of subcutaneous tissue resulting from large volumes of local anesthetic deposition can lead to increased discomfort.

An additional factor that can significantly affect patient comfort during the injection of local anesthetic is the speed at which the solution is administered. For both groups in this study, during the first stage very small volumes of local anesthetic were deposited in slow increments, and during the second stage local anesthetic

was deposited slowly over 60 seconds. This principle of reducing injection discomfort by controlling the injection speed is also being incorporated into more recent technologies like computer-controlled local anesthetic delivery systems.^{18,19} A study by Kanaa et al,²⁰ which evaluated the effect of injection speed on patient comfort during an IANB injection, showed that a slower injection rate was more comfortable to patients and increased local anesthetic efficacy.

There were several areas of weakness in the design of this study that warrant discussion. First, this was a single-blinded study, so operator may have unknowingly contributed to the difference in results between the 2 groups. Another potential confounding factor was related to the positioning of the syringe. In the first stage of the modified technique used for group 2, the barrel of the insulin syringe was located on the same side as the site of injection. This could have also contributed to the positive results noted for group 2. The authors theorize that the lack of interference from the tongue pushing against the barrel of the syringe, which can be a common occurrence in pediatric patients receiving a traditional IANB injection, may give more control to the operator during the initial mucosal penetration and solution deposition.¹¹ The influence of this factor should be further evaluated. Future studies could evaluate this by comparing the first stage of the modified 2-stage

technique with the IANB technique proposed by Boonsiriseth et al,²¹ where the barrel of the syringe is located on the same side as the injection site. Also, this study compared the comfort levels of pediatric patients during the first stage of the conventional and modified 2-stage IANB techniques. Future studies can explore the effect of a painless first stage on the ultimate success of the IANB after 2 stages.

CONCLUSION

According to the results of the present study, use of the modified 2-stage IANB technique was associated with lower FLACC scores and increased patient comfort during the first injection stage compared with the traditional 2-stage IANB technique.

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