Original Article

pISSN 2383-9309 ▮ eISSN 2383-9317
J Dent Anesth Pain Med 2019;19(3):135-141 ▮ https://doi.org/10.17245/jdapm.2019.19.3.135

Making inferior alveolar nerve block more comfortable via computer-controlled local anesthetic delivery: A prospective clinical study

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Background: The fear of needle insertion and pain during anesthesia is a source of patient dissatisfaction in dentistry. Inferior alveolar nerve block (IANB) remains the most common type of block and is in itself painful. Computer-controlled local anesthetic delivery (CCLAD) has been proven to reduce the pain associated with injection of anesthetics in various blocks. However, the efficacy of CCLAD for IANB in adults remains unknown.
Methods: Sixty-four adult patients requiring bilateral IANB were selected and divided into two groups: group A (50 patients receiving IANB via CCLAD) and group B (50 patients receiving IANB using a conventional cartridge syringe). Pain perception and patient comfort were assessed using the visual analog scale and the 5-point semantic scale, respectively.
Results: The pain perception was compared between the two groups using the Mann-Whitney U-test, and the P value was 0.003. The patient comfort was also compared using the same test, and the P value was 0.484.
Conclusion: A significant difference was observed in the pain perception of the patients during CCLAD. The patient comfort was grossly equal for both techniques.

Keywords: Computer-Controlled Local Anesthetic Delivery; Inferior Alveolar Nerve Block; Patient Comfort.

INTRODUCTION

The ability to control pain is an integral part of dental procedures. Throughout the course of history, dentists have attempted to use many different agents from alcohol to herbal remedies to provide a painless environment for patients. The advent of local anesthesia has proven to be helpful for dentists [1].

However, the administration of local anesthesia can itself be a cause of patient anxiety and pain. The injection of local anesthetics is perhaps the greatest source of patient fear [1]. Ironically, patients avoid or postpone dental treatments for the fear of injection.

Inferior alveolar nerve block (IANB) is one of the most effective and commonly utilized methods among various procedures for pain control of the mandibular molars and premolars [2]. However, it is more painful than local infiltration and periodontal injections [3]. Initial needle insertion and needle penetration both elicit pain to patients. Further, block (i.e., deposition of anesthetic solutions) can cause a considerable feeling of pressure and thus discomfort to the patients [2]. Variations in the pressure applied while depositing anesthetic solutions are

Received: March 26, 2019 • Revised: May 16, 2019 • Accepted: June 17, 2019
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also known to elicit a feeling of immense discomfort to the patients [4]. Such pressure variations are mostly iatrogenic in origin.

When an anesthetic solution is injected "slowly," it is both safe and comfortable for patients [4]. The need to achieve optimum pain control with minimum amount of discomfort remains the primary concern for every dental practitioner [5].

A computer-controlled local anesthetic delivery (CCLAD) system has been developed to reduce the pain associated with injection of local anesthetics. The flow of a local anesthetic solution is controlled by a pressure-activated foot control pedal [6]. A pump permits deposition of local anesthetics at two gradual but consistent rates, and a computer nullifies the difference in the resistance to flow. During needle insertion, an uninhibited positive pressure is maintained, which leads to creation of an anesthetic pathway in front of the needle.

Over time, CCLAD has been a proven effective method for painless administration of local anesthetics. However, its use in IANB in adults remains to be explored.

Thus, the purpose of our study was to compare the pain perception and patient comfort between the use of a conventional cartridge syringe and CCLAD in adults requiring IANB for routine oral surgical procedures.

MATERIALS AND METHODS

This comparative, split-mouth, clinical study was conducted in the Department of Oral and Maxillofacial Surgery of our institute. In this study, 50 patients (age, 18-75 years) requiring bilateral IANBs were selected on the basis of the power of the study (two-sided at 90% power, with an error of 5%); their pain perception and comfort during IANB via CCLAD were assessed. The research protocol was initially submitted to our Institutional Ethics Committee and Review Board (DPU/R&R[D]/971/[14]/16). After ethical approval, participants fulfilling the inclusion criteria were enrolled in the study. Adult patients (aged above 18 years) requiring bilateral IANB for various surgical procedures and willing to participate in the study were selected. Medically compromised patients, patients allergic to local anesthesia, and mentally challenged patients were excluded from the study.

1. Sample size calculation

The sample size was derived using the following formula:

$$n = 2\,\frac{S^2(Z1+Z2)^2}{(M1-M2)^2}$$

Thus, the final sample size was 100 IANBs.

2. Split-mouth study design

This study was performed using a model that would reduce the bias as much as possible. The same operator administered the anesthetics bilaterally. The split-mouth study design removes several inter-individual variations in the assessment of the effect of treatments. However, it has an inherent disadvantage of a carry-across effect [7]. To minimize this effect, a group of patients received IANB via CCLAD first and vice versa. The time interval between the two procedures was scheduled at 7 days.

As the split-mouth study design was used, 50 patients requiring bilateral IANBs were divided into the following groups: group A, including 50 patients receiving IANB via CCLAD (WAND, Milestone Dental, CA, USA) and group B, including 50 patients receiving IANB using a conventional cartridge syringe.

3. Patient allocation

A total of 2,130 patients were screened in a period of 6 months. Nine hundred and forty-two patients required bilateral IANB for various treatments. Upon receiving information regarding the study, 850 patients were not interested to participate in the study. Thus, the 64 remaining patients were randomly allotted into the two groups using the sequentially numbered opaque sealed envelope (SNOSE) technique. However, 14 patients failed to report on the second visit. Therefore, 50 patients finally completed the treatments with bilateral IANB (Fig. 1).

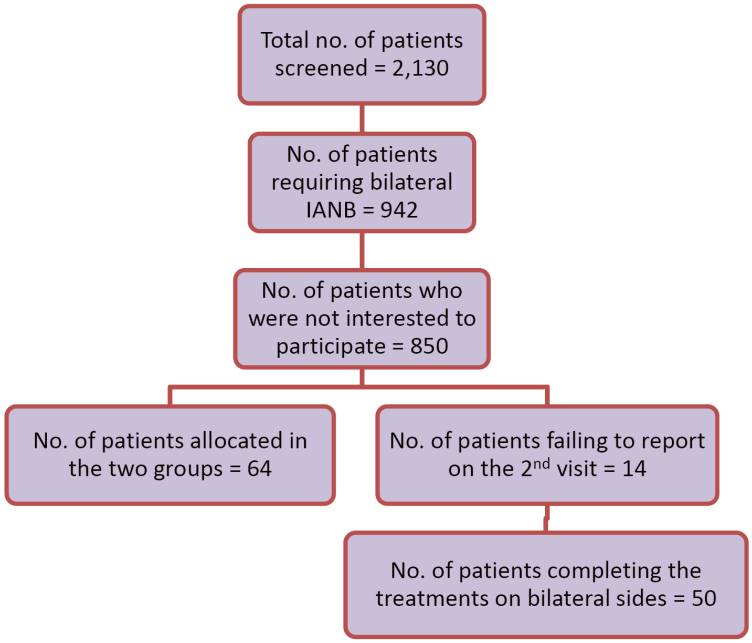

Fig. 1. Patient allocation (IANB, inferior alveolar nerve block).

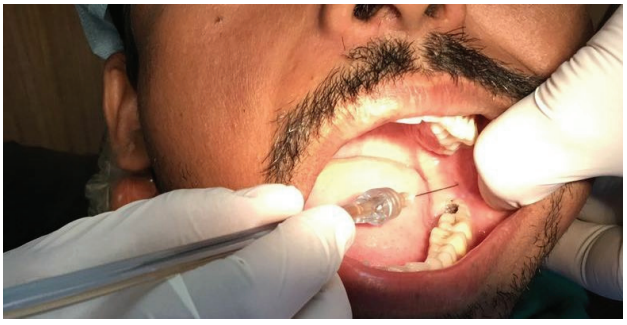

Fig. 2. Inferior alveolar nerve block via computer-controlled local anesthetic delivery

Fig. 3. Inferior alveolar nerve block using a traditional cartridge syringe

4. Procedure

A detailed history-taking was conducted for each patient. The patients were informed of the study details, and a written informed consent was obtained from each patient.

An alternating sequence was followed to ensure that half of the patients received IANB via CCLAD on the first visit and vice versa. Prior to the commencement of the procedure, the use of the visual analog scale (VAS) and semantic scale was explained. To reduce the possibility of confounding variables, the same 30-gauge and 1.5-inch-long needles and 1.8-ml cartridges (Septodont®) were used for both techniques. A slow delivery rate was selected for the CCLAD injections.

The sealed envelopes were numbered to decide which site (right/left) would be allocated to which injection technique (CCLAD/traditional).

The injection technique followed for CCLAD was per the recommendation of the manufacturer. Further, the bidirectional rotation technique was used during needle insertion in both sites. This technique compensates for the vectors of forces acting on the beveled surface of needles, thereby reducing the deflection (Figs. 2 and 3) [8].

Table 1. Comparison of pain perception (VAS score) between inferior alveolar nerve block via CCLAD (group A) and by using a conventional syringe (group B)

VAS score	Mean rank	Mann-Whitney U-test	P value
Group A (n = 50)	41.97	823.5	0.003
Group B (n = 50)	59.03		

P > 0.05, no significant difference P < 0.05, significant difference
VAS, visual analog scale; CCLAD, computer-controlled local anesthetic delivery

Table 2. Comparison of patient comfort (semantic scale score) between inferior alveolar nerve block via CCLAD (group A) and using a conventional syringe (group B)

Semantic scale score	Mean rank	Mann-Whitney U-test	P value
Group A (n = 50)	48.7	1160.0	0.484
Group B (n = 50)	52.3		

P > 0.05, no significant difference P < 0.05, significant difference
CCLAD, computer-controlled local anesthetic delivery

After the injection, the patients were asked to rate their pain on a scale of 10, with 1 being the least possible pain and 10 being unbearable pain. They were also asked to rate their comfort level during anesthesia for both techniques using the 5-point semantic scale (point 1, very much comfortable; point 5, very much uncomfortable).

5. Statistical analysis

The data was analyzed using SPSS for Windows version 16.0. (Chicago, IL, USA). Statistical analysis was conducted using tools of descriptive statistics, such as means and standard deviations (SDs) for representing quantitative data. Qualitative/nominal data were presented as proportions. The chi-square test was used to compare the proportions. The Mann-Whitney U-test was used to compare ordinal/non-parametric data (i.e., VAS score and semantic scale score) between the groups

RESULTS

Fifty patients (age range, 18–75 years; mean age, 36.2 ± 2.02 years) were included in the study. There were 20 male (40%) and 30 female (60%) patients.

1. Comparison of the VAS score

The VAS scores of pain perception in groups A and B were considered ordinal data. Hence, the median was calculated. The median score of group A was 3 (range, 1-6) and that of group B was 4 (range, 1-8).

The Mann-Whitney U-test revealed a significant difference (P = 0.003) in the pain perception (VAS score) between the groups; group A had a significantly lower pain perception than group B (P < 0.05) (Table 1).

2. Comparison of the semantic scale score

Regarding patient comfort, the median semantic scale score of group A was 3 (range, 1-4); that of group B was also 3 (range, 1-5).

The Mann-Whitney U-test revealed no significant difference (P = 0.484) in the patient comfort (semantic scale score) between both groups (P > 0.05) (Table 2).

DISCUSSION

The fear of injections is one of the most common distressing aspects of dental procedures. The notion of

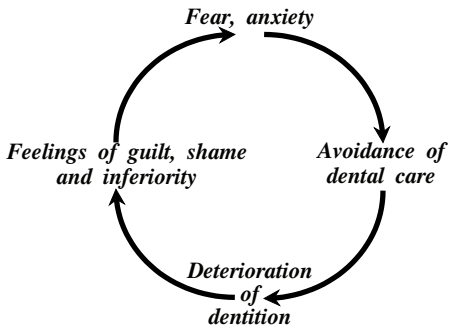

Fig. 4. Schematic diagram of dental fear

a needle being attached to a syringe and then penetrating the oral mucosa is quite fearful, thereby adversely affecting the patients' psychology. Epidemiological studies have shown that many patients delay or avoid dental treatments owing to the fear of needles [1]. Trypanophobia is the extreme fear of medical procedures involving injections or hypodermic needles [9]. One in four adult patients reports a clinically significant fear of dental injections; as a result, 1 in 20 patients avoid dental treatments [10].

Individuals with extreme levels of dental anxiety often experience a never-ending cycle of fear and avoid regular dental treatment. They only seek care when in pain, leading to development of chronic dental conditions. Usually, the treatments are more invasive when these patients finally report to dental offices. These individuals typically report poor oral health in addition to their anxiety (Fig. 4) [3,11].

This fear and anxiety of patients should be given due cognizance in dental practice. It is the duty and responsibility of dentists to search for alternative less painful options to the injection needle. CCLAD can be an option to reduce the pain during administration of local anesthetics. The Wand® is an example of a CCLAD system. The device comprises a control unit, hand piece, and foot pedal. It uses a 1.8-ml cartridge syringe that has to be loaded on the device [6,12,13].

In our study, we compared the pain perception and patient comfort between IANB via CCLAD and using a conventional cartridge syringe in adults for routine oral surgical procedures. Patients who met the inclusion criteria were included in the study. A split-mouth study design was selected to reduce the interpersonal variability and consequently, the bias. However, its major disadvantage is the carry-across effect, in which a downward biased effect might be carried on the difference in the perception of two successive treatments. In our study, we used the split-mouth design because this offers better efficiency than do other randomization methods. To reduce the carry-across effect, we performed IANB via CCLAD first in half of the patients and IANB using the conventional cartridge syringe first in the remaining half of the patients.

The two techniques were assigned to group A and group B using the SNOSE technique to ensure appropriate allocation of the patients. The other options for allocation of the techniques in the selected patients were block randomization or the flip coin method. Block randomization is preferable in larger sample sizes. The sample is divided in blocks; however, if the block size is too small, it may be impractical to use [14]. Therefore, the SNOSE technique was used to allocate the patients into the two groups.

In group A, CCLAD was used to perform IANB. The participants were asked to rate their pain using the VAS and comfort level using the semantic scale. In group B, a conventional cartridge syringe was used to perform IANB. The patients were also asked to rate their pain using the VAS and comfort level using the semantic scale. The VAS was used as it offers an extremely high degree of resolution, thereby allowing the subjects to judge even the slightest of differences precisely [15]. The semantic scale was used to record patient comfort because it is proven to reveal multi-dimensional aspects of mind perception [12].

Age and sex matching was performed to reduce bias. Previous studies on CCLAD have been conducted mostly on pediatric populations [16,17]. Conversely, an adult population was selected as subjects in this study.

While comparing the VAS scores between groups A and B, a significant difference was found ($P = 0.003$), with the pain perception being significantly lower in

group A than in group B. Feda et al. [16] used the SEM scale to compare pediatric patients' pain perception for AMSA injections via CCLAD and that using conventional cartridge syringes and revealed that children experienced less pain with the former technique. Kumar et al. [17] obtained similar results in their study of patients aged 7-11 years in terms of the behavioral response to blocks via CCLAD and that using a cartridge syringe. In most previous studies, pain perception was much lower when a computerized device was used [18].

The lower pain values with the use of a computerized device for anesthetic administration may be attributed to the creation of an anesthetic pathway, which precedes the needle trajectory. Preceding the insertion of the needle, it is pressed against the mucosa, and a small amount of solution is deposited submucosally. This probably reduces the pain of a needle prick. The notable feature of CCLAD is the continuous positive pressure delivery of anesthetic solutions. The anesthetic pathway and monitored flow rate both yield an almost imperceptible injection [4]. The accurate tactile sensation of the lightweight hand piece and the ease of rotating the needle as it is introduced in the tissue aid in reducing needle deflection [5,6].

The hand piece of CCLAD systems appears more like a pen rather than a syringe, which patients find less threatening than a conventional cartridge syringe and needle [6]. The device delivers anesthetic solutions more slowly and precisely than does the conventional injection technique to reduce patient discomfort. Individual semantic scale scores revealed that the comfort levels were slightly higher when using CCLAD. However, no significant difference was found in the semantic scale scores between groups A and B in our study. Thus, it can be stated that both the conventional cartridge injection technique and CCLAD were equally well accepted by the patients. Our findings are similar to those of Chang et al. [19]. Conversely, Sumer et al. [20] found conventional methods to be better than CCLAD.

Although our study showed that the pain perception with the use of CCLAD was significantly lower than that with the use of a conventional cartridge syringe, the patient selection and use of a newer kind of machine, leading to inadvertent partiality while scoring, might introduce a study bias. A study design wherein patients are blinded to the type of the injection technique used may render impartial pain scoring. Moreover, the operator who performs the injection and the individual recording the pain and comfort scores should be different to obtain a more unbiased result. Further, the added expenditure of CCLAD and disposable handpiece for every injection might not be affordable to every practitioner, although the results of our study are in favor of CCLAD. The results of our study are encouraging enough to recommend the use of CCLAD in IANB in adults. If the cost is reduced it may be possible for every practitioner to offer this painless injection technique to every patient. The option for a painless treatment must be seen as a right of every patient.

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CONFLICT OF INTEREST: None of the authors have any conflicts of interest to declare.

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