Title: Does the Use of CBCT Pre-operative Measurements Improve the Success Rate of Inferior Alveolar Nerve Block? - A Randomized Controlled Clinical Trial

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Abstract:

This study investigates whether pre-operative CBCT measurements improve IANB success rates compared to intraoral landmark-guided injections. Twenty participants, aged 18-70, requiring mandibular implant surgery, were randomly assigned to receive IANB either via CBCT-guided measurements or intraoral landmarks. Success was evaluated through anesthesia onset in tongue, lips, buccal gingiva, and lingual tissues at intervals up to one-hour post-injection. Operative tests and Visual Analog Scale (VAS) scores assessed anesthesia efficacy.

Results showed no statistically significant difference in anesthesia onset between CBCT-guided and landmark-guided injections. However, CBCT-guided injections required significantly fewer needle reorientations (9.1% vs. 66.7%, $p = 0.009$) and demonstrated a trend towards reduced supplementary injections (73.9%). The average VAS score was 2.26, indicating moderate anesthesia satisfaction.

This study supports the hypothesis that CBCT-guided IANB may reduce procedural complications associated with needle misplacement and improve injection accuracy. Future research with larger sample sizes could further validate these findings and refine CBCT protocols for routine dental practice.

Introduction:

The inferior alveolar nerve (a branch of the mandibular division of the trigeminal nerve) provides innervation to the molars, premolars, incisors, canine, the anterior buccal mucosa and then the skin of the lower chin and lip (Hur et al., 2013). When proceeding with invasive dental procedures in the mandible, it is routine to give an inferior alveolar nerve block (IANB). The Journal of American Dental Associated identifies anatomical variations including accessory nerve supply, variable course of nerve, variation in foramen position, bifid alveolar nerve or mandibular canal, pathology such as trismus, infection, inflammation or previous surgery, pharmacology such as chronic alcohol abuse or drug abuse, psychological effects of fear, anxiety or apprehension and poor technique as reasons for the failure of conventional IANB (Guatam A et al, 2002). Injection technique is the main contributing factor in the success of an IANB. It is imperative that the clinicians understand the mandibular anatomy and the injection site relative to the mandibular foramen and pterygomandibular space (Palti et al., 2011).Other studies emphasize the failure of IANB can be due to the inability to correctly identify the intra-oral landmarks (Malamed, 2004), anatomical variations (Thangavelu et al, 2012) and the administration of the needle away from the mandibular foramen (Zhou et al., 2017). While the patient's soft tissue acts as a landmark for a successful IANB, it can also contribute to the failure of an IANB by obscuring the bony landmarks (Keetley et al, 2001). With the IAN nerve block, each region has different success rates of pulpal and soft tissue anesthesia. For instance, the buccal mucosa of the mandibular molars was found to have a very low and variable success rate (Cho et al., 2019). A study comparing IANB to the Gow-Gates technique found that an IANB had an overall success rate of 80.82% with 60% of first premolar and 49.3% of canines successfully anesthetized (Haghighat et al., 2015). However, IAN are reported to have an overall failure rate of 20 – 25% by Thangavelu et al (2012) and 15% - 20% by AlHinidi et al (2016).

When testing for the success of an IAN, an electric pulp tester (EPT) can be used to confirm pulpal anesthesia while soft tissue anesthesia is often evaluated by lip numbness which is reported to follow 15-20 minutes after an IANB (Fowler S., et al., 2015). A pressure algometer can also be used to measure the mechanical force used to confirm adequate soft tissue anesthesia with high reliability and validity (Ogimoto T. et al., 2002). However, despite the subjectiveness of reporting numbness, it is the most common method to assess adequate anesthesia. Kholer et al reported that asking if an area feels numb compared to another area is currently the most available and practical clinical test to ensure an objective anesthesia before any dental extraction.

With the advancement of cone beam computed tomography systems (CBCT), the anatomical variation of the mandibular foramen and lingula has been investigated. Unlike other imaging modalities, the CBCT scan generates an undistorted 3-dimentional reconstruction of the mandible and more specifically the mandibular foramen. Previous research has shown that when compared to standardized measurements, the CBCT imaging software had an error range from 0.07 mm to 0.27 mm. While there are many studies that explore the use of CBCT in locating anatomical structures such as the mental nerve, coronoid foramina, mandibular canal, mandibular foramen and lingual, this information has been used to determine average location of these structures and report anatomic variations.

Several studies have investigated the use of CBCT imaging to determine the best technique to administer an IANB. In 2020, Feurestein et al. recommended that clinicians should first place their thumb along the cusp of the erupted teeth to visualize the occlusal plane. They should then proceed to insert the needle at a 45 °angle, 5 mm above the occlusal plane and 19 mm from the anterior edge of the mandibular ramus. While the study Blacher et al. (2016) conducted also located the IAN complex at a 42-45 ° angle from the contralateral premolar contact, his study reported that the mandibular foramen was on average 9.83 mm above the occlusal plane. Nicholson et al found that while 22% of the mandibular foramina were at the level of the occlusal plane, 75% was found to be below the occlusal plane. Hence, there is a high degree of variability across patients that contributes to the failure of IANB.

As previous studies have demonstrated, the position of the mandibular foramen is often irregular and while using intra-oral landmarks is currently the recommended technique used when delivering an IANB, the advancement of CBCT technology can help dental providers in achieving accurate needle position and angle. Currently, CBCT is the standard of care to study the anatomical variations and provide recommendations based on population averages. However, CBCTs have not been used prospectively to locate the mandibular foramen and use that information clinically to administer the IANB. Hence, the purpose of this clinical study is to determine if the success rate of an

IAN block will be improved with the use of a CBCT measurements to guide the position of needle penetration.

Previous studies have demonstrated that CBCT scans can be used to accurately determine the location of the mandibular foramen and have provided average anatomical location based on intra-oral landmarks. However, there are no current studies that apply these operative measurements clinically to guide the clinician's injection technique. We propose that the location of a patient's mandibular foramen can be accurately predicted based on measurements obtained from individualized CBCT scans and that can be used to improve the success rate of IANB injections.
This study hypothesizes that the success rate of an inferior alveolar block is improved by the use of pre-operative CBCT measurements compared to only using intraoral landmarks. The aim is to determine if the use of pre-operative CBCT imaging as a guide will yield better success rate as compared to the use of standard intraoral landmarks

Methods:

Inclusion Criteria:

Male and female patients from the age 18 to 70 years old that are assigned to the 3 clinicians of the graduating class of LSUHSC School of Dentistry Post-graduate Periodontics program. These patients have been reported as an ASA I or ASA II patient that has never had an allergic rection to lidocaine based on previous dental experience. The patient must be missing one or more mandibular teeth and is treatment planned for a mandibular implant and requires an inferior alveolar nerve block during surgery. Patients must have an existing CBCT scan within the last year or is planned for a CBCT scan for the purpose of dental implant treatment. No additional CBCT scans other than those necessary from the standard protocol of placing a dental implant will be taken.

Exclusion Criteria:

The exclusion criteria include patients that have undergone long term use or continuous use within the last week of opioids, analgesics, medications of nerve related pathology and non-steroidal anti-inflammatory drugs. Long-term use of opioids and anti-inflammatory drugs can lead an increased pain sensitivity (Samuelsen et al, 2017)

Patients diagnosed with trismus are excluded due to their hindered ability to open their mouth eliminating any bony landmark applicable to giving an IANB (Thangavelu et al, 2012). Patients that request for Nitrous and IV anesthesia are also excluded from this study due to their altered perception of pain. Kushnir et al (2021) found that when nitrous oxide was used, patients reported a statistically significant reduction in pain during needle insertion, needle placement and solution deposition and increase in IANB success. Patients missing remaining teeth in the quadrant or having a history of endodontic treatment of the remaining teeth in the quadrant will be excluded. Patients having endodontic or pulpal pathology in the teeth in the quadrant will also be excluded.

Random Assignment:

Patients that qualify for this study will be randomly assigned into one of the two study groups.

- Group 1 will receive their IANB using the operative measurements obtained from the CBCT scan.
- Group 2 will receive their IANB using only intra-oral landmarks.

Experimental Overview:

Depending on the group assignment, patients included in the study will receive either an IANB using the intraoral landmarks or using operative measurements taken from CBCT scans. Patient's will then be assessed by reporting numbness of their tongue, lips, buccal gingival tissue of the canine and molar and lingual tissue at 3, 5, 8, 10 minutes and 1 hour. Intraoral numbness of all 7 tests will indicate a successful IANB. The results of each group will be compared for a statistically significant difference.

CBCT Operative Measurements:

CBCT DICOM files using Anatomage software will be used to obtain the operative measurements that will locate the mandibular foramen. The first measurement will be in reference to the occlusal plane. A line connecting the buccal cusps of the two ipsilateral premolars and the first and second molars is drawn onto the DICOM file. The height difference between the mandibular foramen and the occlusal plane is measured and an additional 1 mm will be added onto the value to avoid directly penetrating the inferior alveolar nerve. The second measurement will be in reference to the contralateral premolars. An angle between the 2 buccal cusps of the premolar and the mandibular foramen will be measured to give us the injection angle that allows the needle to be 1 mm distal to the mandibular foramen.

<u>Assessment of IANB:</u>

Anesthesia of the mental nerve, a terminal branch of the inferior alveolar nerve will be assessed by reported numbness or tingling sensation when brushing a probe along the ipsilateral lower lip and using a sharp explorer to probe the buccal gingival tissue of the 1st premolar

Anesthesia of the lingual nerve will be assessed by the reported numbness or tingling sensation of the ipsilateral tongue when brushing a probe along the dorsal surface of the tongue and the lingual soft tissue.

Cold testing of all posterior teeth in the same quadrant will indicate anesthesia of the IAN.

Treatment:

Before anesthetizing the patient, the operative measurements will be tested on the patient as a baseline reference. This will allow the patients to report a more accurate description of the subjective measurements and identify any pulpal pathology that could give false positive results. The injections will be administered by the author of this article using a 32 mm length and 25 -gauge needle to inject 1.8 mL of 2% lidocaine 1:100 000 epinephrine.

<u>Using Intraoral Landmarks:</u> Patient is positioned supine on the operating chair with their mouth open wide. The clinician's left thumb will locate the coronoid notch by running their thumb along the anterior border of the ramus and extending vertically upward. The height of injection will be approximately 6 to 10 mm above the occlusal plane. The syringe will be positioned between the contralateral canine and premolar and insert the needle 8 to 10 mm posterior to the anterior border of the ramus along the imaginary line that runs from the coronoid notch to the deepest part of the pterygomandibular raphe. Bone will be contacted and at this point the needle will be retracted 1 mm and aspiration will be performed. If there is negative aspirate, 1.8 mL of lidocaine will be deposited

slowly over the course of 60 seconds. The needle will be withdrawn, and the clinician will conduct the operative tests at the specified times. It will also be recorded if the clinician needed to reorientate or remove the needle after the initial path of insertion to properly anesthetize the patient.

Using CBCT scan: The patient's pre-existing CBCT DICOM file will be opened on the Anatomage software. The occlusal plane will be drawn on the CBCT scan by establishing a line connecting the buccal cusps of the ipsilateral first premolar, second premolar, first molar and second molar and extending posteriorly beyond the mandibular ramus. Using the ruler tool, the distance from the mandibular foramen to the occlusal plane will be measured and 1 mm will be added to this value to prevent the direct penetration of the inferior alveolar nerve. On the axial plane, an angle will be made from a line connecting the buccal cusps of the first and second premolar and another line extending across the oral cavity and into the mandibular foramen. This will give us the angle at which the needle will penetrate through the soft tissue. A 1 mm thick tongue depressor will be used to visualize the occlusal plane and act as a reference when marking the height of the injection point. A horizontal line will be drawn with a Thompson stick which will indicate the height of the injection point. An orthodontic wire will be bent according to the angle of insertion based on CBCT measurements. The short arm of wire will lay on the buccal cusps of the premolars and the long arm will mark pinpoint the final injection site. The needle will then be inserted at this mark until a bony resistance is met. The needle will be retracted 1 mm and the clinician will achieve negative aspiration before injecting 1.8 mL of lidocaine over the course of 60 seconds. The needle will be withdrawn from the patient's mouth and operative tests will be conducted at the specified times.

At three minutes, all six operative tests will be conducted, and the results will be recorded in the table presented below. The probe tests will be repeated at 5 minutes, 8 minutes and again at 10 minutes. Any sensation or pain felt 1 hour or at 2 hours during the procedure will be recorded using the Heff-Parker visual analog scale (VAS). The number of times the clinician must re-anesthetize the patient and the amount of additional anesthesia used will also be recorded. The Fisher Exact test was used for categorical variables and the Wilcoxon Rank-Sum test was used to test the null hypothesis.

Results:

The study included 10 male and 10 female participants, averaging 61.35 years old. Among them, 11 patients received an IANB via CBCT measurements, while 12 received it via intraoral landmarks. 47.8% of injections targeted the left IANB, and 52.2% targeted the right IANB. On average, the mandibular foramen was positioned 7.89 mm above the occlusal plane, with an average angle of 77.5° from the contralateral premolar buccal cusp to the mandibular foramen.

Among the six operative tests conducted, no statistically significant difference was found between IANBs administered via CBCT measurements or intraoral landmarks. Tongue numbness typically began 7.67 minutes post-anesthesia (Group 1= 8.2 minutes; Group 2= 7 minutes). Five patients, one from Group 1 and four from Group 2, did not experience tongue numbness. All patients experienced lingual tissue numbness, with an average onset of 6.7 minutes (Group 1= 7.27 minutes; Group 2= 6.17 minutes). The average onset of buccal gingival numbness at the mandibular canine was 5.31 minutes (Group 1= 5.14; Group 2= 5.44 minutes). Seven patients reported no buccal gingival anesthesia from the IANB, four from Group 1 and three from Group 2. Lip numbness typically began at 6.21 minutes (Group 1= 6 minutes; Group 2= 6.38 minutes), with nine patients not experiencing it, five from Group 1 and four from Group 2.

Teeth excluded from the cold test were either extracted, getting replaced with an implant, non-vital, had a crown, or showed a positive cold test response. Twenty-two observations did not undergo a 1st molar cold test, and one vital 1st molar had a negative cold test three minutes after the IANB. Five 2nd molars had a negative cold test after an average of 4.2 minutes (Group 1= 3 minutes, Group 2= 4.5 minutes), while eighteen 2nd molars did not qualify for the test (16 teeth were extracted and 2 teeth had crowns). Fifteen 1st premolars had a negative cold test at an average of 7 minutes (Group 1= 7.29 minutes, Group 2= 6.88 minutes), excluding eight 1st premolars. Of these 8 teeth, 3 teeth were extracted, 4 teeth did not get numb and 1 tooth had a crown.

The final test revealed seventeen 2nd premolars with a negative cold test at an average of 6.87 minutes (Group 1= 6.86 minutes, Group 2= 6.88 minutes), with eight 2nd premolars excluded from the test. Four of the 2nd premolars were missing and the other four 2nd premolars did not get numb.

The results indicated that 17 (73.9%) patients required a supplemental injection via local infiltration or mental nerve injection, on average 15 minutes after the initial IANB, with no significant difference between CBCT measurements (Group 1= 12.5 minutes) and intraoral landmarks (Group 2= 18.11 minutes). Among the 23 observations, 15 patients required a reinjection of the IANB at 57.67 minutes (Group 1= 57.86 minutes, Group 2= 57.5 minutes). However, a statistically significant difference was observed in the need to re-orient the needle. Only 9.1% of IANBs via CBCT measurements required reorientation compared to 66.7% of IANBs via intraoral landmarks (p-value = 0.009). Additionally, the overall VAS analog score was 2.26.

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Discussion:

Thangavelu et al. (2012) and AlHindi (2016) previously reported failure rates of 20–25% and 15-20% respectively for inferior alveolar nerve blocks (IANB). Factors contributing to IANB failures include accessory nerve supply, variation in foramen position and nerve course, infection, inflammation, trismus, fear, anxiety, chronic alcohol and drug abuse (Guatam et al., 2002). Al-Shayyab (2018) also noted racial, age, ethnic, and individual variations.Improper injection technique was identified by Palti et al. (2011) as a significant factor affecting IANB success.

Cone beam computed tomography (CBCT) allows for 3-dimensional imaging and has been utilized in various studies to accurately locate the mandibular foramen to improve surgical techniques. For instance, Al-Shayyab (2018) recommends using a 40% rule derived from CBCT scans, which involves intersecting horizontal and vertical lines calculated from specific anatomical landmarks.

In our study, the mandibular foramen averaged 7.89 mm above the occlusal plane. This measurement contrasts with Feuerstein et al. (2020), who reported distances of 3.2–3.8 mm, likely influenced by our older study population (average age 61 years), where mandibular remodeling and tooth loss may shift foramen position. Blacher et al. (2016) found the angle from the contralateral premolar to the mandibular foramen to be approximately 43°. Due to missing ipsilateral premolar teeth in our patients, we used a modified angle reference, resulting in an average angle of 77.5° to broaden our inclusion criteria.

Cold tests yielded limited conclusive data due to missing, non-vital, or crowned teeth in our sample. It is important to note that out of the twenty-three observations, only one first mandibular molar and five second mandibular molars were included in the cold test. In addition, four first mandibular premolars and four second mandibular premolars did not get numb within the 10 minutes period and required additional numbing via local infiltration to become anesthetized.

There were 3 patients in the study that received contralateral IANB using both techniques. All 3 patients had no significant difference in occlusal plane and angle from contralateral premolar to mandibular foramen when comparing the right and left side. With both techniques, patients resulted in similar onset of tongue, lip and buccal gingival numbness.

Although 73.9% of patients required a supplemental injection, this was expected in region of the buccal gingiva in the molar region since no long buccal injection was completed until 10 minutes after the IANB. For longer procedures, fifteen patients required additional IANB at an average of 57.67 minutes.

Overall, this study found no statistically significant difference between IANB administered via CBCT measurements or intraoral landmarks for any of the six operative tests and the VAS analog score. A statistically significant difference in the need to re-orient the needle was examined with less frequency when CBCT measurements were used. In other words, when CBCT measurements were used, 9.1 % of cases required reorientation compared to 66.7% of IANBs via intraoral landmarks (p-value = 0.009). This finding may suggest that by using CBCT measurements, IANB can be performed more accurately and may reduce the incidence of complications associated with IANB. This may reduce the incidence of mucosal tearing from the progression and withdrawal of the needle which can cause trismus and pain (Tzermpos et al 2012).

There were several limitations in the study, most notably the small sample size. The technique used to translate the CBCT measurements was also a source of inaccuracy. To the best of our ability, orthodontic wire was bent to the angle and attempted to be stabilized in the mouth to mark the injection point. As mentioned, in most cases, the mandibular first and second molar was missing, resulting in less accurate reference points to create the occlusal plane on the scan and intraorally. Future studies might benefit from 3D-printed stents to enhance measurement precision.