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AN IN VIVO SPLIT-MOUTH RANDOMISED CONTROLLED TRIAL STUDYING THE EFFECT OF INFERIOR ALVEOLAR NERVE BLOCK AND INTRALIGAMENTARY ANAESTHESIA ON ANXIETY LEVELS OF PATIENTS UNDERGOING SINGLE SITTING ROOT CANAL.

Dentistry

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ABSTRACT

Aim: This in vivo split-mouth randomised control trial was carried out to study and compare the effect of Inferior alveolar nerve block and Intraligamentary anaesthesia (when used as primary anaesthetic technique) on anxiety levels of patients undergoing single sitting root canal. **Methods:** A total of 30 patients with bilateral symptomatic irreversible pulpitis in mandibular molars were selected to be included in the study. In each subject, molar in one quadrant was randomly assigned to Group 1 (Intraligamentary injection), and the molar in the opposite quadrant was assigned to Group 2 (Inferior alveolar nerve block).The heartrate of the patients was noted at 4 periods during the administration of the local anaesthetic solution. The readings obtained were tabulated and subjected to statistical analysis. **Results:** As compared to Group 1, Group 2 patients demonstrated an increase in mean heart rate through all 4 periods of delivery of local anaesthetic solution and this increase was sustained even after the injection protocol was over. Comparison between the two groups at each time interval showed a difference which was statistically significant ($p > 0.05$). **Conclusion:** There is a significant increase in heart rate in patients being administered Inferior alveolar nerve block as the primary anaesthetic technique for single sitting root canal, as compared to patients being administered Intraligamentary injection as the primary anaesthetic technique.

KEYWORDS

Anxiety, Heart Rate, Intraoral Anesthesia, Single Sitting Root Canal Treatment

INTRODUCTION

Anxiety is commonly associated with dental treatment, and the root canal procedure is no exception. Even the thought of a root canal makes patients anxious and hesitant in approaching a dental practitioner for treatment. The greatest anxiety producing protocol is administration of local anaesthesia.

Administration of local anesthesia forms a significant part of the work routine of a dental practice. But the anxiety it causes right from the beginning of the appointment is counterproductive for the clinician. Anxiety reduces the cooperation and acceptance from a patient and may dissuade the patient from reporting for further treatment.

Intraligamentary anesthesia is now commonly used as it is efficient and easy to administer. Some authors consider it to be more efficient than conduction anesthesia[1]. Meechen has found that Intraligamentary anesthesia is an efficient anesthetic technique but stresses the necessity of an accurate conduction of the procedure[2].

A search of literature showed that few clinical studies have evaluated anxiety levels of patients (by measuring heart rate) when using Intraligamentary anaesthesia and Inferior alveolar nerve block (IANB) as primary anaesthetic technique for single visit root canal therapy. So, an in-vivo study using a crossover design was planned to note the effect of IANB and Intraligamentary anaesthesia on anxiety levels of patients undergoing single sitting root canal by monitoring the patients' heart rate throughout the local anaesthetic delivery protocol.

The study hypothesis proposed was that there is no difference in the anxiety levels during delivery of anesthetic solution by Intraligamentary injection technique, or by means of IANB technique, when employed as primary local anaesthetic protocol in single-sitting root canal treatment.

METHOD

Thirty patients (18- 70 years) were included in the split mouth clinical study, from the referred patient pool of the institute. The protocol was appraised and accepted by the Ethical Committee of the institute. The subjects were treated in accordance with the Declaration of Helsinki. The subjects were patients on their first treatment visit to the department. A detailed history was noted and informed signed consent was taken from each patient.

The inclusion criteria included all healthy controls (defined by American Society of Anaesthesiology - I or II) who required root canal treatment in the left or right mandibular first molar. The teeth were vital, with untreated root canals, and absence of any drainage through the canal. The teeth chosen were confirmed to have straight canals that were visible clearly on the radiograph, with no anatomic variations like recession of pulp chamber and/or calcification or curvature of the canals. The teeth had no draining sinus tract and a sound periodontal apparatus. The exclusion criteria were teeth with restorations that were large, old endodontic treatment, with periodontal involvement and also those having poor cavosurface margins. Teeth with pulp necrosis, having periapical lesion >2mm, vital teeth with full crowns and teeth with curved canals were also excluded from the study. Immunocompromised patients, those who were prescribed antibiotics in the previous month or required antibiotic prophylaxis for root canal treatment, or had a positive history of analgesic use within the previous 3 days were deemed to be excluded from the study.

Study Design

Crossover Split mouth study.

Method

30 patients were included in the study. Sample size determination was based on previously published data for postoperative pain following single visit root endodontic therapy. Every patient presented with bilateral pulpal involvement of mandibular molars (tooth number 36 or 37 and tooth number 46 or 47) which required endodontic treatment.

Vitality testing was done using electric pulp tester. Preoperative radiographs confirmed patent canals, good gingival and periodontal status and presence/absence of periapical radiographic changes. A detailed history of the patient was noted and a systematic clinical examination performed. On determination that the patient fulfilled the selection criteria, he/she was given the details of the study and signed consent was obtained.

Before administering local anaesthetic injection, the patient was connected to a pulse oximeter. In every patient, the mandibular molar in one quadrant (left or right) was allocated to Group 1, and the molar on the other side was allocated to Group 2 (Alignment of sides was done randomly). As the study design was cross over, it was ascertained that half of the sample of patients received Periodontal ligament injection first and the other half were given IANB as the first injection, to eliminate any bias.

Group 1 molars were given Intraligamentary anaesthesia 0.4 ml of Lignocaine with 1:80,000 epinephrine and Group 2 molars were given IANB. 1.8 ml of Lignocaine 2% with 1:80,000 epinephrine was the anesthetic solution used for the study. The heart rate of every patient in both groups was monitored and noted by dividing the anaesthetic delivery phase into 4 periods.[3] Same operator performed all anaesthetic

procedures while another operator assisted with recording heart rate readings simultaneously.

Group 1- Patients were injected with Periodontal ligament injection (0.4 ml of Lignocaine)

Four time periods were monitored:

- Period 1 - This was the five-minute period when baseline heart rate was noted at one-minute intervals during the pre-injection period (5 readings)
- Period 2 (A) - Noting of heart rate at 15-second intervals through the time of deposition of anesthetic solution on mesial aspect of the molar (2 readings)
- Period 2 (B) - Noting of heart rate at 15-second intervals through the time of deposition of anesthetic solution on distal aspect of the molar (2 readings)
- Period 3 - Noting of heart rate at 15-second intervals through 2 minutes soon after anesthetic solution deposition (8 readings)
- Period 4- Noting of heart rate at 2-minutes intervals through 10 minutes after completion of the Intraligamentary injections (5 readings)

In Group 2, subjects were given IANB (1.8 ml of the same anesthetic solution as used for Group 1 patients). The block was given using routine dental aspirating syringe with 1.5inch needle of 27 gauge.

Four time periods were monitored:

- Period 1 - This was the five-minute period when baseline heart rate was noted at one-minute intervals during the pre-injection period (5 readings)
- Period 2 - Noting of heart rate at 15-second intervals through the time of deposition of anesthetic solution by inferior alveolar nerve block (4 readings)
- Period 3 - Noting of heart rate at 15-second intervals through 2 minutes soon after anesthetic solution deposition (8 readings)
- Period 4 - Noting of heart rate at 2-minutes intervals through 10 minutes after completion of the IANB injection (5 readings)

For comfort during the root canal treatment, all patients in Group 2 received long buccal nerve block prior to start of root canal treatment.

After local anaesthesia and recording of heart rate in all 4 periods, rubber dam was applied for isolation and routine root canal therapy was performed for all patients in single visit. The technique employed was Crown Down using hand Protaper™ and obturation was done by Lateral Condensation technique. The sealer used was a Zinc oxide eugenol-based sealer. Time period between the two anaesthetic techniques was maintained at one week. The study was carried out over a period of 6 months.

Heart rate readings of both groups were tabulated and tested for normality using Shapiro-Wilk test. Paired t-test was employed to test the significance of difference between groups at different periods. The comparison was taken as significant provided the value of p was found to be less than 0.05.

RESULTS:

Table 1. Mean Pulse Rates for Group 1 and Group 2 at all 4 periods.

TIME PERIOD	GROUP 1	GROUP 2
Period 1	84.7933	90.4867
Period 2	94.8917	93.5167
Period 3	91.0083	96.6292
Period 4	83.6400	94.1133

Table 2 gives the Descriptive Statistics and Paired sample test results for Period 1 for both groups.

Descriptive Statistics:

	Mean	N	Std. Deviation	Std. Error Mean
Group-1	84.7933	30	11.26036	2.05585
Group-2	90.4867	30	14.17318	2.58766

Paired sample test results:

Mean Difference	t-test	d.f.	p-value
-5.69333	-3.194	29	.003

Interpretation:

P-value for the paired t-test at period-1 when compared between two groups is less than that of 0.05 indicates significance of difference between two groups. Average of Group-2 is significantly more than that of Group-1.

Table 3 gives the Descriptive Statistics and Paired sample test results for Period 2 for both groups.

Descriptive Statistics:

	Mean	N	Std. Deviation	Std. Error Mean
Group-1	94.8917	30	11.19761	2.04440
Group-2	93.5167	30	17.14793	3.13077

Paired sample test results:

Mean Difference	t-test	d.f.	p-value
1.37500	.489	29	.629

Interpretation:

P-value for the paired t-test at period-2 when compared between two groups is greater than that of 0.05 indicates no significance of difference between two groups. Therefore we conclude that the Average of Group-1 and Group-2 is not significant when compared between each other.

Table 4 gives the Descriptive Statistics and Paired sample test results for Period 3 for both groups.

Descriptive Statistics:

	Mean	N	Std. Deviation	Std. Error Mean
Group-1	91.0083	30	10.04639	1.83421
Group-2	96.6292	30	12.18188	2.22410

Paired sample test results:

Mean Difference	t-test	d.f.	p-value
-5.62083	-3.419	29	.002

Interpretation:

P-value for the paired t-test at period-3 when compared between two groups is less than that of 0.05 indicates significance of difference between two groups. Average of Group-2 is significantly more than that of Group-1.

Table 5 gives the Descriptive Statistics and Paired sample test results for Period 4 for both groups.

Descriptive Statistics:

	Mean	N	Std. Deviation	Std. Error Mean
Group-1	83.6400	30	10.07618	1.83965
Group-2	94.1133	30	10.98911	2.00633

Paired sample test results:

Mean Difference	t-test	d.f.	p-value
-10.47333	-6.448	29	.000

Interpretation:

P-value for the paired t-test at period-4 when compared between two groups is less than that of 0.05 indicates significance of difference between two groups. Average of Group-2 is significantly more than that of Group-1.

RESULTS AND STATISTICAL ANALYSIS

The readings in Table 1 give the mean pulse rate in the 4 periods of injection of both Group 1 and Group 2.

Table 2,3,4 and 5 give descriptive statistics and paired sample test results for Period 1, 2,3 and 4 respectively for both groups.

DISCUSSION

Dental anxiety is the patient's reaction towards the stress that is anticipated along with dental treatment, where the reason is not known or may not even be present at that time. It is a common problem that persists in spite of the advances that make dentistry more tolerable, pain-free and less uncomfortable than in the previous decades. Depending on the sample studied and the technique of measurement, 2.5% to 20% people suffer high dental anxiety. Anticipated fear and anxiety show a tendency to change as per the type of treatment planned. Endodontic and Periodontal treatments seem to cause more anxiety than simple prophylactic treatments. There is no doubt that root canal treatment has been known to cause an increase in

physiological and psychological stress levels.[4]

Anxiousness, fear, pain and distress associated extreme emotions raise the cortisol and adrenaline levels. Subsequently, the raised levels bring about an increase in the heart rate, and if the stress persists, it can result in the individual presenting with an elevated resting heart rate. So, heart rate is a good variable for measurement of the anxiety in a patient[4].

Techniques of administration of local anaesthesia in the oral cavity has seen several advances in the last few decades and one of them is the Periodontal ligament injection. As compared to IANB, it demonstrates a more localised action by anesthetizing only the tooth of concern and not the whole quadrant.

In our study, we assessed and compared the change in anxiety associated with administration of Local anesthetic by 2 different techniques - Inferior alveolar nerve block and Periodontal ligament injection by measuring heart rate before, during and after injection.

A cross-over split-mouth method was selected in order to eliminate any potential bias in group assignment and patient responses. The main advantage of this technique is that comparison of the responses is not between two different patients as both techniques are performed on the same patient, but on opposite sides.[5]

Table 1 give the mean pulse rate in the 4 periods of injection of both Group 1 and Group 2.

On comparison of readings, we found that the average reading for each period was lower in Group 1 as compared to Group 2 except in Period 2 where Group 1 reading was higher than Group 2.

In Group 1, the heart rate in Period 4 was lower compared to Period 1; whereas in Group 2, the opposite was found. The heart rate in Period 4 was noted to be higher in comparison to Period 1.

The readings in Table 1 were tested for normality and the data was found to be normally distributed. Hence statistical analysis of the readings was obtained by Paired T test.

Period 1:
In Period 1, the heart rate was noted at one-minute intervals during the 5-minute pre-injection period (5 readings) for both groups.

Table 2 gives descriptive statistics for Period 1 and the paired sample test results for Period 1for the two groups.

Analysis shows that there was a difference between averages of Group 1 and Group 2 in Period 1. The average of Group 2 readings was significantly more than Group 1 (since $p < 0.05$).

This shows that during Period 1 itself the heart rate of patients to receive inferior alveolar nerve block was significantly higher than the heart rate of patients to receive Periodontal ligament injection. While the statistical significance seems to have no real connection with the method of injecting, it could be attributed to anxiety in the patient due to visualization of syringe, needle and other paraphernalia associated with the block technique.

Period 2:
Period 2 consisted of readings that were recorded during deposition of anaesthetic solution for both groups.

In Periodontal ligament injection technique (Group 1), Period 2 was divided into 2 (A) and 2 (B).

- Period 2 (A) - Noting of heart rate was done at 15-second intervals during deposition of anesthetic solution on mesial aspect of the molar (2 readings)
- Period 2 (B) - Noting of heart rate was done at 15-second intervals during deposition of anesthetic solution on distal aspect of the molar (2 readings)

In IANB technique (Group 2), Period 2 heart rate was noted at 15-second intervals through the period of anesthetic solution deposition (4 readings).

Table 3 gives descriptive statistics for Period 2 and paired sample test results. It is observed that the mean heart rate for Group 1 is marginally higher than in Group 2 in Period 2. This difference from the pattern of Group 2 readings higher than Group 1 readings is probably just a chance of mathematical averages and not significantly related to overall presentation of data collected.

For paired t test at Period 2, there was no significance of difference between the 2 groups. This may indicate that the actual insertion of needle and process of solution deposition over Period 2 (consisting of four, 15 seconds interval) did not cause immediate anxiety in either group patients.

Period 3:
In Period 3, heart rate was noted at 15-second intervals through 2 minutes soon after deposition of the anaesthetic solution (8 readings). Table 4 gives descriptive statistics for Period 3 and the paired sample test results for those readings.

The mean obtained for Period 3 of Group 1 patients is less than in Group 2. The comparison of the results of Paired t-test for Period 3 between the two groups indicated significance of difference between the two groups.

Period 3 consisted of 8 readings over 15 seconds interval, totalling to 2 minutes. In these 2 minutes, the anxiety of the patient in relation to the injection technique showed evidence by definite increase in heart rate, with Group 2 (patient receiving inferior alveolar nerve block) showing significantly higher increase in heart rate as compared to Group 1 (patient receiving Intraligamentary anaesthesia). This difference was statistically significant as $p < 0.05$. There may be several reasons for greater anxiety in patients in Group 2 receiving IANB. About 1.8 ml of anaesthetic solution is deposited into the pterygomandibular space over a period of approximately 2 minutes. The patient received a greater quantity of local anaesthetic and the needle is within the tissues for a longer duration of time. Both these factors can cause increased anxiety in the patient and influence the heart rate with a spike.

Period 4:
In Period 4, heart rate noted at 2-minutes intervals for 10 minutes following completion of local anaesthetic delivery (5 readings). Table 5 gives descriptive statistics for Period 4 and the paired sample test results. It is the longest period in which 5 readings were taken at 2-minute intervals, totalling to 10 minutes from start to end. In this period on application of the paired t test, the average of Group 2 was found to be significantly more than Group 1.

Period 4 readings should ideally show an approximate return of heart rate to the baseline readings and Group 2 readings show a significantly higher end reading as compared to Group 1. This indicates that even after the administration of Inferior alveolar nerve block, there is a sustained higher heart rate in Group 2. We observe that in Group 1, Period 1 readings showed increase in heart rate but by the end of Period 4 heart rate was found to return back to the baseline readings whereas in Group 2, Period 1 demonstrated an increase in heart rate which remained high even at the end of Period 4.

This suggests that even after completing the delivery of anaesthetic solution, Group 2 patients still demonstrated significant increase in heart rate which indirectly is an indicator of anxiety experienced even after the delivery of anaesthetic solution by IANB.

One argument for raised heart rate in Group 2 patients is that the adrenaline in anaesthetic solution causes a sustained increase in heart rate. The Group 1 patients also receive the same anaesthetic solution but in a smaller quantity, as Intraligamentary anaesthetic delivers 0.2 ml of the anaesthetic cartridge, per root or site whereas IANB delivers 1.8 ml anaesthetic solution.

In a study comparing the effect of 4% Articaine with 1:100,000 epinephrine v/s 1:200,000 epinephrine, Lasemi et al found that the pulse rate with 1:100,000 Articaine to epinephrine was a little higher than with 200.000 epinephrine. The alterations in this parameter were kept constant in both groups and no significance of difference was found between them ($P = 0.6$). In this study, both groups received Inferior alveolar nerve block[6].

Troullos et al. also reported an increase in heart rate with larger volumes of epinephrine containing anaesthetic formulations[7]. Various

authors [8,9,10,11] have reported an increase in heart rate which was found to be transient (46% to 85% of the time) with the Stabident IO injection of epinephrine-containing solutions. A study compared the anaesthetic efficacy of intraosseous injection of 0.9 ml of 2% lidocaine (1 : 100,000 epinephrine) with IANB. In the study, Reitz et al[19] found that 68% of the subjects reported raised heart rate during the deposition or for 2 minutes after the injection. This was compared with only 5% reporting such an increase during the mock intraosseous injection. This subjective reporting of raised heart rate was found to correlate with objective findings of the patients' ECG recordings by Replogle et al[12] in their study.

In a study of effect slow and fast deposition rate of anaesthetic solution in intraosseous injections, Susi et al observed that intraosseous injection of 1.4 mL of 2% lidocaine with 1:100,000 epinephrine using Wand™ at a rate of deposition of 45 seconds resulted in a higher heart rate (21 to 28 beats/min) when compared to 4-minute and 45-second deposition rates when either Wand™ or traditional syringe was used (10 to 12 beats/min).[13] Both these studies showed a correlation between increased heart rate and intraosseous nature of the anaesthetic technique. But Periodontal injection is not directly intraosseous in nature, hence rapid absorption into systemic circulation does not happen.

Nusstein et al compared the pain of injection, increase in heart rate, and pain after injection of articaine and lidocaine in Intraligamentary injection given using a computer-controlled local anaesthetic delivery system. They found that there were no significant differences in pulse rate between Period 1 (baseline) and Period 2-5 for both anaesthetic solutions, which would indicate that the Intraligamentary injection did not cause a significant or meaningful increase in heart rate. That is, the readings during and after the Intraligamentary injection were statistically the same as at baseline.[3]

Smith et al reported that the epinephrine (1:100,000) present in anaesthetic solutions which are administered via intraosseous, periodontal ligament, or intravenous routes caused a rapid and transient period of hypotension along with tachycardia that could be significant.[14] Lillienthal described similar changes in patients given catecholamine-containing anaesthetics by intraosseous route.[5]

From the above comparative discussion, it is apparent that Periodontal ligament injection has significantly lesser potential to cause anxiety when used in patients being treated with single sitting root canal treatment as compared to patients receiving Inferior alveolar nerve block. Thus, the Null hypothesis is disproved and the Alternate hypothesis is accepted.

CONCLUSION

Within the limits of human error, we surmise that Periodontal ligament injection has significantly lesser potential to cause anxiety when used in patients being treated with single sitting root canal treatment as compared to patients receiving Inferior alveolar nerve block. We further recommend that Periodontal ligament injection may replace IANB in the recommended protocol for single sitting root canal treatment as this could lead to reduced fear and anxiety in the patient and improve patient's compliance towards root canal treatment.

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