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Needle Gauge Influences Pain Perception During Intrapulpal Anaesthesia - A Randomized Clinical Trial

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ABSTRACT

Objective: The purpose of this randomized trial was to assess the pain perception during intrapulpal anesthesia (IP) using thinner gauge needles and syringes with or without topical anaesthesia as an adjunct.

Methods: One hundred patients, on whom the inferior alveolar nerve block and intraligamentary injections failed, were recruited for the trial. Block randomization was performed and the patients were allocated into 4 groups based on the needle gauge and topical application of anaesthesia prior to IP injection. In two groups (27GN, 31GN) the patients received IP injection with 27 gauge or 31 gauge needles. The patients of other two groups received topical lignocaine-prilocaine mixture prior to the IP injection with 27 or 31 gauge needles, respectively (27GT, 31GT). The visual analogue scale (VAS) was used to assess the pain immediately after IP injection and after cleaning and shaping by a blinded outcome assessor. The Kruskal-Wallis test for overall comparisons followed by the post-hoc analysis using the Conover's test ($P<0.05$) was done. Chi-square and Fischer exact test was used to assess the proportion of patients who were comfortable during IP anaesthesia.

Results: The intensity of pain during IP administration with 31GN and 31GT (3.7 and 2.3 respectively) was significantly less in comparison to 27GN and 27GT (5.6 and 5.7 respectively). The proportion of patients who were significantly comfortable with IP injections in the groups 31GN and 31GT (52% and 80% respectively) were more (VAS<4) when compared to 27GN and 27GT (12% and 8% respectively). Topical application of lignocaine-prilocaine reduced the pain on IP injection significantly when used as an adjunct with 31 gauge needles. The anaesthetic success of IP anaesthesia was comparable and 100% (VAS scoring <4) in all the groups.

Conclusion: Thinner gauge needles (31 gauge) significantly reduce pain perceived during IP anaesthesia. Topical anaesthesia with lignocaine-prilocaine acts as an effective adjunct only with 31gauge needle.

Keywords: Anesthesia, dental pulp, inflammation, intraoperative pain, lidocaine, prilocaine

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HIGHLIGHTS

- The gauge of the needle strongly influences the pain perceived while administering intrapulpal (IP) injection.
- Thinner gauge insulin needles (31 gauge) significantly reduce pain during IP anaesthesia and ensures higher patient comfort during the procedure.
- The use of topical anaesthesia further reduced the pain perception with use of 31 gauge insulin needles.

INTRODUCTION

Achieving profound anaesthesia for endodontic treatment in patients with symptomatic irreversible pulpitis of mandibular molar is unpredictable. The success of inferior alveolar nerve block (IANB) in such clinical condition ranges approximately between 28-45% in mandibular molars (1). The two main techniques that are practised to increase the anaesthetic efficacy during the procedure are prescribing pre-emptive medication and supplemental intraoperative anaesthesia administration. Clinically, various supplemental anaesthetic techniques have been used for managing a tooth which resists anaesthesia and the success rates of achieving pulpal anestheisa with these techniques are varied (2). It has been observed that 5-10% of the patients ultimately will require intrapulpal (IP) anaesthesia for continuance of the endodontic treatment (2). Birchfield and Rosenburg attributed the efficacy of intrapulpal anesthesia to the backpressure created during the administration of injection, irrespective of the solution being injected. (3).

The main disadvantage of this technique is that the patient has to endure sharp severe pain during the administration of the intrapulpal anaesthesia. Although being a successful supplemental technique in achieving profound anaesthesia for endodontic procedure, this remains a less adopted and practiced anaesthetic technique. Application of topical anaesthesia with 20% benzocaine gel and hyaluronidase on the exposed pulp prior to intrapulpal supplemental anaesthesia has been shown to reduce the pain perception during endodontics (4). The topical application of a lidocaine/prilocaine combination performs similar to benzocaine and ropivacaine gel in reducing pain from needle insertion but has longer duration of soft tissue anesthesia when applied on oral mucosa (5).

In medical literature, it has been observed that the apprehension of needles perceived by the patients has led to evolution of practises that can reduce pain during injections. One such modification is the use of thinner gauge needles for reducing the pain perception during the procedure. Needle designs like gauge, bore diameter, bevels and sharpness contribute to the perception of pain during the injection procedure (6). The use of thinner gauge needles are effective in reduction of pain during needle insertion in medical procedures like arterial puncture (7), intravitreal puncture (8) and insulin administration (9). On the contrary, the role of needle gauge during IANB has proven to be not significant in reducing the pain perception during injection (10). However, needle insertion into skin and mucosa may be different from inserting a needle into the pulp tissue. Usually, a 27 gauge short needle is used for intrapulpal injections (11).

Erten et al., evaluated that 25% of patients were fearful at the sight of the needle and 24% had fear for the sensation of the injection (12). A recent systematic review reported that the apprehension of injection, produced the most anxiety amongst patients, requiring non- surgical root canal treatment or dental extraction (13). It has been observed that by reducing the pain during supplemental injections, during endodontic procedures, it minimizes the fear and anxiety of patients and increases the co-operation of the patient for the procedure (14). There is lack of evidence on the role of needle gauge in pain perception and discomfort while administering the intrapulpal anaesthesia.

Thus, the null hypothesis of this double blinded randomized clinical trial was that there will be no difference in pain perception during intrapulpal injection with thinner gauge needles and topical anaesthesia. Hence, the primary objective of the study was to assess the pain perception during intrapulpal anaesthesia using thinner gauge needles and syringes with/without topical anaesthesia as an adjunct in mandibular molars. The secondary objective is to assess the anaesthetic efficacy of intrapulpal injection using different needle gauges.

MATERIALS AND METHODS

A prior protocol approval and registration

This study was designed as a parallel arm randomized double blinded clinical trial and reported according to the revised consolidated standards of reporting trials (CONSORT) statement updated in 2010 (Fig. 1). The study protocol was reviewed and approved by Institutional Ethics Committee of Meenakshi University, Chennai, India. (Ref.No. MADC/IRB/XVII/2017/327). The trial was conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). The protocol was developed and registered at the clinical trial registry of India, (www.ctri.nic.in, CTRI/2018/08/015227).

Sample size calculation and patient participants:

In order to determine the sample size a pilot study was conducted. The minimum number of patients to be enrolled in each group was calculated to be 25 (allocation ratio of 1:1) using OpenEpi (www.openepi.org) (15) with an alpha error set at 5% and statistical power of 80%. Based on the primary objective, i.e., the difference in pain perception between the groups was set at 40% (based on the pilot study). The trial was commenced in March 2018 and completed in July 2018. A total of two hundred and twenty-one patients were screened by a postgraduate student (not related to the trial) in the out-patient clinic of Department of Conservative Dentistry, Meenakshi Ammal Dental College and Hospital, Chennai, India. Based on the inclusion criteria, two hundred and twelve patients consented and enrolled in the study.

Inclusion criteria

Systemically healthy patients (Category: ASA 1) aged between 18-50 years with mandibular molar teeth diagnosed with symptomatic irreversible pulpitis were included. Diagnosis was based on clinical and radiographic examination and pulp sensibility testing. Teeth with moderate, sharp, spontaneous pain, preoperative VAS score: >5 or pain stimulated with hot or cold with lingering response even after removal of the stimulus, without pain on biting and on percussion, as well as with no periapical changes/lesion (periapical index ≤2) were included. The teeth that responded positively to electric pulp tester as well as a those exhibiting a lingering, exaggerated response of more than 10 seconds to cold test (ethyl chloride spray) were included.

Exclusion criteria

Teeth with crown/root fractures, acute or chronic apical abscess, necrosis, compromised periodontium and open apex were excluded. Patients who could not provide consent, interpret the Visual Analog Scale (VAS), medically compromised patients, pregnant and lactating women were excluded. Patients having history of allergies to local anaesthetic solutions, long term medications that influenced pain threshold, analgesics, steroids and/or antibiotics in the past 24 hours were excluded from the trial. Teeth which were observed to be non-vital on access cavity preparation were also excluded.

Intervention

Standard inferior alveolar nerve block (IANB) was administered using a 27 gauge 1 1⁄2-inch needle (Monoject; Sherwood Medical, St. Louis, MO) containing 1.8 ml of 2% lidocaine with 1:100.000 epinephrine (Sigma Pharmaceuticals, Bhopal, India) attached to a standard aspirating syringe. The needle was inserted laterally at the middle portion of pterygomandibular raphae to contact bone, with the needle bevel directed toward the bone, slightly withdrawn, aspirated, and the solution was deposited. After a 10 minute interval, pulpal anaesthesia

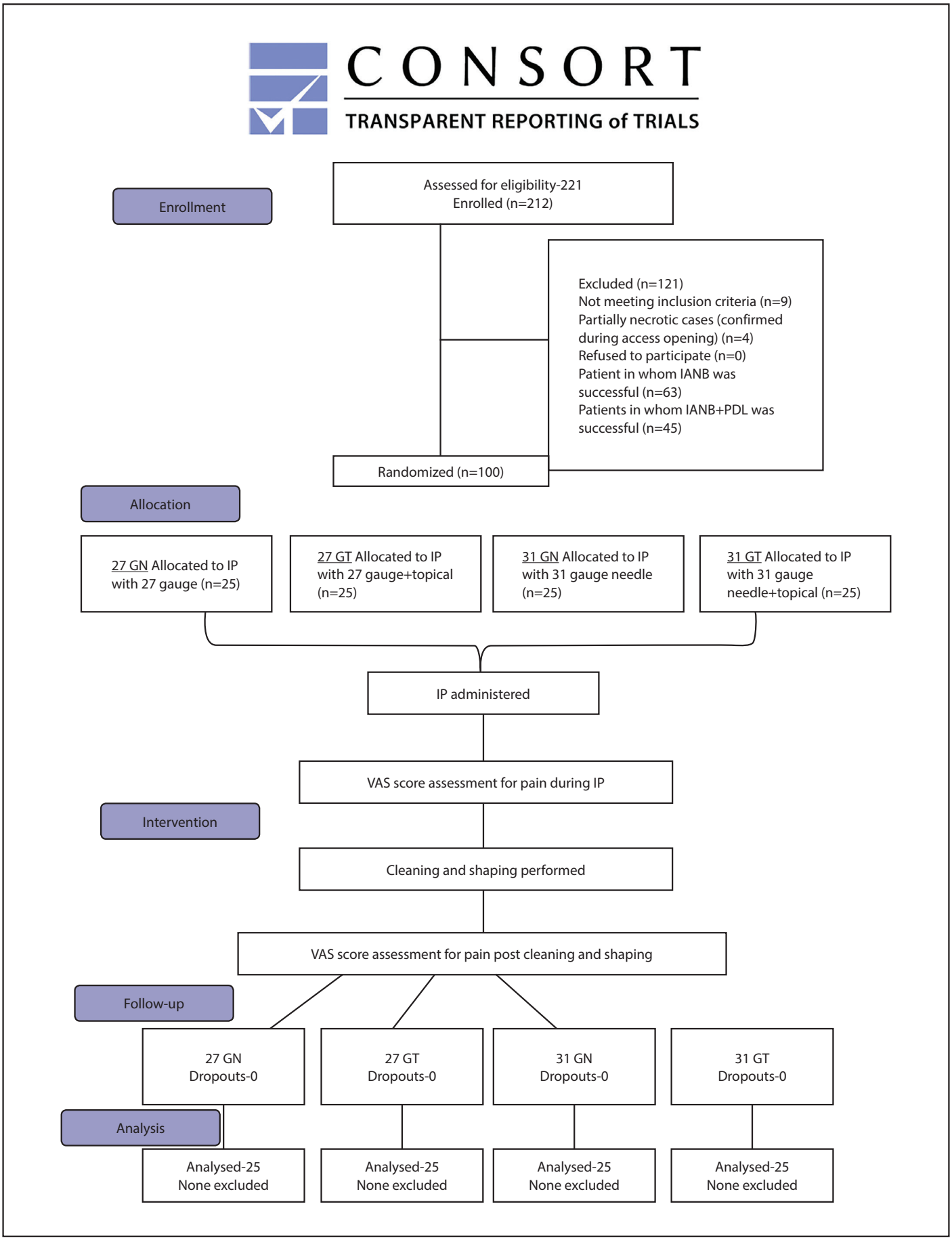

Figure 1. Consort flow of the participants throughout the trial

was confirmed using electric pulp tester. The anaesthesia was considered successful if the subject did not respond to the maximum output of the pulp tester. Additionally, the patient was also asked for lip numbness. If the patient reported sensitivity to vitality testing or if profound lip numbness was not achieved, the procedure was considered as missed IANB and the nerve block was re-administered. The tooth was isolated with a rubber dam, and endodontic access was initiated using a 014 round carbide bur (Dentsply International York USA). Intraligamentary injection was administered as supplemental anaesthesia with 2% lidocaine with 1:100.000 epinephrine at the line angles of the tooth to those patients who experienced moderate to severe pain during access opening. The 27 gauge needle was inserted at a 30 degree angulation to the long axis of the tooth penetrating until it was wedged between the tooth and the crestal bone, the bevel of the needle facing the root and 0.18-0.2 ml of anaesthetic solution was deposited into the periodontal ligament on the mesial and distal aspect. All the anaesthetic procedures were performed by a senior endodontist with 5 years clinical experience. The patients were instructed to report any discomfort during the procedure. Success of anaesthesia was defined as the ability to obtain access and instrumentation of the root canals with no pain or no more than mild pain (VAS<4, patients with no/mild pain scores).

The simple visual analogue scale (VAS) pain scoring system was employed in this study for recording the level of pain during recruitment of patients, after intrapulpal injection and after cleaning and shaping. The VAS system of pain assessment is a line of 10 cm length, with 0 signifying no pain on one end and 10 representing the worst pain imaginable (score 1-3 is considered mild pain, 4 and 5-moderate pain, 6 and 7-severe pain, 8 and 9-very severe pain).

Randomization /Allocation concealment /blinding

One hundred patients who experienced pain (moderate to severe pain) on pulpal exposure were randomized and recruited into the trial. Random sequence generation and allocation concealment was undertaken by a person not involved in the trial. Permuted block randomization with 20 patients in each block was generated using randomization software (www.randomiser.org). Sequentially numbered opaque sealed envelopes (SNOSE) were used for allocation concealment and the code generated by the randomization was written on the envelope. Once the patient was allocated to the intervention group, the number was noted in the patient's case sheet and decoded in the end of the trial. The patients received an intrapulpal anaesthesia either with 27 gauge (½ inch needle, Nipro Corporation, Osaka, Japan) or 31 gauge, (6 mm Needle Insulin Syringes 1 mL, Ultra-Fine™ Beckton Dickinson, New Jersey, USA) insulin needles and syringes. The patients were sub-categorised based on the application of topical eutectic mixture of local anaesthesia (Prilox, Neon Laboratories Ltd Mumbai, India) gel, which consists of 2.5% lidocaine and 2.5% prilocaine, measured using spoon excavator of 1.5 mm head diameter (Patterson dental supply, Inc. Mendota Heights, Minnesota, United States). The topical anaesthesia was carried with a cotton pellet (Size # 000, Roeko, Coltene, Germany) measuring 3 mm in diameter.

27GN - Patients randomized into this group received (IP) supplemental anaesthesia with 27 gauge insulin needle of 12.7 mm length in the exposed pulp. Prior to the intrapulpal injection, a cotton pellet (Size # 000, Roeko, Coltene, Germany) without any topical anaesthesia was held firmly on the exposed pulp for 30 seconds to mimic application of topical anaesthesia.

27GT - Patients randomized into this group received topical anaesthesia with lidocaine-prilocaine mixture for 30 seconds on the exposed pulp prior to administration of IP anaesthesia with 27 gauge insulin needle.

31GN - Patients randomized to this group received intrapulpal supplemental anaesthesia with 31 gauge insulin needle. A cotton pellet without any topical anaesthesia was applied, identical to the 27GN group.

31GT - Patients randomized into this group received topical anaesthesia with lidocaine-prilocaine mixture for 30 seconds on the exposed pulp prior to administration of IP anaesthesia with 31 gauge needle.

IP anaesthesia was administered by wedging the needle in to the exposed pulp and 0.2 ml of 2% lidocaine with 1:100.000 epinephrine was administered under pressure. To achieve adequate pressure build up, stoppering technique with cotton pellet (Size # 000, Roeko, Coltene, Germany) was performed.

Outcome assessment

Pain during the IP injection was assessed immediately after the supplemental injection by a blinded assessor using VAS scoring (NS). The access cavity was completed using 014 round carbide bur and Endo Z burs (Denstply International, York, USA). The root canals were subsequently cleaned and shaped using M two NiTi rotary files (VDW, Munich, Germany). Post instrumentation, the patient was assessed for discomfort during the instrumentation procedure using VAS scoring by a blinded assessor (anaesthetic efficacy) (NS). In our study, the patient and the outcome assessor were blinded. The intrapulpal anaesthetic procedure was considered to be comfortable (assessment after IP anaesthesia) and successful (assessment after cleaning and shaping) when the VAS was <4 (patients with no/mild pain scores) and procedure was continued.

The needle cross section of both 27 gauge and 31 gauge insulin needle was analysed using SEM (FEI Quanta 200 F, ETH Zurich, Switzerland) for the measurement of number of bevels as well as inner and outer diameter, respectively. (Figs. 2, 3).

Statistical analysis

The data was analysed using R version 3.5.1. Following descriptive analysis, the intensity of pain (mean, median pain score) after IP injection and after cleaning and shaping were analysed. As the variables were not normally distributed by the Shapiro Wilk test, the inter group comparison was performed using Kruskal-Wallis test. The post -hoc analysis was performed using Conover's Test using the PMCMR package for R statistics software. The proportion of patients who perceived lesser pain between the groups (incidence of pain) were analysed using Chi Square and Fischer exact tests. A p value<0.05 was considered to be statistically significant.

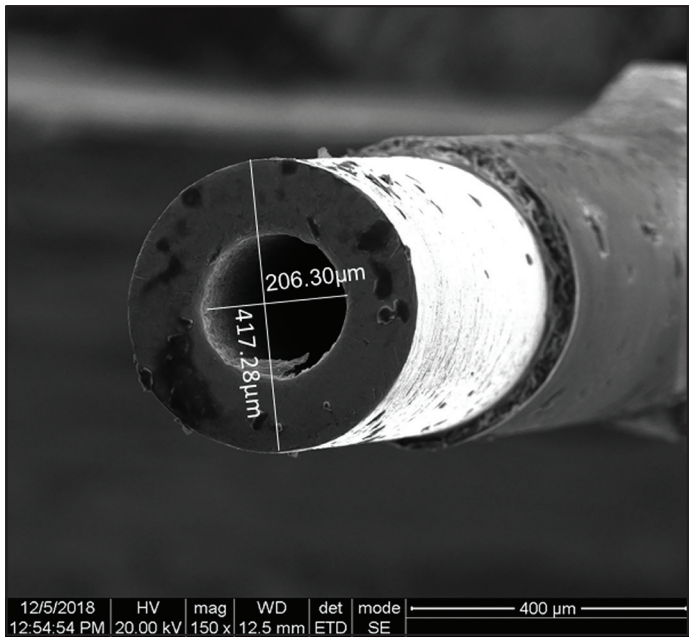

Figure 2. The inner and outer diameter of 27-gauge needle

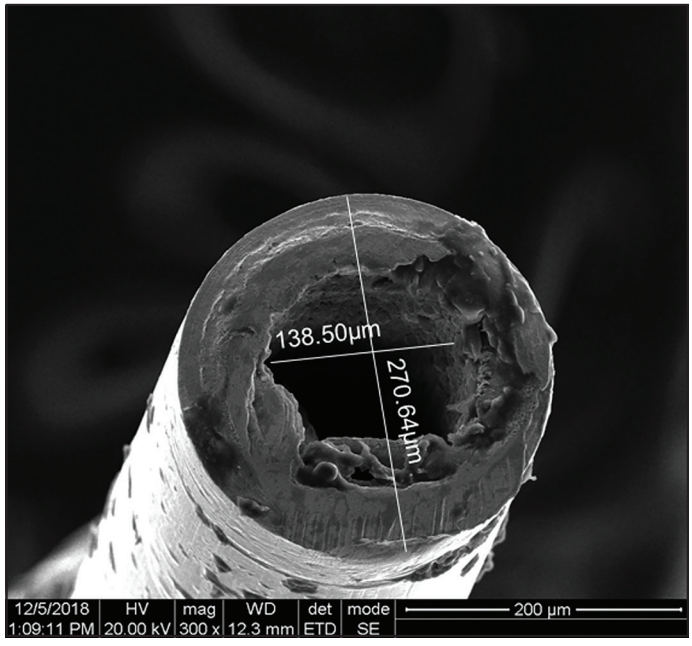

Figure 3. The inner and outer diameter of 31-gauge needle

RESULTS

The baseline demographic details and clinical characteristics are tabulated (Table 1). Analysis of baseline data showed no statistical difference in terms of age, gender, tooth type and preoperative VAS scoring. The intensity of pain (Mean, SD) during the administration of intrapulpal anaesthesia in 27 GN, 27GT, 31GN and 31GT was 5.7 (1.6), 5.6 (1.7), 3.7 (1.9) and 2.3 (1.5), respectively (Table 2). It was observed that 80% of patients were comfortable during IP administration in 31GT in comparison to 52% of patients in 31GN. Whereas, the proportion of patients observed to be comfortable during administration of IP with 27GN and 27GT were 8% and 12%, respectively (Fig. 4). The mean VAS scoring during cleaning and shaping in 27 GN, 27GT, 31GN, 31GT was 0.32 (0.6), 0.4 (0.8), 0.08 (0.3), 0.08 (0.4), respectively (Table 3). There was no statistical difference between the anaesthetic efficacy among the four IP techniques administered (P>0.05). The success of anaesthetic technique was found to be 100% regardless of the gauge of the needle or topical anaesthesia used.

DISCUSSION

Perception of pain during an injection is due to insertion of needle and deposition of drug. Needle insertion triggers type A nerve fibres which cause the initial sharp intense pain (6). Further, depositing the anaesthetic solution expands the tissue and both type A and type C nerve fibres are stimulated which leads to pain perception. Pain during needle insertion is influenced by the needle design, gauge, and use of topical

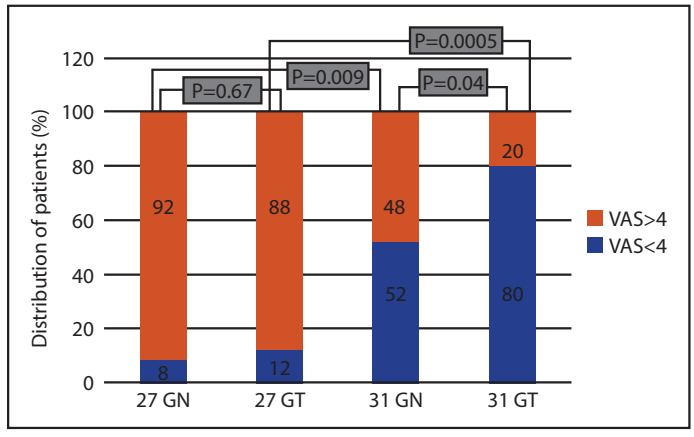

Figure 4. Distribution of patients with different VAS Score during Intrapulpal injection among the groups

TABLE 1. Base line demographic data and preoperative VAS score for the four IP techniques

Parameter	27GN (n=25)	27GT (n=25)	31GN (n=25)	31GT (n=25)	P value
Age					
Years (SD)	36.68 (9.75)	37.2 (11.0)	33.16 (11.82)	38.8 (13.73)	0.38
Gender, n (%)					
Male	13 (52)	16 (64)	12 (48)	15 (60)	0.65
Female	12 (48)	9 (36)	13 (52)	10 (40)	
Tooth type, n (%)					
First molar	159 (60)	17 (68)	18 (78)	20 (80)	0.48
Second molar	10 (40)	8 (32)	7 (28)	5 (20)	
Preop VAS Score					
Mean (SD)	7.20 (1.2)	6.92 (1.3)	7.04 (1.50)	6.64 (0.99)	0.461

TABLE 2. Mean and Standard deviation (SD), Median, Interquartile (IQR) VAS pain score during intrapulpal anaesthesia among the groups 27GN, 27GT, 31GN, 31GT

Parameter	27 GN	27 GT	P value
Mean (VAS score)	5.7	5.6	
Standard deviation (SD)	1.6	1.7	0.08*
Median	6	6	
Interquartile (IQR)	3	2	
	31 GN	31 GT	
Mean (VAS score)	3.7	2.3	
Standard deviation (SD)	1.9	1.5	<0.0001*
Median	3	2	
Interquartile (IQR)	3	2	
P value	0.03**	<0.0001**	

*Comparison between (27 GN and 27 GT) and, (31GN and 31GT), **Comparison between (27 GN and 31 GN) and, (27GN and 31GT)

TABLE 3. Mean and Standard deviation (SD), Median and Interquartile range (IQR) VAS pain score during cleaning and shaping among the groups 27GN, 27GT, 31GN, 31GT

Group	Mean	SD	Median	IQR	P value
27GN	0.32	0.62	0.00	0.00	
27GT	0.40	0.81	0.00	0.00	>0.05
					Statistically not significant
31GN	0.08	0.27	0.00	0.00	
31GT	0.08	0.40	0.00	0.00	

anaesthesia, depth of insertion and the nature of the tissue into which the drug is deposited. The rate of deposition, bore of the needle, buffering agents and compliance of the tissue influence the pain during deposition of the solution (6).

The low compliance of pulpal tissue opposes the spread of deposited solution along the path of least resistance which in turn increases the interstitial pressure (16). This increase in back pressure is speculated to produce the anaesthetic effect. The other probable mechanism by which IP injection causes pulpal anaesthesia is by direct tissue injury or compression of nerves (16). The cumulative effect of increase in interstitial tissue pressure and the tissue/nerve injury might directly trigger the fast conducting, myelinated A delta fibres (6) which is probably responsible for the intense pain during intrapulpal injection. Pain creates an unpleasant emotional experience leading to increased patient anxiety and may also reduce patient's confidence on the endodontist. Unfortunately, not many clinical trials have addressed to reduce the pain perceived during IP injections. The role of topical anaesthesia prior to intrapulpal injection has been previously studied (4). This may only improve the patient's comfort during needle insertion but the major discomfort during deposition is scarcely discussed. This is the first clinical trial that assessed the role of needle gauge in reducing pain during intrapulpal injection.

Anxiety plays a major role in non-adherence of insulin therapy among diabetic patients. It has been proven that up to 94% of insulin users had phobias, distress and anxiety (17) and 33% of patients dreaded their injections (18). To overcome these injection related discomforts newer insulin needles (ultrafine, micro-fine, nanofine) have evolved by modifying the gauge, bore, length and bevel of needles (19).

The insulin needles are triple bevelled and treated with special Microbonded lubrication for comfortable injection (20). Thus, in this trial ultrafine 31 gauge and 27 gauge insulin needles and syringes were used for administering intrapulpal injection. Therefore, the other syringe dimensions and needle designs were standardised.

In this trial, 31G needle produced the least pain perception than 27 gauge needle during IP injection. It was observed that 80% of patients were comfortable during IP injection with 31 gauge with topical anaesthesia whereas, only 8-12% of patients were comfortable during IP injection with 27 gauge needles. The outer and inner diameter of the 31 gauge is 270µ and 134µ while that of 27 gauge is 417µ and 206µ respectively (Figs. 2, 3). The outer and inner diameter of 27 gauge needle is 1.5 times more than a 31 gauge needle, thus, probably during needle insertion, it contacts a greater area of pulp and might trigger more type A nerve fibres. Secondly, the volume of solution deposited with a 31 gauge needle is comparatively lesser because of smaller bore diameter which might have created lesser interstitial pressure during deposition of anaesthetic solution.

It has been proved that the gauge of the needle does not affect the pain perception during IANB procedure. The tissue distensibility at the inferior alveolar area is high and pressure at the tip of needle during the IANB procedure is less when compared to that of intrapulpal injection (16). The time taken for the anaesthetic solution to spread which causes the peak initial pressure to reduce by 50% is 1.6 seconds for IANB, whereas it takes 650 seconds during an IP injection (16). Thus, IANB may not be as painful as an IP injection.

Anaesthetic efficacy of topical application of lidocaine-prilocaine mixture prior to IP injection, when used as an adjunct, produced significant reduction in pain perception only with patients who received IP with 31 gauge. This probably could be attributed to the masking of anesthetic effect of the topical anesthetic by the excess back pressure created by thicker 27 gauge needle. Hence, it was concluded that, the use of topical anaesthesia as an adjunct for intrapulpal injection was beneficial only with 31 gauge needle.

In this trial the success of anaesthetic technique was found to be 100% regardless of the gauge of the needle used. The success of IP anaesthesia depends on the back pressure created. Pashley et al observed an average pressure of 170 psi during intrapulpal injection technique. Gutta-percha, cotton or polymer can be used as a stopper (if the needle cannot be wedged) to achieve adequate pressure (16). The increase in intrapulpal pressure can act as a double-edged sword by enhancing the anaesthetic effect and also the pain perception during the procedure. It has been proven that the use of an obturator increases the backpressure 6 times during IP injection (21).

The use of polymer obturator in an empty root canal could have produced such high values. The presence of a resilient

pulp tissue with an inherent interstitial pressure in the canal might alter the results. In order to achieve adequate pressure during IP injection, a stopper with cotton pellet was performed in this trial. A stopper is usually required when the pulpal exposure is larger than the needle size, a cotton pellet is pulled over the needle and placed into the chamber. This pellet is firmly packed and held in place during IP injection procedure (22).

The advantage of using a 31 gauge needle was that it allowed wedging of needle even through a smaller pulpal exposure and the volume of solution delivered through the thinner bore (134 µ) would have been less. It can be assumed that, adequate pressure to cause pulp anaesthesia was created even with less volume of solution. The advantage with the lesser outer diameter (270µ) is that the excess solution seeps out through the side of the 31 gauge needle and did not increase the pressure extensively on the pulp. The insulin syringes have an advantage of smaller barrel and plunger diameter when compared to standard syringes. The intra-barrel pressure created during injection might be comparatively less for insulin syringes when compared to standard syringes due to the difference in the diameter of plunger (16). Thus, the use of insulin syringes and 31 gauge needles aided in creating adequate pressure to achieving successful pulpal anaesthesia with minimal pain perception. An interesting finding was that patients with pulp chamber calcifications required intra pulpal injection in more than one orifice (4-6 patients/group). This finding has not been reported previously and needs further investigation. The finer and flexible 31 gauge needle allowed easier placement of needle compared to 27 gauge in the calcified canals.

The use of computer controlled local anaesthetic delivery (CCLAD) system has proven to increase the efficiency of IANB and intraligamentary supplemental techniques. The use of CCLAD could have improved the success of IANB and intraligamentary injection in the present trial. The overall success rate of IANB and intraligamentary supplemental anaesthesia in our study was found to be 52% (108 patients) which is in accordance to previous literature (23). The other factor that needs to be observed is the manual pressure given during the IP injection might vary between operators. To overcome this, all the anaesthetic procedure was performed by a single operator.

Potential limitation of the present clinical trial could be the lack of standardisation of the size of pulp exposure and the depth of insertion of the needle into the exposure. It is proven that the efficacy of IP anesthesia depends on how far the needle is advanced and wedged under pressure, more than the standard depth of needle penetration (24). Thus, we ensured that the needle was wedged adequately before anesthesia. By having stringent clinical conditions (confounders), the internal validity of the study improves, but compromises the external validity (generalising the effects to the population). Extrapolation of the results to a defined population within a pertinent clinical setting determines the usefulness of any clinical trial (25).

This randomized trial was performed using the CONSORT guidelines and was double blinded to avoid bias. The results of the trial are translatable into clinical practice to reduce the pain during IP administration, together with good anesthetic efficacy, without the need of any computerized device.

Use of insulin needles for IP anesthesia provides a pragmatic, simple and cost effective, alternative to the conventional techniques in reduction of pain perception during the administration of intrapulpal injection. Convincing a highly anxious patient for intrapulpal anesthesia is a great challenge. The smaller size and lesser pain produced by 31 gauge needle would help managing such difficult clinical situations.

CONCLUSION

Within the limitation of this trial, it has been concluded that the pain perception and discomfort during IP was significantly lesser in patients who received IP injection with 31 gauge insulin needles and syringes. Use of topical anesthesia was found to be effective in reducing pain when used as an adjunct with 31 gauge needles during IP injection.

Disclosures

Conflict of interest: The Author(s) declare(s) that there is no conflict of interest.

Ethics Committee Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Meenakshi Academy of Higher Education and Research/Indian Council of Medical Research MADC/IRB/XVII/2017/327) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Peer-review: Externally peer-reviewed.

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Authorship contributions: Concept – N.S., V.N.; Design – N.S., V.N., D.K.; Supervision – N.S., V.N., D.K.; Materials - None; Data collection &/or processing – V.K., K.K.; Analysis and/or interpretation – V.K., K.K., N.S.; Literature search – V.K., K.K., D.K.; Writing – N.S., V.K., K.K.; Critical Review – N.S., V.N., D.K., K.K., V.K.

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