



PATIENT RELATED OUTCOMES OF 2% LIDOCAINEHYDROCHLORIDE INFILTRATION FOR SUBGINGIVAL SCALING AND ROOT PLANING: A RANDOMIZED DOUBLE-BLIND SPLIT-MOUTH STUDY

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ABSTRACT

BACKGROUND AND OBJECTIVES

The selection of a particular anaesthetic agent depends on the arch, number of teeth requiring anesthesia, the area of soft tissue anesthesia required for the subgingival scaling. The objectives of this study were to evaluate and comparative anaesthetic efficacy of the infiltration anesthesia of 4% articaine with 1:100,000 epinephrine (4%Ar + Ep) and 2% lidocaine with 1:100,000 epinephrine (2%Li + Ep) for subgingival scaling and root planing (SRP) in mandibular arch in terms clinical anaesthetic parameters in relation to patient compliance including anxiety level, duration of anesthesia, pain perception and patient satisfaction with the procedure.

MATERIALS AND METHODS

This was randomized double blind split-mouth study. Study included 50 adult patient with generalized periodontitis received 4%Ar + Ep with 2%Li + Ep for subgingival SRP. Comparison of these anaesthetic solution was evaluated with the success rate, onset and duration of anesthesia. Anxiety level and VAS score were also recorded.

RESULTS

Both anaesthetic solutions were effective during subgingival scaling and root planing. The results of the study had shown no significant difference between both groups in terms of anxiety level. Subjects receiving 4% Articaine local anaesthetic solution has experienced less pain during the subgingival scaling and root planing. 4% articaine has shown longer duration of anesthesia of up to 2.61 hours. Results indicates that all patients were satisfied with both anaesthetic solutions for subgingival scaling and root planing.

CONCLUSION

Articaine was a suitable alternative for lidocaine for mandibular local infiltration in subgingival scaling and root planing. It was superior to lidocaine. CLINICAL RELEVANCE 4%Ar + Ep provides an effective anesthesia for routine subgingival SRP with better patient compliance.

Keywords: Local Anesthesia; Articaine; Lidocaine; Mandibular Infiltration Injection; Buccal Infiltration; Local Infiltration

INTRODUCTION

Non-surgical removal of plaque and calculus has been part of the initial phase of the management of patients with gingivitis and periodontitis for decades. It consists of patient motivation and oral hygiene instruction as well as mechanical removal of supra and subgingival plaque deposits¹.

Scaling and root planing have been shown in many studies to be an effective phase I treatment for periodontitis²⁻⁴ When utilized as part of a comprehensive treatment plan, scaling and root planing result in decreased gingival inflammation, bleeding on probing⁵, clinical attachment levels⁶, and probing depths⁷. The required complete removal of calculus from the root surface is technically and physically very demanding and becomes

more difficult as the periodontal sulcus becomes deeper with periodontal disease progression and in order to instrument the pocket and the root surface, anesthesia may be needed.

Local anaesthetic agents are the mainstay of intraoperative pain control. However, some patients are afraid of the pain associated with intraoral injections and may not like the prolonged numbness. This might lead to a reduced compliance in periodontal maintenance, especially for pain-sensitive patients or patients with needle phobia, also called trypanophobia⁸ One of the results from an observational study in China was that comfort during treatment is an important factor influencing compliance of patients with chronic periodontitis by educating patients about oral health and managing their comfort as much

as possible during treatment, enhances patient compliance for achieving better treatment efficacy.⁹

Achieving profound anesthesia is a prerequisite for most dental treatments as it allows the patient to be comfortable and the clinician to deliver treatment¹⁰ forty percent of all periodontal scaling procedures performed involve some kind of anesthesia (Astra Pain Control, personal communication, January 1997). Adequate pain control may be extremely important in gaining patient compliance with the maintenance therapy. The selection of a particular anaesthetic technique and agent depends on the arch, number of teeth requiring anesthesia, the area of soft tissue anesthesia required, and duration of the effect¹¹

Lidocaine, amide type revolutionized pain control in regional anesthesia by replacing procaine and other closely related ester-type compounds. Lidocaine when compared with procaine shown to be more potent having significantly rapid onset of action, profound anesthesia as well as longer duration of action. Lidocaine is the most widely used local anaesthetic agent for pain control because of its pharmacokinetic characteristics and low toxicity compared with other anaesthetics and hence make it safe for use in dental practice¹².

Lidocaine is contraindicated in patients with a known allergic reaction with local anesthesia. Stating that anaphylactic reactions to lidocaine are possible but rare. Lidocaine overdosing may lead to adverse effects such as drowsiness followed by loss of consciousness and even respiratory failure later on¹³. Highly concentrated lidocaine may be used when prolong the duration of anesthesia is required, However, care must be taken as the toxicity also increases¹⁴.

Rusching et al in 1969, articaine hydrochloride was synthesized by the name of carticaine and was first marketed in Germany in 1976. Malamed et al. reported articaine to be a safe local anaesthetic after comparing the drug with 2% lidocaine and epinephrine 1:100,000 and can be used in both adults and children. Articaine is out outstanding as the local anaesthetic indicated for dental procedures and control of postoperative pain. It has been reported that the duration of the articaine anaesthetic effect was longer when 2% lidocaine and 4% articaine were used for the inferior alveolar nerve block. Moreover, Articaine group has lower the number of cases in which re-anesthesia was needed¹⁵.

Various studies study were conducted to compare the clinical efficacy of 4% articaine with 1:100,000 epinephrine with 2% lidocaine with 1:80,000 epinephrine in patients undergoing irreversible pulpitis (Kanaa D et al 2012)¹⁶ (Shapiro et al 2018)¹⁷, dental extractions of impacted lower 3rd molar (Alejandro 2007)¹⁸, maxillary premolar (Hassan et al 2011)¹⁹ (Thakur et al 2020)

As the studies comparing of 4% articaine and 2% lidocaine in periodontal therapy are limited in the literature. To our knowledge this was to the first study aiming to evaluate anaesthetic efficacy of 4% articaine hydrochloride and 2% lidocaine hydrochloride infiltration in mandibular arch for

subgingival scaling and root planing.

OBJECTIVES

1. To assess anesthetic effectiveness of 2% lidocaine HCL infiltration for subgingival scaling and root planing in mandibular arch
2. To assess anesthetic effectiveness of 4% articaine HCL infiltration for subgingival scaling and root planing in mandibular arch
3. To evaluate and compare the anaesthetic efficacy of 4% articaine hydrochloride with 2% lidocaine hydrochloride for subgingival scaling and root planing in mandibular arch.

MATERIALS AND METHODS

Fifty patients were recruited from the outpatient Department of Periodontics at S.D.M. College of Dental Sciences and Hospital, Dharwad. The study protocol was reviewed and approved by the institutional review board (IEC Number: 2021/P/PERIO/94, Annexure 1) and was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000.

This trial was registered under clinical trial registry (ClinicalTrials.gov ID: CTRI/2021/06/034099 & Annexure 2) Fifty patients were selected according to above criteria. The informed consent was signed by them and information sheet regarding the need and design of the study was given to them.

Sample size calculation

The sample size determination was done using G Power sample size estimation software. Based on the prevalence of periodontitis as 28% (p), confidence interval of 95% (z) and confidence level of 10% (d), Sample size (N) was calculated by formula. $N = z^2 pq/d^2$ where q equals 1-p.

The error kept at 0.005 and power of the study kept at 0.8. The total estimated sample size was 27 and it was rounded off to 50. Since this was a split mouth design, the sample size of 50 indicates, 50 pair of sites with one treatment given on each site.

Inclusion and Exclusion Criteria

Inclusion criteria:

1. Subject with age group ≥ 18 years
2. All patient diagnosed with generalised periodontitis (classification 1999)
3. Subjects in whom the use of local anesthesia (Lignocaine and Articaine) is not contraindicated due to hypersensitivity or any other systemic condition
4. Subject without significant systemic illness.
5. Subjects indicated for subgingival scaling and root planing under local anaesthesia.

Exclusion criteria:

1. Pregnant & lactating females
2. Smokers
3. Subject who are otherwise not able to understand and interpret the verbal pain or anxiety scale due to mental challenge or any other reason
4. Subjects on medication such as antipsychotics, anti

depressants, and sedative hypnotics

Fifty patients were selected according to above criteria. The informed consent was signed by them and information sheet regarding the need and design of the study was given to them.

Experimental design

The split mouth double blind randomized clinical trial was conducted from November 2021 to May 2022. In each patient, the lower quadrants were randomly allocated to one of the two anesthetic solutions: A (SRP with 4% articaine solution right side; SRP with 2% lidocaine solution left side) or B (SRP with 4% articaine solution left side; SRP with 2% lidocaine right side). An investigator with no clinical involvement in the trial generated the allocation sequence using a permuted block design with a computer random number generator (allocation ratio 1:1). The allocation sequence was concealed in opaque sealed envelopes and the details of the series were unknown to the patients and investigator of the study. An investigator who was not involved in the data collection and treatment, performed the enrolment of patient and the assignment of sealed envelopes containing the treatment modalities of each quadrant. The opaque envelopes were identified with the initials of the patients name and date of birth. For each patient the envelope was opened immediately before the procedure. Anesthetic solution assigned in each patient was registered by a non-clinical investigator and kept concealed until completion of this study.

Treatment protocol

4% articaine hydrochloride with epinephrine 1:100,000 (Septanest Septodont, France) and 2% lignocaine hydrochloride with epinephrine 1:100,000 (lignospan special, septodont, France) cartridges were used in this study. A single experienced operator gave the infiltrations for all the subjects before the procedure using a standard aspirating syringe with 27 gauge (Septodont fusion syringe septodont Cambridge, ON, Canada) and 1.5 inch needle (septojet, septodont, France)

The following clinical parameters were recorded

Clinical Measurements

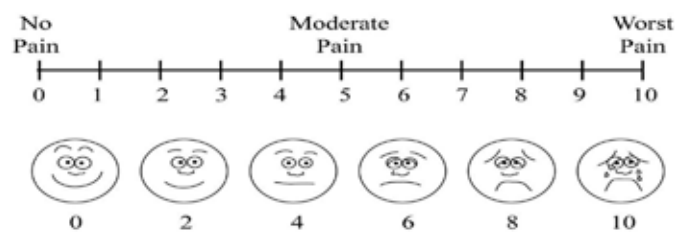
Before procedure:

1. Corah's anxiety scale score²⁰

This scale contains four multiple-choice items dealing with the patient's subjective reactions about going to the dentist, waiting in the dentist's office for the procedure and anticipation of scaling.

2. Visual analogue scale scores²¹ (VAS)

It is a straight, 100-mm line (10 cm), has marking from 0 to 10. While, 0 indicates no pain score 10 indicates worst pain. which was recorded before administration of anesthesia, during the procedure and after the completion of scaling and root planing



3. Duration of anesthesia²²

It was recorded from time of administration of anesthesia to time of wear-off of anesthesia.

4. Standardized Patients Satisfaction Questionnaire²³

The satisfaction with respect to procedure is evaluated by five multiple-choice items from extremely satisfaction to dissatisfaction

- Extremely satisfied
- Satisfied
- Little Satisfied
- No change
- Dissatisfied

Statistical Analysis

All clinical parameters were recorded and data was entered in excel sheet and it was subjected to SPSS 23 version software for statistical analysis. The significance level was set at 5% with P value 0.005. Chi square test was used to evaluate comparison of anxiety scale scores between group A and group B and the mean anxiety scores between the groups were calculated by independent-t test. Comparison of pain scores at different time points was calculated by Man-Whitney test and Wilcoxon matched pair test. The mean duration of anesthesia comparing group A and group B was evaluated with Independent-t test. Satisfaction with the procedure was evaluated with Chi-square test

RESULTS

This randomized split-mouth study was conducted from November 2021 to May 2022. Figure 1 presents the flow chart of the study design. All patients successfully completed the study.

Fifty patients were included in the study. There were 18% subjects of ≤ 30 years age, 40% subjects of 31-40 years of age, 28% subjects of 41-50 years and 14% patients of ≥ 51 years of age with mean age of 39.86. And standard deviation of 9.67. (Figure 2 & 3)

Clinical Measurements

1) Corah's anxiety score

The anxiety level was evaluated with corah's anxiety scale which has three questions with five multiple choice answers for each score.

On comparing of Group A and Group B with opinion on "when you are waiting in the dentist office for your turn in the chair, how you feel?" Was evaluated using Chi-square. The results indicated that there was no significant difference between both the anesthetic solution with p value of 0.420 (Table 1 & Fig.4) Results of this evaluation shown 34% of the subjects felt a little

uneasy during waiting in dentist chair before starting of the procedure

Group A and group B were compared for the opinion on “when you are in the dentist chair waiting while she gets her injection ready” and the scores of this opinion indicated there was no significant difference two groups. However, 40% of Group B subjects shown opinion of Tense feeling during waiting period before initiation of procedure. (Table 2 & Fig 5)

Chi-square test was used to evaluate intergroup comparison between two groups with opinion on “Use to scrape your teeth around the gums. How do you feel?” (Table.3& Fig. 6) results of this evaluation shown no significant difference between two groups

Inter group comparison of mean anxiety scores was carried out by independent t test. The results of this comparison shown that there was no significant difference between both groups with p value of 0.0149 (Table 4& Fig.7)

Therefore, the overall results of corah’s anxiety scale indicated that subjects receiving 2% lidocaine infiltration anesthesia and 4% articaine infiltration anesthesia had shown similar results. This indicates that all individual had anxiety prior to administration of local anesthesia irrespective of the anesthetic solution used.

2) VAS scale

The visual analogue scale was used in this study to evaluate pain scores at different time period that was from “before the administration of anesthesia to after the completion of procedure”

The intergroup comparison of VAS scale was evaluated with Mann-Whitney test. The results of the study has shown that there was a significant difference between Group A compared with Group B. Subjects treated with administration of 4% Articaine local anesthetic solution has shown less pain scores.

This results indicate that subjects receiving 4% Articaine local anesthetic solution has shown less pain during the subgingival scaling and root planing till the completion of procedure.

On intragroup comparison of pain scores at different time points Group A has shown significant results when compared from “during procedure to after the procedure with significant p value (0.0001) (Table 6& Fig.8)

3) Duration of anesthesia

Duration of anesthesia was evaluated by period from the “time of administration of anesthesia to time of wear-off of anesthesia”. (Table.7) the mean duration of effect of anesthesia was calculated with independent t test. The results of this study shown that Group A has shown significant scores when compared with Group B. Group A has anesthetic efficacy upto 2.61 hours

4) Satisfaction with procedure

The satisfaction with the procedure was evaluated with five multiple choice answers stating from “Extremely satisfied to Dissatisfied” with procedure.

The intergroup comparison between groups opinion with satisfaction of procedure demonstrated in Table 9. The results of the data indicated that there is no significant difference between two groups after completion of procedure. Wherein, 30 patients stated extremely satisfied procedure. Whereas, 20 patients indicated satisfied score with articaine administrated procedure. These results indicates that all patients were satisfied with the procedure.

DISCUSSION

This experimental design of present study was a randomized split-mouth study and it was double-blinded to avoid the bias in the treatment. To remove inter-individual variability from the estimates of the treatment effect, we adopted split mouth design. To our knowledge no study has compared anesthetic efficacy of 4% articaine and 2% lidocaine hydrochloride infiltrations for subgingival scaling and root planing in mandibular arch. Therefore we tend to evaluate the efficacy of these anesthetic solutions in terms of pain perception as well as for better patient compliance.

SRP constitutes the central element in the periodontal component of the disease control phase.²⁴ sometimes, it is difficult to exclude the influence of stress during procedure²⁵ since subgingival scaling and root planing is considered one of the fearful and painful dental procedures with myth that the procedure leads to tooth loosening.

Tenacious calculus, tortuous pockets, irregular root anatomy and the inability of the operator to visualize the tip of the instrument during the procedure, which makes it demand for the requirement and need of local anesthesia during instrumentation²⁶. Thus, adequate pain control may be extremely important in gaining patient compliance with the maintenance therapy and also for many dental procedures²⁷.

The anesthetic agents have been formulated as foams²⁸, ointments²⁹, pastes³⁰, creams³¹, gels³² and patches³³ to be applied onto the affected area intraorally. These topical medications generally do not provide sustained action (short retention time) and they usually act on other non-targeted parts of the oral cavity as well, which can cause numbness of the mouth and throat, leading to trouble swallowing and even choking³⁴. Therefore we selected Lidocaine and Articaine in injecting solution to optimize drug delivery for therapeutic outcomes.

Studies have reported superior anesthetic effects for articaine in comparison with lidocaine or 3% mepivacaine, when these agents were infiltrated in the mandibular buccal aspect when used for the treatment of irreversible pulpitis^{35,36}. However, a recent study by Olmedo-Gaya in 2018³⁷ showed no significant differences between lidocaine and articaine after buccal infiltrations after inferior alveolar nerve block for intraoperative pain control during impacted mandibular third molar surgery.

The anticipation of forthcoming dental treatment induces a physiologic stress response in patients that manifests in corticoid release, blood pressure change³⁸. Therefore we included anxiety scale as a parameter in our study wherein, Corah's questionnaire was given to patient before receiving anesthetic injection for subgingival scaling and root planing. The results of the anxiety scale were consistent with the results obtained by clinical trial by Piano, Renata P et al 2019³⁹, where the corah anxiety scale was used to measure anxiety level prior to surgical extraction of mandibular 3rd molars.

VAS have been used in the literature to assess the pain complaints during entire procedure^{40,41}. Therefore, the pain perception was one of the parameter in our study. The pain experienced by the patient while administering the injection was measured and results of our study showed no significant differences between both groups at baseline indicating both anesthetic solution led to a decrease in mean values of pain scores ($P < 0.05$).

However, on comparing pain score from "before treatment" to "after treatment" and from "during treatment" to "after treatment" time period, 4% Articaine hydrochloride had shown significant difference when compared with 2% lidocaine solution. These results were consistent with the study done by Haridas et al 2020⁴² in which comparison of same anesthetic solutions was carried out and 4% articaine anesthetic agent shown superior pain control during the periodontal flap surgery procedure. Similar results were obtained by Balachandra et al in 2018⁴³ where in evaluation the anaesthetic efficacy of 4% articaine and 2% lignocaine in achieving palatal anesthesia following a single buccal infiltration during periodontal therapy was assessed in terms of onset of anesthesia and pain scores during access flap surgery and observed that the efficacy of 4% articaine was superior to 2% lignocaine to induce palatal anesthesia following maxillary buccal infiltration in maxillary posterior sextants. Also articaine has shown better anesthesia effects than other amides^{44,45}, especially in mandibular infiltration, probably due to its tissue diffusion.

With regard to the anaesthetic onset time, there is no difference found between articaine and lidocaine in our study. Moreover, anaesthetic onset times for articaine were superior to lidocaine, which differ from the results found by Coasta et al 2005⁴⁶ in clinical trial showing that both anesthetic solutions had a shorter onset time.

The duration of anesthesia was calculated in this study. The starting point of this parameter was from the time of anesthesia administration till the wearing off its anesthetic effects. The time at which the infiltration was administered was informed to the patient at the end of procedure and the patient was asked to follow up the timing. The patients were asked to record the timing of wearing off anesthesia and it was reported to the clinician by a telephone call.

Duration of anaesthesia with the present study was in accordance to the results shown by Khan Q et al 2021 stating that articaine had a longer duration of action than lidocaine when used for

management of irreversible pulpitis⁴⁷

Subjects treated with 4% articaine were extremely satisfied results compared to 2% lidocaine. These results are consistent with the results obtained by Vishal et al 2021⁴⁸ wherein, same anesthetic agents were assessed for satisfaction with respect to irreversible pulpitis procedure.

We observed in our study that 2% lidocaine hydrochloride had shown oedema and redness at infiltration sites after the wearing-off of anesthesia. However, sites with 4% articaine has not shown any effects. During scaling procedure minimal bleeding was observed with Articaine than that of lidocaine. Articaine had the added therapeutic benefit of better visualization of the surgical area and reduced intraoperative bleeding.

Future research in the field of alternative methods of local anesthetic solutions in periodontal patients, considering the variations in anxiety patterns should be explored, to efficiently and comprehensively render dental treatment to the patient

CONCLUSION

2% lidocaine HCL infiltration was effective for subgingival scaling and root planing in mandibular arch, 4% articaine HCL infiltration for was effective for subgingival scaling and root planing in mandibular arch. And on comparing these anaesthetic agents, 4% articaine hydrochloride had shown better anesthetic efficacy when compared with 2% lidocaine hydrochloride for subgingival scaling and root planing in mandibular arch.

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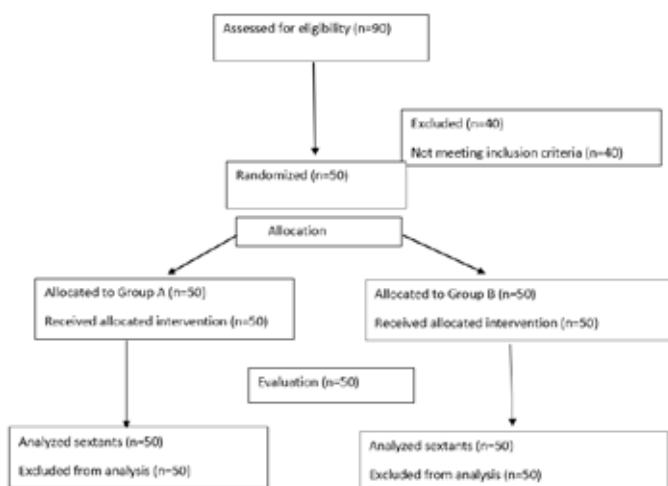


Fig. 1: Flow chart of the study design

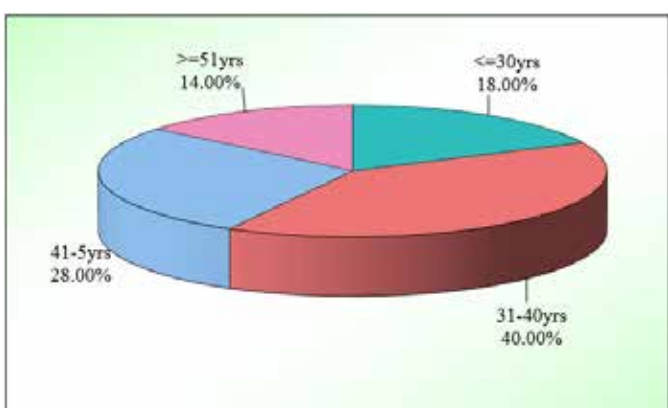


Figure 2: Age wise distribution of participants

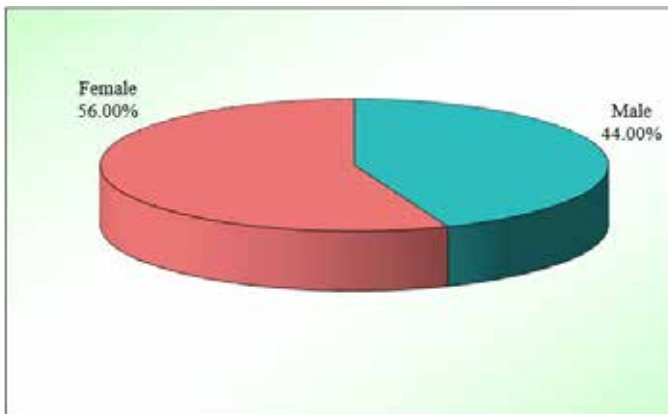


Figure 3: Gender wise distribution of participants

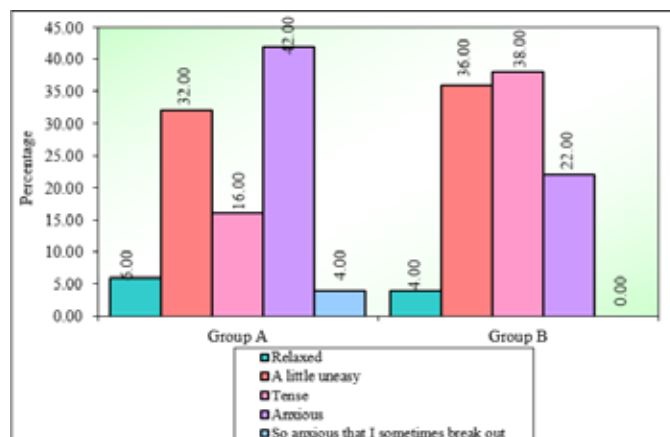


Figure 4: Comparison of Group A and Group B with opinion on when you are waiting in the dentist office for your turn in the chair, how do you feel?

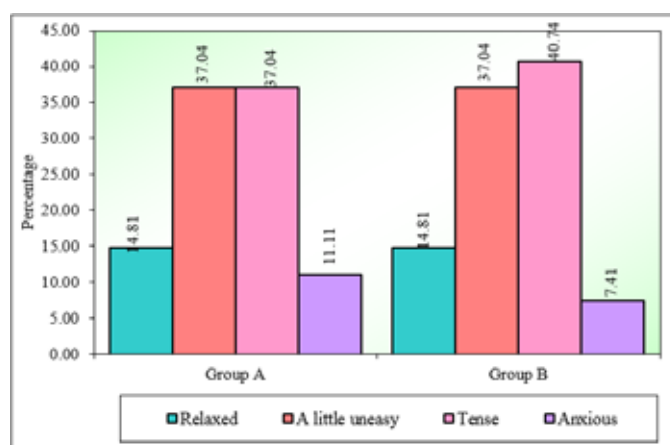


Figure 5: Comparison of Group A and Group B with opinion on when you are in the dentist chair waiting while she gets her injection ready

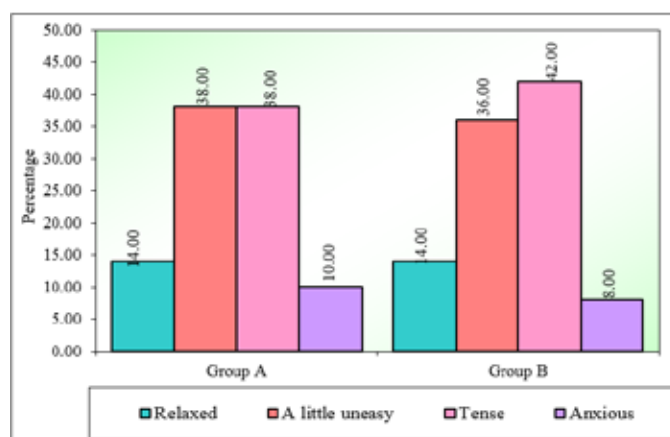


Figure 6: Comparison of Group A and Group B with opinion on Use to scrape your teeth around the gums. how do you feel?

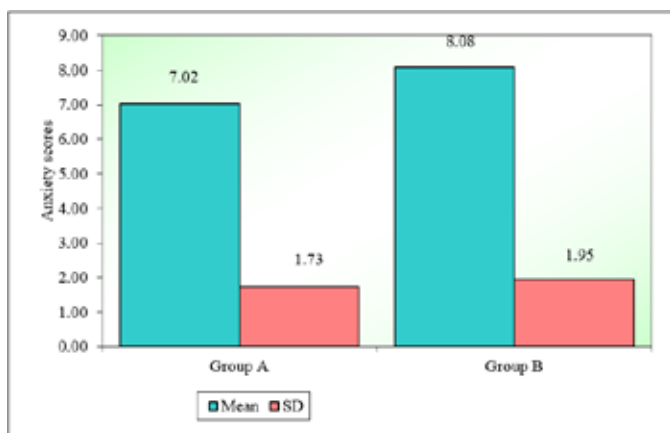


Figure 7: Comparison of Group A and Group B with mean anxiety scores by independent t test

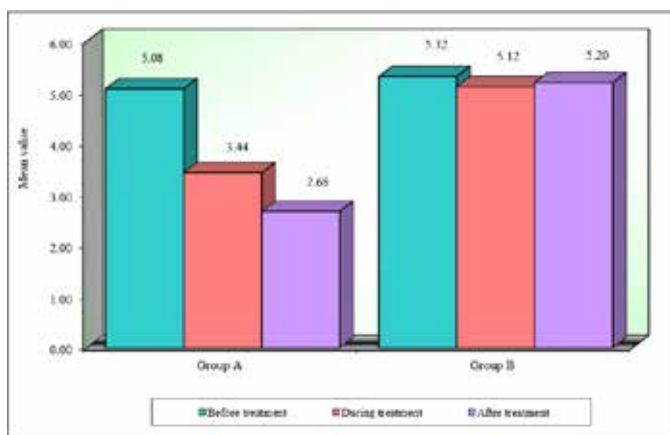


Figure 8: Comparison of different treatment time points with pain scores in Group A and Group B

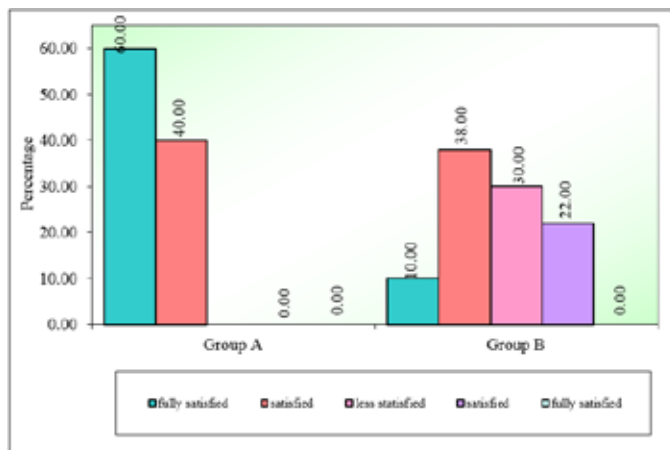


Figure 9: Comparison of Group A and Group B with opinion on satisfaction on procedures



1. ARMAMENTARIUM USED FOR THE STUDY



2. MATERIALS USED FOR THE STUDY



3. LOCAL INFILTRATION WITH CARTRIDGE LOADED WITH ANESTHETIC SOLUTION