



Original Research

Effect of a novel intracanal medicament on the inter-appointment pain in patients undergoing endodontic therapy - A randomised clinical trial

Aishwarya Ranganath

Elegant Caine's Crest, Flat No 3, New no 38, old no 71/1, BR Adhithnar Road, Gandhinagar 4th main road, Adyar, Chennai -600020

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ABSTRACT

Introduction: Interappointment flare-up may be defined as the occurrence of severe pain, swelling or both, following an endodontic treatment, which requires an unscheduled visit for emergency treatment. Various intracanal medicaments are advocated to eliminate bacteria and prevent multiplication of bacteria between the appointments. Calcium hydroxide has been the most commonly used medicament, and its dressing is shown to provide more bacteria-free canals than those devoid of any dressing. Chitosan and hekla lava have shown potential antimicrobial activity in invitro tests but there are no in vivo studies demonstrating the interappointment pain when used as intracanal medicaments.

Aim: To evaluate and compare the effect of calcium hydroxide, chitosan and hekla lava on the inter-appointment pain in patients undergoing endodontic therapy.

Materials and Methods: Thirty patients requiring root canal treatment were assigned into Group I, Group II, and Group III. In Group I calcium hydroxide, Group II Chitosan and Group III Hekla lava were placed respectively. Patients were instructed to record their pain on days 1,3 and 5. Interappointment pain was evaluated using Visual Analogue scale.

Results: P-value of <0.05 was considered. At the end of Day 1, Group II and III showed statistically significant difference, At 3rd Day Group III showed statistically significant difference.

Keywords: *Interappointment pain, Intracanal medicaments, Calcium hydroxide, Chitosan, Hekla Lava*

Address for Correspondence:

Dr. Aishwarya R,

Elegant Caine's Crest , Flat No 3, New no 38, old no 71/1, BR Adhithnar road , Gandhinagar 4th main road , Adyar , Chennai -600020

Phone No: 9566061031

Email:ash.ranganath@yahoo.com

INTRODUCTION

Endodontic pain is a concern for both the patients and the clinicians. There are several factors that influence pain that includes mechanical, chemical, and biological. Microbial injury is said to be the commonest cause of interappointment pain.¹ Mechanical instrumentation along with chemical disinfection eliminates only 50-70% microbes, thus intracanal medicaments are recommended to render the root canal microbes free.² Various intracanal medicaments are advocated to eliminate bacteria and prevent multiplication of bacteria between the appointments.^{3,4} The null hypothesis stated that there was no difference in the interappointment pain between all the three groups. Alternate hypothesis stated that there was difference in the interappointment pain between all the three groups.

Calcium hydroxide (CH) has been the most commonly used medicament, and its dressing is shown to provide more bacteria-free canals than those devoid of any dressing.⁵ Calcium hydroxide diffuses hydroxyl ions, results in high pH (Alkaline pH), also alters the biological properties. They act by damaging the bacterial cytoplasmic membrane and through protein denaturation.^{6,7} They are the most commonly used intracanal medicaments in endodontics. Chitosan on the other hand are natural derivatives.

Chitosan is a natural polysaccharide comprising of copolymers of glucosamine and N-acetylglucosamine. Partial deacetylation of chitin results in production of chitosan. It is biocompatible, biodegradable, bioadhesive and there is no reported toxicity. Besides it is a good antimicrobial agent. Its low production costs have increased its utility for various applications in the areas of medicine and pharmaceuticals. In dentistry it has been used as a barrier membrane for periodontal therapy and as oral mucosal delivery agent for chlorhexidine.⁸ In a study conducted by Silva et al chitosan has effectively removed smear layer from the root canals after instrumentation.⁹ In endodontics its role as antibacterial and antifungal agent has not been subjected to adequate scrutiny. They are derived from shrimp cells; they act against a wide antimicrobial spectrum and extremely bacteriostatic. The absorbed chitosan changes the structure and permeability of the cell membrane. Binding of chitosan with microbial DNA results in the inhibition of mRNA and protein synthesis that penetrates the nuclei of microbes. It also causes the chelation of metals, suppression of spores and binding of nutrients.

Hekla lava is yet another natural product derived from fine ash- Mount Hekla. It is composed of sulphur, silica, lime, magnesia, ferrous oxide, fluoride.¹⁰ Calendula belongs to the family Asteraceae. It's shown to have both antimicrobial and anti-inflammatory effect.^{11,12} The objective of this study was to compare and evaluate the interappointment pain after using calcium hydroxide, chitosan and hekla lava as intracanal medicament.¹³

Materials and Methods:

It was a prospective randomized controlled clinical trial. The sample size was determined using G power 3.1 version. The minimum sample size of each group was calculated by assuming alpha- and beta-errors at 0.05 level and sample size arrived were 10 per group. The inclusion criteria include age group of 18-55 years who signed the informed consent, patient requiring endodontic therapy, molars that were diagnosed as symptomatic apical periodontitis, healthy patients without systemic disease, patients with pain score ranging from moderate to severe (4-10) on a Visual analogue scale (0-10).¹⁴ The exclusion criteria include- patient who are medically compromised, pregnant patients, teeth with incomplete apex formation, teeth with calcified canals, sinus opening, periapical abscess, patients on antibiotic therapy.¹⁵

Randomization was done using block randomization. The groups designated Group I –Calcium hydroxide, Group II –Chitosan and Group III –Hekla lava. Double blinding was done.

TREATMENT PROCEDURE

Prior to the treatment, a careful medical and dental history was taken. Preoperative data for each patient was recorded in the predesigned patient's chart which includes age, sex, and tooth number prior to the treatment. The treatment and the study design were explained to the qualifying patients and informed consent was obtained from the voluntary patients who were willing to participate in the study. Patients who signed the informed consent were randomly divided into 3 groups.

The severity of pain was measured using the VAS.¹⁴ According to this scale, the level of pain was documented in the range of 0–10 numerically and verbally as no pain (0), mild pain (1–3), moderate pain (4–6) and severe pain (7–10).¹⁶

Endodontic Protocol

All the treatment was carried out by a single operator. Vitality was assessed using cold tests and Electric pulp testing before the procedure was carried out for the teeth. All the patients received a local anesthesia (Lidfast; India). Each tooth was isolated using rubber dam and the access cavity was prepared using sterile carbide burs. Access of the tooth is done using Endo access bur size 2 (Dentsply).

A working length was determined with stainless steel hand K- files size #10 (Mani, Tochigi, Japan) and the use of an apex locator (Propex Pixi, Dentsply). It was confirmed using intra oral periapical radiographs and it was repeatedly checked throughout the procedure. Canals were then preflared using Gates Glidden drills upto size 2 and prepared in a crown down technique.

Preparation started with initial 10 size 0.04% file, and all the instruments were used to the full sequence upto 25 size 0.06% file and to the full working length as recommended by the manufacturer. All the canals were prepared using M-two rotary files (VDW, Munich, Germany) with 25 size .06 taper file 0.5mm short of apex following manufacturer's suggested sequence using reduction gear hand piece powered by an electric motor (X-Smart; Dentsply).¹⁷

Apical patency was maintained throughout the shaping procedure using #10 file between each instrument. Intracanal medicaments were mixed with saline and placed in the root canals according to the groups allocated. Interappointment pain score was recorded at 1-, 3- and 5-day intervals using VAS scale. Any intake of analgesics at this point was said to be noted by the patient.

Results:

One Way ANOVA tests was performed to compare the pain scores between the groups. Post Hoc Bonferroni was done for multiple comparison of pain reduction values. Chi Square test to compare tablet intake. SPSS version 22.0 was used to analyse the data. [Table 1]

GROUPS		DAY 1	DAY 3	DAY 5
Calcium hydroxide	Mean	4.2000	1.0000	.3000
	N	10	10	10
	Std. Deviation	1.13529	.81650	.48305
Chitosan	Mean	.8000	.3000	.0000
	N	10	10	10
	Std. Deviation	.78881	.67495	.00000
Heklalava	Mean	.3000	.1000	.0000
	N	10	10	10
	Std. Deviation	.48305	.31623	.00000
Total	Mean	1.7667	.4667	.1000
	N	30	30	30
	Std. Deviation	1.94197	.73030	.30513

Table 1 – Statistical analysis done for multiple comparison of pain reduction values recorded at 1-, 3- and 5-day intervals.

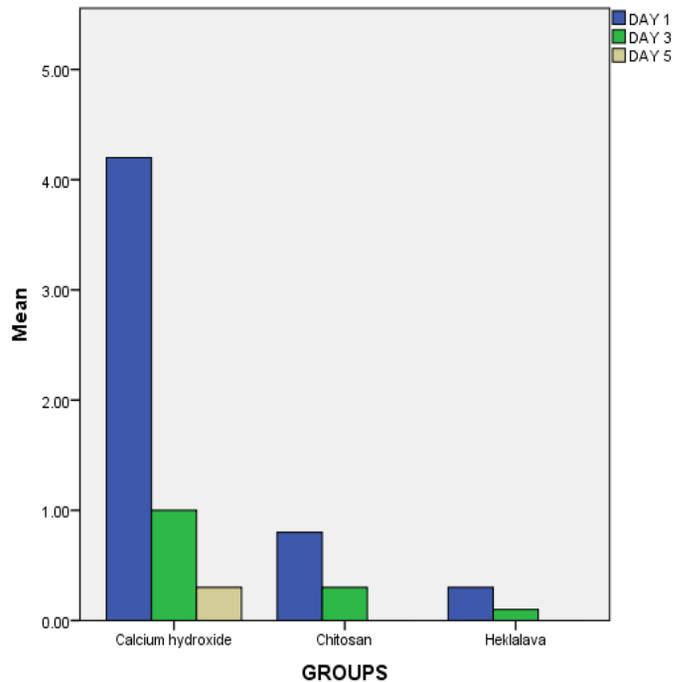


Figure 1 - Graph showing significant reduction in pain experienced by patients in Hekla lava group at Day1 and Day3.

DISCUSSION

The purpose of this randomised controlled clinical trial was to compare and evaluate the interappointment pain after using calcium hydroxide, chitosan and hekla lava. Null hypothesis was rejected as there was difference in the pre-operative and post-operative pain values. Alternate hypothesis was proven that there was difference in the pre-operative and post-operative pain values.

The production of biodegradable polymers which are decomposed by microorganisms and photodegradable polymers that are decomposed by sunlight is a priority among researchers. An ideal biodegradable polymeric material is one which after being disposed of can be recycled many times before promptly being decomposed by microorganisms or sunlight providing carbon dioxide and water. Chitosan is such a type of polymer which is degradable in natural environment.

Chitosan is a polycationic naturally occurring bio-degradable, non-toxic, non-allergenic biopolysaccharide derived from chitin which is found in abundance in nature. It contains more than 5000 glucosamine units and is obtained commercially from shrimp and crab shell containing chitin which is an *N*-acetyl glucosamine polymer. The *N*-acetyl glucosamine gets converted into glucosamine units by alkaline de-acetylation with NaOH (with 40-50% conc.)³⁻⁵. Chitosan is considered as most promising materials for future applications on account of its excellent biodegradability, biocompatibility, non-toxicity, antimicrobial activity, and its economic advantages⁶. The chemical structure of chitin is made up of linear monomeric units of 2-acetamido-2-deoxy-D-glucopyranose attached through β -(1-4) linkages.¹⁸

It is manufactured commercially by a chemical method; for example, the isolation of chitin from shellfish waste consists of three steps: deproteinization (Extraction and/or removal of protein), demineralization, followed by the decolourization/de-pigmentation. The initial two steps are usually considered to be irrelevant if protein or pigment recovery is not an objective. Various procedures have been proposed for the preparation of chitin and chitosan from different shellfish wastes have been developed over the years, some of which form the basis of the process that's chemical used for the production of chitin and its derivatives.¹⁹

Firstly, the sources such as crab or shrimp shells are washed and grinded into powdered form and then it is deproteinized by treatment with an aqueous 3-5% solution of sodium hydroxide. Following this, it is neutralized and demineralized at a room temperature by treating it with aqueous 3-5% of hydrochloric solution to form a white or slightly pink precipitate of chitin. After that chitin is deacetylated by treatment with an aqueous 40-45% solution of sodium hydroxide and the precipitate is then washed with water. The insoluble part is removed by dissolving in an aqueous 2% acetic acid solution. The supernatant solution is then neutralized with an aqueous sodium hydroxide solution to obtain a purified chitosan.²⁰

Enzymatic methods are an alternative to the chemical method for chitin and chitosan production. In addition, the protein often remains high and reaction times are significantly increased compared to chemical methods. Enzymatic methods are limited in industrial production of chitosan, due to higher cost of enzymes. Numerous commercially available enzymes are used for the production of chitosan such as alcalase, chymotrypsin, and papain.²¹

Among the groups, there was no statistical difference in the pain score preoperatively. Postoperatively, at Day 1 pain was experienced more in Calcium hydroxide group as compared to Chitosan and Hekla lava group, which was statistically significant, there was no statistically significant difference between Chitosan and Hekla lava. At Day 3 Hekla lava showed statistically significant difference when compared to calcium hydroxide and hekla lava [Figure 1]. At Day 5 there was no statistical difference in all the groups.

60% of patients in Group A consumed analgesics at Day 1, 10% Group B and none in Group C. According to the results of the present study there was less pain experienced by patients in Group III followed by Groups II and Group I at various intervals. Pain score in all the groups gradually decreased over time.

Among the NSAIDS, Aceclofenac was selected because it has been known as the prototype medication for postoperative pain relief after root canal treatment. Minimal dose of Aceclofenac was prescribed because higher dose may obscure the outcome especially with very low pain levels created by our endodontic treatment protocol in general.²² All the pain intensity scores, and number of pills taken at each follow-up period were recorded through phone calls and questionnaires. This was done to improve patient cooperation, marking the pain intensity at proper follow-up time, and to avoid the possible loss of follow up from the study. This helps us obtain 100% data from all the patients at all the follow-up time.

Each clinician should evaluate the benefits and risk of prescribing analgesics after root canal treatment (Keisner et al 2011). Parirokh et al 2013 showed that there was no significant difference on postoperative pain reported by patients with irreversible pulpitis after using either on demand or regular prescribed medication.

Calendula is an annual plant of the family Asteraceae. The following chemical components are found in calendula sesquiterpenes, flavonoid glycosides, triterpene saponins, triterpene alcohols, flavonoids, carotenoids, xanthophylls, phenolic acids, steroids, mucilage, tocopherol, and calenduline.²³ Hekla' s ash is tephra, that contains a lightweight material such as silica, like a very small grain of sand containing bubble cavities which have dissolved acidic salts attached to the surface as a precipitation This tephra is known to have great healing properties. Calcium hydroxide has shown to contain a range of antimicrobial activity and its action on microbial biofilms is controversial.

CONCLUSION

Within the limitations of this study, it was observed that there was significantly reduced pain experienced by patients in Hekla lava group at Day1 and Day3, although all the groups showed a drastic reduction in pain at the end of 5 days.

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Conflicts of interest - There are no conflicts of interest.

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