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Research Article

To Compare and Analyze the Efficacy and Effect of Post Endodontic Pain with Herbal Extract and Nsadis as Intra Canal Medicament along with Oral Intake Using Visual Analog Scale an *In-Vivo* Study

Rohit Chadha[1]* and Namita Singh[2]

[1]*Conservative and Endodontics, Implantologist, Smile Designer, India*

[2]*DR Teeth Clinic, India*

***Corresponding Author:** Rohit Chadha, Conservative and Endodontics, Implantologist, Smile Designer, India.

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Abstract

The purpose of this study is to compare the pain-reducing efficacy of *Spilanthes acmella* extract and ketorolac Tromethamine when used as an intracanal medication, and oral ibuprofen when administered orally. A total of 30 patients diagnosed with symptomatic irreversible pulpitis as determined by patient history and with electric pulp tester (Analytic Technology, Redmond WA) and thermal testing, were included in this study. Patients were randomly assigned into 1 of 3 groups of Oral ibuprofen, ketorolac tromethamine and *Spilanthes acmella.*

The root canal treatment was performed in two appointments. The first appointment consisted of cleansing and shaping of the canal/s, using standard aseptic technique. After complete cleansing and shaping, the Canals were dried and in groups 2 and 3, *Spilanthes acmella* herbal extract (US Herb Pharm) and ketorolac tromethamine was placed intracanal. Patients in group1 received oral ibuprofen (600 rags). All teeth were closed with a sterile cotton pellet and IRM (Intermediate Restorative Material, L. D. Caulk Division, DENTSPLY International, and Milford, DE).The patients were asked to evaluate their pretreatment pain with a Visual Analog Scale (VAS) to determine if any relationship would be found to exist between pretreatment and post treatment pain. Each patient was dismissed with a VAS to fill out at 6, 12, 24, and 48 h after initiation of therapy. Statistical analysis was done using an analysis of variance (ANOVA) and Post-Hoc Tukey test (bonferroni test).

Keywords: Ibuprofen; Ketorolac Tromethamine; *Spilanthes acmella*; Vas Scale; Bonferroni Test

Introduction

Pain of endodontic origin can be a major concern to the patient and the clinician, public perception of endodontic treatment is often associated with pain, expectations of a painful experience can increase a patient's anxiety level making treatment more difficult. O'Keefe., et al. found that patient's responses to an analgesic may also vary and these too may be linked to genetic variations or issues associated with a patient's sex or level of anxiety. In his study 16% of his patients had moderate to severe pain either during or after treatment visits, he also found that there is a strong relationship between preoperative and postoperative pain, patients with moderate to severe pain prior to treatment were five times more likely to experience moderate to severe pain post treatment [1].

An objective of endodontic therapy is to relieve and to prevent patient pain and suffering. By using good anesthetic technique, this pain can be largely eliminated during treatment; in contrast, posttreatment endodontic pain remains a significant problem [2].

The increasing demand on herbal medicines and their acceptance in international market because of potent pharmacological potential and high therapeutic value have been proving to be real blessing to the people, however, efforts are needed to explore, standardize, and validate Ayurveda medicines for their potency, safety, and efficacy in order to bring them to market as main line therapeutics [3].

Hence, in our study *Spilanthes acmella* is used and compared it with the two other allopathic NSAID's when placed orally and as intracanal medicament.

Aims

The aim of this study is to compare the pain-reducing efficacy of *Spilanthes acmella* extract and ketorolac Tromethamine when used as an intracanal medication, and oral ibuprofen when administered orally.

Methods and Material

Patients who presented were evaluated for this study, and a total of 30 patients participated. A complete medical history of all patients was taken. Only those patients who had no significant medical problems met the following criteria for the study, Patients between 18 and 65 years of age, excluding pregnant or nursing women, patients having no history of peptic ulcer or gastrointestinal bleeding, patients who are not hypersensitive

or allergic to nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids, excluding any patient at risk for renal failure or renal impairment and no radiographic evidence of periapical pathosis [1].

Only patients with a vital pulp (either diagnosed as an irreversible pulpitis or symptomatic, but in need of endodontic therapy), as determined by an electric pulp tester (Analytic Technology, Redmond WA) and thermal testing, were included in the study. If the patient met all of the above criteria, he/she was informed of the study and invited to participate. He/she was asked to read and sign a consent form approved by the institutional ethical committee. Patients were randomly assigned into 1 of 3 groups (n=10), drugs used are as in figure 1.

Figure 1: Ibuprofen, keterolac tromethamine, Spilanthes acmella.

Group	Drugs used	Manufacturer
1	Oral ibuprofen	Alb. David
2	Ketorolac tromethamine	Cipla
3	*Spilanthes acmella*	US Herb Pharm

Table 1

The root canal treatment was performed in two appointments [1]. The first appointment consisted of access opening and cleansing and shaping of the canal/s, using standard aseptic technique as shown in figure 2 and 3.

Figure 2: Rubber dam application (asepsis achieved).

Figure 3: Access opening.

The RCT procedure was conducted utilizing a crown-down technique using J. Morita Tri Auto ZX-2. The canals were enlarged to minimum size of a #40 file or larger, depending on the size of the canal shown in figure 4.

Figure 4: Biomechanical preparation done using J. Morita tri-auto ZX2.

Chlorhexidine (2%) was used as an irrigant, and the cleansing and shaping were conducted in the presence of RC-prep EDTA (Premier Dental Products Co., Philadelphia, PA). After complete cleansing and shaping, the canals were dried and in groups 2 and 3, *Spilanthes acmella* herbal extract (US Herb Pharm) [9] and ketorolac tromethamine [1] was placed intracanal. The method of placement was as follows: a 27-gauge needle was placed into the canal until resistance was felt, and then 0.1 ml of the medication solution was expressed slowly into each canal [5] as depicted in figure 5.

Figure 5: Method of delivering drug intracanal.

The two solutions were ketorolac tromethamine (60 rag/2 ml) and *Spilanthes acmella* (1 FL oz.). Patients in group1 received oral ibuprofen (600 rag) [1]. All teeth were closed with a sterile cotton pellet and IRM (Intermediate Restorative Material, L. D. Caulk Division, DENTSPLY International, and Milford, DE).

The patients were asked to evaluate their pretreatment pain with a Visual Analog Scale (VAS) [6] to determine if any relationship would be found to exist between pretreatment and post treatment pain. Each patient was dismissed with a VAS to fill out at 6, 12, 24, and 48 h after initiation of therapy. Because the patients were

allowed to take over-the-counter medication during the study, they were asked to indicate on the scale what type of medication and when they took it on the VAS. The scale contained a mark at the center of each word designation. At the midpoint between the marks, boundaries for each of the categories were established so that each pain levels designation had a possible range of values in order to accommodate patients who marked the scale between the marks. In addition, for the sake of statistical analysis, the scale was converted to a continuous scale by measuring where the patient designation of pain was in relation to the 0 point on the scale. The original scale was 150 mm in length, and it was standardized so that the final scale measured 100 mm, the usual length of a VAS scale [1]. The final scale was as follows: The success of pain relieve using medication was defined as the tooth without pain (VAS score, 0), patients with mild pain (VAS score,>1-3), The patients who reported moderate pain (VAS score,>3-5) or serious pain (VAS score, >5-7 mm) and those who reported severe pain (VAS score,>7-9) and worst pain possible (VAS score,>10).

Statistical analysis used: An analysis of variance (ANOVA) and Post-Hoc Tukey test (bonferroni test), was performed using pretreatment pain as a variance to adjust for differences in initial pain.

Results

Drugs	Intervals	Minimum	Maximum	Mean score	Std. Deviation
Ibuprofen	Pre	1	8	4.60	2.87
	6 hours	0	4	1.40	1.43
	12 hours	0	3	.70	.94
	24 hours	0	3	1.30	1.33
	48 hours	0	7	1.30	2.16
Ketorolac	Pre	1	8	3.80	2.89
	6 hours	0	8	1.80	2.39
	12 hours	0	3	.90	1.10
	24 hours	0	0	.00	.00
	48 hours	0	0	.00	.00
Spilanthes	Pre	1	10	4.20	3.04
	6 hours	0	8	2.20	2.44
	12 hours	0	4	1.80	1.54
	24 hours	0	3	.70	1.25
	48 hours	0	3	.60	.96

Table 2

Both spilanthes and ketorolac showed statistically significant relief at 12-hr time period, compared with oral ibuprofen. Ketorolac demonstrated statistically significant pain relief over Ibuprofen and spilanthes at the 24-h time period. There was no significant difference among the groups at 6 or 48 hrs. In addition, no significant differences were demonstrated between ibuprofen and either spilanthes or ketorolac as demonstrated in Graph 1. Patients were allowed to take over-the-counter pain medication, but none of them took it.

Graph 1

Discussion

Ketorolac tromethamine is the first and only NSAID that is available in an injectable formulation in the United States. It is a member of the pyrrolo-pyrrole group, and its primary mode of action is the inhibition of the cyclo-oxygenase pathway that metabolizes arachidonic acid to prostaglandins and thromboxanes. It has been shown to be extremely effective for pain reduction from a variety of etiologies, such as oral surgery, cancer, and migraine headaches. Prostaglandins play a role in the induction of inflammation, lowering the pain threshold, and sensitizing nociceptors to other pain mediators, such as histamine and bradykinin [4].

Ibuprofen acts by inhibiting the production of prostaglandins through the inhibition of cyclo-oxygenase. This provides the rationale for the efficacy of ketorolac tromethamine as an analgesic for the relief of odontogenic pain. Pulpal inflammation and necrosis are known to cause the release of chemical mediators, including prostaglandins, which are involved in the mediation of pain. Placing the drug directly at the site of tissue injury may be more effective in controlling pain and inflammation than waiting for absorption through the gastrointestinal tract. This method of placement could give practitioners another option for pain control in endodontics. NSAIDs have been shown to be effective in the relief of post treatment pain by many investigators [1].

It has been suggested that antibiotics must be given in conjunction with NSAIDS to prevent secondary infection. The implication is that suppression of inflammation also means a decrease in local defenses permitting proliferation of pathogenic microorganisms. We found no evidence of this phenomenon in our study. No patients reported fever, malaise, or any fluctuant swellings

after the administration of ibuprofen. Therefore, the routine use of antibiotics in conjunction with NSAID's may not be necessary [1].

Suchita Dubey., *et al.* in their literature stated that *Spilanthes acmella* is an important medicinal plant, found in tropical and subtropical countries mainly India and South America [3]. Popularly, it is known as toothache plant which reduces the pain associated with toothaches and can induce saliva secretion [3,8]. Various extracts and active metabolites from various parts of this plant possess useful pharmacological activities. Literature survey proposed that it has multiple pharmacological actions, which include antifungal, antipyretic, local anaesthetic, bio insecticide, anticonvulsant, antioxidant, aphrodisiac, analgesic, pancreatic lipase inhibitor, antimicrobial, antinociception, diuretic, vasorelaxant, anti-human immunodeficiency virus, toothache reliever and anti-inflammatory effects [3].

Analgesic activity of *Spilanthes acmella* was attributed to the presence of flavonoids, alkamides which are potent inhibitors of prostaglandins at later stages of acute inflammation [7].

Savitha Sathyaprasad., *et al*. in their literature learned that Spilanthes possesses remarkable antibacterial and antifungal activity against common root canal pathogens which are responsible for repeated endodontic failures like E. faecalis and C. albicans when compared with medicaments like $Ca(OH)_2$ [9].

In the present study, two patients experienced a gastrointestinal reflux from group ibuprofen which was than cured by administering PAN40 (proton pump inhibitors).

In our study, there were no noted adverse side effects from the use of Ketorolac and spilanthes when used as an intracanal medicine.

Penniston and Hargreaves., *et al*. injected ketorolac tromethamine periapically and noted no adverse effects or tissue toxicity in any of their subjects. It would appear that the use of ketorolac tromethamine at the doses available in the methods described herein is a safe method of delivery. It was interesting to note that, when the solutions of either ketorolac tromethamine or spilanthes were injected into the canals as described, the majority of the 0.1 ml was expressed back out of the canal into the chamber [4].

Negm., *et al.* incorporated hyaluronidase into the solution of the NSAIDs, ketoprofen and diclofenac; and, although he stated that more patients were pain-free when the combination was used, there was no statistically significant difference [5].

The intracanal use of ketorolac tromethamine or spilanthes provided statistically significant pain relief at the 12-h time period, compared with ibuprofen. Ketorolac tromethamine also provided statistically significant pain relief at the 24-h time period, compared with ibuprofen and spilanthes.

Future research should help quantify how much of the drug is actually reaching the periapical region and whether or not the addition of other agents, such as hyaluronidase or ledermix paste would be beneficial.

Conclusion

The study on prophylactic intracanal administration of ketorolac tromethamine provides effective reduction of postoperative treatment pain up to 48hours when compared to intracanal spilanthes extract and oral ibuprofen.

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