

Effectiveness of a novel topical anesthetic gel in patients undergoing non surgical periodontal therapy

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ABSTRACT

Objectives: To evaluate the efficacy of a topical anesthetic gel containing potassium nitrate, benzocaine and tetracaine in patients undergoing non surgical periodontal therapy.

Materials and Methods: The present study was a randomised, double blind, placebo controlled, split mouth design trial carried out in 300 patients. Two quadrants in each patient were selected for non surgical periodontal therapy. The drug gel and placebo were liberally applied over the teeth and gingiva on the selected quadrants and the treatment was started after two minutes. Patients were asked to evaluate their pain experience at the end of treatment of their respective quadrants using verbal rating scale.

Results: The mean pain score on using the drug gel was 0.433 ± 0.737 as compared to the mean pain score of 2.35 ± 0.761 on using the placebo gel, and the results were statistically significant. The drug gel out performed the placebo gel. None of the patients reported of any local or systemic side effects.

Conclusions: The topical anesthetic gel provided excellent pain control for the patients undergoing non surgical periodontal therapy. It can also be considered as a good option during periodontal examination and maintenance visits to increase the patients comfort.

Keywords: Anesthetic gel, potassium nitrate, benzocaine, tetracaine.

INTRODUCTION

Periodontitis is one of the most ubiquitous diseases known to mankind. In order to eliminate and control periodontal disease and prevent further tissue destruction, periodontal pockets need repeated subgingival mechanical debridement and cleansing. Non surgical therapy, scaling and root planning (SRP) is the most common procedure used to treat gingivitis and periodontitis.¹ Scaling is associated with discomfort if not pain; subgingival scaling and root planing appear to be more painful than supragingival scaling. There is enough

evidence to document that few patients find the non surgical treatments painful.²⁻⁵

Pain management as we know is necessary to perform clinical dentistry efficaciously and is of major concern to the dentist. Injectable local anesthesia has contributed greatly to patient comfort and compliance with periodontal procedures; but, many patients fear injections and refuse to have them. Patients avoid professional dental care when experiencing severe tooth pain. A study by Milgrom et al., concluded that more than 25% of adult patients expressed fear of dental injections. At times topical anesthesia is often used, but, efficacy, uncontrolled spreading and undesirable taste limit topical agents.⁶

So there is a need for a fast acting anesthetic that is easy to apply and is painless. So, the purpose of this study was

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to evaluate the efficacy of a topical gel containing potassium nitrate, benzocaine and tetracaine in patients undergoing scaling and root planning (SRP).

MATERIALS AND METHODS

The present study was a randomized, double-blind, placebo controlled, split mouth design trial. A total of 300 patients who visited the department of Periodontics, School of Dental Sciences were randomly included in the study. Systemically healthy subjects and those who required SRP in at least two quadrants and those who had not undergone any periodontal therapy in earlier six months are included in the study. Subjects with any allergic history to the ingredients used in the gel, pregnant and breast-feeding women and those with any significant oral mucosal diseases are excluded from the study. Patients with pain, mobility, abscess or endodontic infection, those who are using any analgesics and those who had preferred injectable anesthetics are excluded from the study. Necessary approval from institutional review board and an informed consent from each subject were obtained before the study.

Preparation of gel:

All standard formulary chemicals only were used in the gel preparation. The active gel consisted of Potassium nitrate, Benzocaine, Tetracaine hydrochloride, carbopol, purified water, cinnamon flavour and colouring agent as required. The placebo gel was the one without active drug ingredients.

The drug and placebo gel were packed in identical containers and marked as A and B for the purpose of blinding, the code of which, was broken at the end of the study. After recording a brief case history two quadrants in each patient were selected for study purpose. Gel to be used on the selected quadrants was decided by flip of a coin. The gel was liberally applied over the teeth and gingiva on the selected quadrants and the treatment was started after two

minutes. Those who experienced more pain were given a second dose of gel. If pain still persisted alternative anesthetic would be given after recording their pain scores.

Patients were asked to evaluate their pain experience at the end of treatment of their respective quadrants using verbal rating scale (VRS). The evaluation was done within 15 seconds after completing the treatment of respective quadrants. Pain was evaluated using a 5 point verbal scale with the following ratings; 0= none, 1= slight, 2= moderate, 3= severe and 4= very severe. Provisions were made to record any untoward side effects. Subjects were given a 24 hours helpline number in case of any emergency.

RESULTS

Among the total subjects 186 were males (mean age of 33.8182 ± 6.8668), and 114 females (mean age of 35.0588 ± 6.8142). Among 300 patients after using the active drug gel, 204 of them experienced no pain, 76 experienced slight pain, 16 experienced moderate pain and 4 of them severe pain. None of them experienced very severe pain (Table 1). A paired student t-test was conducted to test the efficacy of drug gel over the placebo. There was a statistically significant difference between the pain scores on using drug gel (Mean=0.40; SD=0.65) and the placebo gel (Mean=2.25; SD=0.68); $t=90.5866$; $p=0.0001$ at a confidence interval of 95 % (Table 2). The active drug gel out performed the placebo gel. None of the patients reported of any local or systemic side effects neither any untoward incidents were recorded.

DISCUSSION

According to Van Steenberghe, SRP was considered to be a painful or at least uncomfortable form of treatment with 8 to 9% reporting severe pain and 10% to 21% moderate pain, especially during a primary appointment.⁷ Approximately 2/3rds of

Table 1. Distribution of patients according to Verbal Rating Scale.

Gel	Verbal grade	No. of patients
Gel A (Placebo)	0	0
	1	30
	2	174
	3	86
	4	10
B (Drug)	0	204
	1	76
	2	16
	3	4
	4	0

Table 2. Students t-test to compare the efficacy of placebo and drug gel.

Gel	Mean + Sd	t-value	p-value
Gel A (Placebo)	2.25+0.68	90.5866	<0.0001*
Gel B(Drug)	0.40+0.65		

*Statistically significant; confidence interval 95%

patients undergoing periodontal debridement consider the procedure painful and unpleasant.⁸ In a Belgian survey, 32% of treatment-naïve SRP patients and 64% of maintenance patients reported willingness to accept mild to moderate pain than opting for an injectable anesthetic.⁹ LA is often administered; but they pose limitations like: Pain associated with needle insertion, solution injection, lengthy duration and unnecessary anesthesia in surrounding tissues. Hence an effective, fast acting topical anesthetic preparation is desirable.

The primary means of determining the gel efficacy was the measurement of treatment associated pain. Certainly pain is difficult if not impossible to quantify. Huskinson stated that "pain is a personal psychological experience and an observer can play no legitimate part in its measurement". The use of VAS and VRS for scoring pain has been validated in a

variety of studies for different conditions.¹⁰ Their reliability has been demonstrated by using the test/re-test method for repeated measurements subjective sensations.¹¹

Various agents are available for topical analgesia. While lignocaine serves as the gold standard,¹² benzocaine is known for its excellent surface anesthetic properties.¹³ In a study by Nayak R et al., evaluation of three topical anesthetic agents against pain was done wherein Benzocaine, Lignocaine and EMLA were used. Results suggested that benzocaine had the rapidest onset of action followed by lignocaine and EMLA cream.¹⁴

The findings of the present study are consistent with a study done by Milton Hodosh et al wherein the same anesthetic gel was found to be effective for maintenance visit pain control.¹⁵

The literature has increasingly recognized potassium as a therapeutic agent and an effective advance for pain

management. As potassium does not easily enter deeper gingival tissues other topical anesthetics benzocaine and tetracaine were added and a gel was prepared to test its efficacy during phase 1 periodontal therapy.

On application of the gel, potassium ions enter the orifices of dentinal tubules and flow through the networks of dentinal tubules and the odontoblastic processes into the pulp. It results in an increased external concentration of K ions around the nerves and interruption of neuron functions. This is caused by the actual bathing of nerve tissue with a high grade of potassium because of which the nerve enters an absolute refractory period allowing no stimulus to excite the nerve and thus anesthetizes the tooth.¹⁶ Benzocaine acts faster and lasts for short duration and Tetracaine is a long lasting anesthetic. So the combination of these agents provides a synergistic effect. Direct pulpal anesthesia with potent topical gingival anesthetics, serve in providing genuine patient comfort.

CONCLUSION

Fear of pain is a common reason patient avoids professional dental care, with the sight of an anesthetic needle the most fearful experience in dentistry. It is a common experience that the same procedures elicit different levels of pain in different patients. Based on the findings of our study, the gel provided excellent pain control for the patients undergoing phase I therapy. The product was well tolerated with no signs of adverse reactions. The active gel was overall significantly effective than the placebo in reducing pain associated with periodontal debridement. It can be considered as a good choice during periodontal examination and maintenance visits to increase the patients comfort.

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