Comparison of Efficacy of Sensodyne Rapid Relief Containing Strontium Acetate with Placebo in the Management of Pain During Ultrasonic Scaling

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ABSTRACT

Introduction: Sensodyne Rapid Relief is a dentifrice containing 0.454% Stannous Fluoride as an active ingredient has a desensitizing effect observed over a period of 8 weeks.

Aim: To assess the efficacy of the Sensodyne rapid relief toothpaste containing Stannous Fluoride as the active ingredient in relieving pain during the ultrasonic scaling procedure.

Materials and Methods: This study is a randomized clinical placebo controlled trial with a split mouth design. A total of 50 patients were included in this study with informed consent. The respective contralateral areas with pain during ultrasonic scaling were identified and patient Visual Analogue Scale (VAS) was recorded. The selected contralateral areas were isolated. Test area was applied with Sensodyne Rapid Relief toothpaste (SRRT) and left in place for 5 minutes and the control area was applied with a placebo toothpaste (PT) with no active ingredient. Then ultrasonic scaling was done in both the test and control areas. The water and power control was kept constant throughout the study. During ultrasonic scaling, the patient visual analog scale (VAS) was recorded again for both the test and control areas. The statistical analysis was done using SPSS 20.0 software with significance fixed at 95 % CI ($p < 0.05$).

Results: The mean difference VAS scores between pre and post application for the test group (SRRT) was statistically significant higher ($p < 0.001$) than the control group (PT).

Conclusion: SRRT containing 0.454% Stannous Fluoride (an active ingredient) can be effectively used to reduce pain and discomfort during the ultrasonic scaling procedure.

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1. Introduction

Scaling is an important part of non-surgical therapy in periodontics. Among the machine-driven scaling, sonic and ultrasonic scalers are in demand among patients for their time-saving nature. Ultrasonic scalers include magnetostrictive and piezoelectric scalers. The vibrations are transferred to the tip of the instrument, resulting in the shuddering of the scaler tip in the range of 25,000 to 42,000 Hz.[1] The ultrasonic scalers exhibit the property of acoustic micro streaming which helps remove calculus.[2] The oscillatory action of the tips of the scalers in the water flow causes different velocity gradients to be created in a small distance, which satisfactorily destroys the viable cells and tissues. Biofilm is affected by the ultrasonic mechanism and thus removes plaque effectively.

Pain is a subjective sensation that is characterized based on various entities like type, nature, duration etc. It is linked with the receptors on the unmyelinated and myelinated, C and Aσ fibres respectively. [3] The discernment of pain occurs usually in three stages. The primary stage involves the sensitivity, the second stage involves the peripheral nervous system and the third stage involves the transmission to the central nervous system. Since pain is not an objective sensation, it can only be measured subjectively by measuring it on different types of scales. [4]

Jacobson et al in 1994 suggested that the use of ultrasonic scalers is the most favourable in generating a smooth root surface that does not favour plaque retention. [5] The working parameters, shape and size of the scaler tips

can be adjusted to cater to the needs of the clinical condition. [6]

Although ultrasonic scaling is a fundamental part of non-surgical periodontal therapy, some patients regard it as irritating and painful. [7] However, the discomfort or pain produced during the procedure differs for different patients. Many procedures like the use of topical anaesthesia or the use of local anaesthetics have been applied to reduce the discomfort during the procedure. Patients' resistance to the treatment could be due multifactorial including lack of inspiration, considering the treatment unimportant as well as the attitude and belief of the patient. Thus, as a clinician it is important to deliver the treatment as smoothly and painlessly as possible.

Stannous fluoride as a desensitizer in toothpaste has proved to be effective in reducing dentinal hypersensitivity following 8 weeks of use. [8] The purpose of this study is to assess the usefulness of the SRRT containing 0.454% Stannous fluoride as the active ingredient in relieving pain during the ultrasonic scaling procedure.

2. Materials and methods:

This study had a split mouth design and was randomized, placebo controlled clinical trial. 50 patients with 30 male subjects and 20 female subjects with a mean age of 31.8 years who came with the chief complaint of deposits, no systemic illness, with chronic generalized gingivitis and pain or sensitivity in the contralateral posterior sites during the procedure were included in this study. Patients with abrasion, attrition or caries were excluded from the study. Informed consent was obtained from the patient. The study was carried out per the ethical guidelines of the Helsinki Declaration 1975, as revised in 2000. The Institutional Ethical Committee approved the study. The study was carried out from January 2019 to June 2019. The subjects were randomly divided into two groups by single investigator (ACD) using block randomization as follows.

Test group - Sensodyne Rapid Relief containing 0.454% Stannous Fluoride + Ultrasonic scaling.

Control group – Placebo without any active ingredient + Ultrasonic scaling

The respective contralateral posterior sites with pain during ultrasonic scaling were identified, and the patient's Visual Analogue Scale (VAS) was recorded using the index. The selected contralateral areas were isolated. The test area was applied with Sensodyne Rapid Relief toothpaste and left in place for 5 minutes, and the control area was applied with placebo toothpaste with no active ingredient. Then, ultrasonic scaling was done in both the test and control areas. The water and power control was kept constant throughout the study. During ultrasonic scaling, the patient visual analog scale (VAS) was recorded again for both the test and control areas. The VAS scores were recorded two times, before and after the application of paste, in both the test and control groups. An ultrasonic piezoelectric scaler unit (MECTRON MULTIPIEZO with Slim line insert, GE, Italy) was used for the scaling. All the procedures were performed by a single operator (MD). The data were then analyzed statistically using SPSS version 20 (IBM, Chicago, USA). The normality of the data was done through the D' Agostino and Pearson omnibus normality test. Student's unpaired "t" test was used to compare the data between the two groups. A p-value of less than 0.05 was considered statistically significant.

3. Results:

The results of the present study showed that the application of Sensodyne Rapid Relief during ultrasonic scaling significantly reduces the VAS score, thus indicating a reduction in pain and discomfort during the procedure. The unpaired T-test was used for the group comparison of VAS scores, and the Paired T-test was used for the intra-group comparisons. Table 1 represented the mean [±SD (Standard deviation)] VAS scores of the test and control group prior to application of Sensodyne Rapid Relief toothpaste and the placebo, which was found to be 8.16±1.00 and 8.18±0.72 respectively and the differences between the groups were not statistically significant ($p > 0.05$). However, post-application mean (±SD) VAS scores of the test and control groups were found to be 4.08± 1.05 and 6.30±0.93 respectively, as shown in Figure 1, and the differences between the groups were found to be statistically highly significant ($p < 0.001$), as shown in Table 2.

Table 1: Inter-group comparison of mean VAS score between test and control sites at Pre-treatment

Group	N	Mean	Std. Deviation (SD)	Std. Error Mean	95% CI of the difference		*p*-value*
					Lower	Upper	
Test	50	8.16	1.00	0.14	-0.37	0.31	0.909
Control	50	8.18	0.72	0.10	-0.37	0.31	

*Unpaired't' test, $p<0.05$ (statistically significant difference)

Table 2: Inter-group comparison of mean VAS score between test and control sites at Post-treatment

Group	N	Mean	Std. Deviation	Std. Error Mean	95% CI of the difference		*p*-value*
					Lower	Upper	
Test	50	4.08	1.05	0.15	-2.61	-1.83	0.000
Control	50	6.30	0.93	0.13	-2.61	-1.83	

*Unpaired‘t’ test, p<0.05 (statistically significant difference)

Table 3: Inter-group comparison of mean difference VAS scores between pre and post application

Group	N	Mean	Std. Deviation	Std. Error Mean	95% CI of the difference		*p*-value*
					Lower	Upper	
Test	50	4.10	0.95	0.135	1.87	2.57	0.000
Control	50	1.88	0.82	0.117			

*Unpaired‘t’ test, p<0.05 (statistically significant difference)

Table 3 represented the mean difference (±SD) in VAS score between the pre-application and post-application of the dentifrices of the test and control group, and the values were found to be 4.10±0.953 and 1.88±0.824, which were found to be statistically significant differences (p<0.001).

4. Discussion:

The present study imparts information regarding the patient’s pain perception during a routine dental procedure i.e. ultrasonic scaling. It is a vital part of the periodontal therapy both during the initial and the maintenance phase of the treatment. Although the procedure is very controlled and non-invasive in nature, the patient experiences pain or discomfort due to various factors. During the procedure, the patient experiences pain due to the high vibrating scaling tips along with the water spray.[9] Many approaches have been tried to make the scaling procedure trouble free for the patient. Malagi et al in 2014 used two types of scaler inserts (Slim line insert and Focus spray insert) during scaling and found no statistically significant difference in the intensity of pain sensed.[10] Discomfort during ultrasonic scaling can be controlled by decreasing the rate of water flow and also using lavage warm water for irrigation.[11] Chung et al in 2011 conducted a study to estimate the clinical effectiveness of Eutectic Mixture of Local Anaesthetic(EMLA) in reducing the pain during ultrasonic scaling procedure and concluded that a significant reduction in pain was observed with its use during the procedure.[12] Antoniazzi et al in 2015 studied the effect of topical intrapocket anesthesia on pain sensitivity during ultrasonic scaling and concluded that injectable anesthesia and EMLA showed the equivalent effect on pain perception and proved to be better than 2% benzocaine during ultrasonic scaling. Shaju et al in 2012 compared the clinical efficacy of a topical anaesthesia in controlling pain during ultrasonic scaling with placebo and concluded that pain was effectively decreased on intrasulcular application of 20% benzocaine gel in periodontitis patients. [13] Unlike previous reports, scaling was initially done in this study to record the contralateral areas that induced pain during the procedure to avoid embroidered response and bias. In addition to that a standardized environment was provided to every patient where only one investigator treated each patient in the same dental chair, with the same power settings and same environment. Also to minimize the interpatient variability, only systemically unhealthy patients were excluded from the study as some systemic factors could alter the reaction of an individual to stimuli. [14]

Many desensitizing agents like oxalates, potassium nitrate, and adhesive resins have been previously used to treat hypersensitivity. Sensodyne Rapid Relief contains Stannous fluoride and the polymer that results in faster occlusion of dentinal tubules, resulting in faster relief from pain sensation. The polymer facilitates the formation of a gel-like scaffold that holds the fluoride in place. This results in fixation of the stannous ion in the peritubular dentin thus causing desensitization of the nerve endings at a faster rate.[15] He et al. in 2011 evaluated the use of 0.454% stannous fluoride dentifrice in the treatment of hypersensitivity and concluded that it significantly reduced hypersensitivity following immediate application and after 8 weeks of use.[16] In a recently conducted study, the clinical efficacy of 0.454% stannous fluoride was evaluated in treating dentinal hypersensitivity and it concluded that dentifrice with 0.454% stannous fluoride significantly reduced hypersensitivity following immediate use.[17] A recent study by Attar et al. in 2019 evaluated the effectiveness of 5% KNO3 in the treatment of hypersensitivity and concluded that 5 % potassium nitrate dentifrice significantly reduced sensitivity in case of low and moderate VAS scores but for higher VAS scores, the agent was found to be ineffective.[18] Jena et al. in 2015 compared the clinical efficacy of three different desensitizing agents in the treatment of hypersensitivity and concluded that 15% hydroxyapatite nanoparticles were more effective in

reducing hypersensitivity than 5%Novamin and 8% Arginine following immediate application.

In this study, scalers were used at a slant close to zero degree. Sites treated with Sensodyne Rapid Relief containing 0.454% Stannous Fluoride showed a reduction in VAS scores and provided immediate relief from pain during ultrasonic scaling. The pain recorded was done simultaneously with the procedure, making the pain assessment very specific. The VAS scores showed a statistically significant difference in the test group compared to the control group, thus demonstrating the effectiveness of the Sensodyne Rapid Relief toothpaste.

The limitations of this study are that there wasn't any standardization for how deep the scaler tip is being entered into the sulcus and the force applied by the operator during the procedure. The socioeconomic factors and the gender that bring variation in the pain sensation have also not been considered. The intensity of pain could have been measured using more factual or objective techniques.

5. Conclusion

Within the limitations of this study, it can be concluded that using Sensodyne Rapid Relief containing 0.454% Stannous Fluoride could relieve pain and discomfort during the ultrasonic scaling procedure compared to a placebo dentifrice. However, further studies need to be done to assess pain intensity using more objective methods and compare different pain-relieving agents.

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