Effect of Anaesthetic Gel while Probing in Patients with Chronic Periodontitis: A Comparative Clinical Study

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Abstract

Aim

The aim of this study was to evaluate the efficacy of an intrapocket anesthetic gel in the reduction of pain on periodontal probing in a group of individuals with untreated periodontitis.

Materials and Method : A randomized, double-masked, split mouth clinical trial was conducted in 30 patients with chronic periodontitis with probing depth greater than 5 mm. Selected patients were randomnly divided into 2 groups. Test group (15 patients) anaesthetic gel (2% lignocaine) was placed in the pockets for 30sec and then probed. Control group (15 patients) was evaluated without gel placement. Each tooth was assessed at 6 sites and the clinical parameters included were probing depth, plaque index, pocket probing depth and clinical attachment level. Quantification of pain was done by using ungraded visual analogue scale with the left endpoint marked "no pain" and the right end point marked "worst imaginable pain".

Result : There were no significant differences in the mean number of teeth probed in the test side of the mouth versus the placebo side, nor was there any significant difference in the amount of gel each tooth received in test sides of the mouth. There was also no significant difference in the amount of time it took to probe placebo or test sides. The results demonstrated a statistically significant reduction in patient's perception of pain for the side of the mouth having the gel compared to the side of the mouth without the gel, reported through VAS pain scoring.

Conclusion : The anesthetic gel provides a statistically significant reduction in patients reporting of pain on periodontal probing in patients with untreated periodontitis. It suggests that the gel may be used for those patients who find the full-mouth periodontal probing experience particularly painful.

Keywords : Intrapocket Anesthetic Gel, Chronic Periodontitis, Comparative Study.

Introduction

Periodontitis is a common chronic infectious disease affecting the adult population and is characterized by a progressive gingival inflammatory response to bacterial dental plaque, eventually leading to tooth loss.[1] The patient's comfort during periodontal instrumentation especially when used for diagnostic purposes has received little attention despite it being one of the most frequent oral treatment procedures.[2] Periodontal probing has been reported to be a

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significantly painful experience for as many as 15% to 77% of patients with untreated periodontal disease, mainly attributable to the fact that periodontal tissues are in their most inflamed state.[3] The degree of inflammation can influence the pain threshold of the tissues.[4] The use of periodontal probes, scalers and/or curets is essential for the diagnosis and pre surgical treatment of periodontitis. Evaluation of any response to periodontal therapy is measured most of all through the surrogate variable of periodontal probing depth (PD) and its derivatives (attachment loss/clinical attachment level [CAL]).[5] A common method used in pain studies is the visual analog scale (VAS).[6]A study investigated the relationship between pain on periodontal probing and inflammation of the gingival tissues through studying the degree of pain on periodontal probing before and after initial periodontal therapy. They observed that, as visual signs of inflammation and bleeding on probing (BOP) decreased, so did the VAS pain scores, suggesting that the degree of periodontal inflammation is related to the pain and discomfort associated with periodontal probing.[7] Only recently has the pain threshold during probing been determined in patients with a healthy periodontium.[8] Currently, there are limited practical techniques to reduce this pain. Topical anesthetics (jellies, ointments, or sprays) may be preferred because they produce less post procedure numbness, but problems relating to lack of efficacy attributable to inadequate depth of penetration, uncontrolled spreading, insufficient duration of action, and difficulties of administration have limited their use.[9]

More recently, an intrapocket anesthetic gel has been evaluated.[10] This anesthetic gel contains the active ingredients 2% lignocaine. At room temperature, it exists as a low-viscosity fluid, whereas when applied into a periodontal pocket, it transforms to an elastic gel. This feature allows it to remain at the application site, providing controlled anesthesia. So far, studies have evaluated the use of this anesthetic gel for purposes of scaling and root planing (SRP) procedures in a variety of patients.[11] As yet, the use of this anesthetic gel has not been evaluated for purposes of anesthesia for full-mouth probing procedures. Thus this study was conducted to evaluate the efficacy of an intrapocket anesthetic gel in the reduction of pain on periodontal probing in a group of individuals with untreated periodontitis.

Materials and Method

A randomized, double-masked, split mouth clinical trial evaluating the efficacy of the anesthetic gel in group of individuals with untreated periodontitis with probing depth greater than 5 mm. The study gained ethical approval from the ethical committee at ITS Dental College. The study period was from December 2012 to Feburary 2013.

Study Population

Thirty participants were recruited from patients that were referred (internal and external referrals) to the Department of Periodontology and Oral Implantology, ITS Dental College, Ghaziabad in relation to their periodontal condition.

Screening Visit

This visit comprised a routine dental history (including presenting complaint, medical history, dental history, social history, oral hygiene practices, etc) and examination (including extra-oral and intra-oral examinations, examination of dental hard

tissues, and when indicated, radiographic tests and vitality testing).

Inclusion criteria : 1) 18 to 65 years of age; 2) patients with ≥4 sextants with a PSR of 4 (i.e., denoting the presence of ≥1 teeth with PD >5 mm in that sextant); 3) patients needed to have a minimum of two incisors, one canine, one premolar, and one molar in all four maxillary quadrants 4) patients should not have undergone SRP/detailed periodontal treatment in the previous 12 months and 5) a signed informed consent form approved by the ethics committee of the ITS Dental College, Ghaziabad.

Exclusion criteria : The following individuals were excluded from the study: 1) those requiring prophylactic antibiotics before periodontal probing 2) those suffering from any psychiatric disorders or with chronic pain problems 3) those with coagulation disorders or on anticoagulation therapy 4) pregnant or lactating patients 5) patients with congenital or idiopathic methemoglobinemia or those receiving treatment with methemoglobin-inducing agents 6) those reporting allergies to dental anesthetics 7) those taking non-steroidal anti-inflammatory drugs 3 days before participation in the study and 8) patients having acute periodontal pain, pulpitis, abscesses, or other acute infections. Of the 64 patients examined, 38 met the entry requirements, and 30 agreed to take part in the study. An information sheet was issued to them and they were subsequently invited to a second "test visit."

Test Visit

This study uses a single caliberated examiner to perform periodontal probing at the test visit for all patients. It was decided to use a non-standardized probing force to reflect the conditions applicable to private practice.

The study was performed in a split-mouth manner, incorporating left and right sides. Only one side of the mouth would receive the "anaesthetic gel" other side would be probed without the gel. Gels was placed in 2-mm graduated locking syringes with a blunt-ended needle applicator (23 gauge, 0.6mm).

The examiner began with the lower right side, the quadrant was dried and then isolated with cotton rolls, and a lingual aspirator was used as tongue retraction. The anaesthetic gel was then administered around each of the gingival margins of the test teeth and also into the periodontal pockets. Central incisors were excluded from gel application to avoid cross-side contamination with test gel and subsequently excluded from the actual periodontal probing. The gel was left in situ for a period of 30 sec after application and before probing began. Periodontal pocket measurements were taken using a Williams probe. The amount of recession was recorded, as well as the presence of BOP and/or suppuration. The amount of time taken for application and probing was noted. This was to ensure that the amount of time spent injecting the gel and probing around teeth was relatively equal for each quadrant. After completion of recording the details in one quadrant, the gel was washed away with 30 seconds of water spray. The same examiner then proceeded to other side/quadrant. This was dried and isolated, and the procedure was repeated without placement of the anaesthetic gel. After washing this quadrant, the patient was then asked to fill out a pain assessment for probing in the right side of their mouth using graded VAS of 0-10, with 0 marked as "no pain" and 10 marked as "worst imaginable pain" and 5 marked as “moderate pain ” as the primary efficacy parameter. By compiling results in

this manner, each patient was effectively acting as their own control, producing two separate VAS for probing on both the right and left sides of their mouth. (Fig. 1)

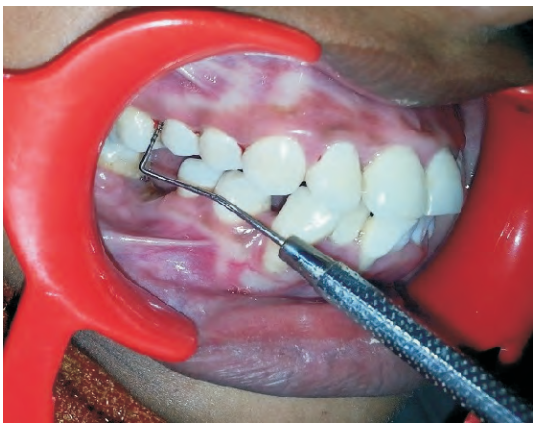

Fig.1: Periodontal Probing After Local Anaesthetic Gel Placement.

Statistical Analysis

Descriptive statistics and data analyses were performed using statistical software. Basic analysis was performed within a side results were compared by a paired t test.

Results

There were no significant differences in the mean number of teeth probed in the test side of the mouth versus the control side, nor was there any significant difference in the amount of gel each tooth received in test sides of the mouth. There was also no significant difference in the amount of time it took to probe control or test sides. All 30 patients who participated in the study completed the full probing examinations, with no adverse events being reported.

Efficacy Results

A box plot demonstrates the VAS in millimeters for both the test and control group. The bottom edge of the box is the 25th percentile, the top is the 75th, and the thickened center line is the median. (Fig. 2, Table 1-3)

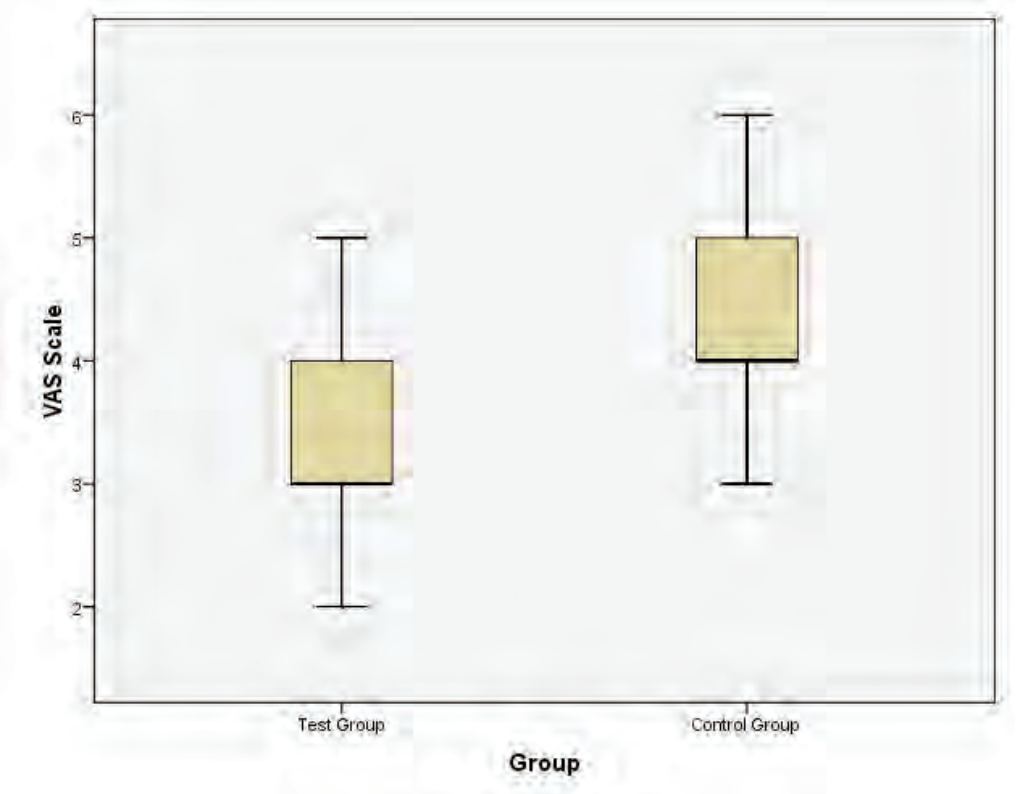

Fig. 2: Box Plots Of Test And Control Group

Table 1: Paired Sample Statistics Of Test And Control Group
Showing that the mean ±sd was 3.17 ± 0.74 for Test Group and 4.40 ± 0.72 for Control Group.

Groups	Mean	N	Std. Deviation	Std. Error Mean
Control Group	4.40	30	0.724	0.132
Test Group	3.17	30	0.747	0.136

Table 2: Paired Differences Of Control And Test Group

	Paired Differences					T	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Control Group - Test Group	1.233	0.858	0.157	0.913	1.554	7.870	29	0.000*

*The Paired T-test Was Highly Significant ($p<0.001$).

Table 3: Descriptive Statistics Of Various Parameters

Parameters	N	Minimum	Maximum	Mean		Std. Deviation
	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic
PPD	30	5.0	7.0	5.957	0.1008	0 .5519
CAL	30	4.1	56.2	7.273	1.6924	9.2699

Discussion

The results demonstrated a statistically significant reduction in patient's perception of pain for the side of the mouth having the gel compared to the side of the mouth without the gel, reported through VAS pain scoring.

Three previous multicenter, double-masked, randomized, placebo-controlled clinical trials studied the efficacy of the anesthetic gel for purposes of SRP procedures.[12] These three studies included 337 individuals at 18 study centers. The studies used Hodges-Lehmann point estimate of treatment differences and found that the results favor the anesthetic gel by reducing VAS pain scores by magnitudes of 8[11], 4[13] and 10 mm.[10]

Pain experienced during SRP is from two sources: one is the manipulation of the gingival tissues, and the second is the disturbing of the dentinal tubules, which produces pain from the non-anesthetized nociceptive fibers in the tooth pulp itself. The test anesthetic gel is not known to provide any form of pulpal anesthesia. Therefore, for a procedure like periodontal probing, in which the pain is purely from manipulation of periodontal tissues only, the test anesthetic gel may be more effective when compared to SRP procedures.

Studies have shown that full-mouth periodontal probing can potentially be a more painful experience compared to SRP procedures when reporting using a VAS pain scoring system .[10]The amount of pain during probing procedures is associated with the extent of periodontal inflammation. In the present study only newly referred patients with severe chronic periodontitis who had not had any treatment for 12 months fulfilled the inclusion criteria. By selecting patients with severe periodontitis, it was more likely that they would find the probing procedure painful; therefore, there is a potential for a bigger effect of the anesthetic gel in this study.

The gel used in the present study is 2% lignocaine with the addition of a thermosetting agent. This enables the gel to flow into the periodontal pocket, in which it becomes an elastic gel at body temperature. The onset of anesthesia has been shown to be 30 seconds after application.[14]

The present study relies on the use of the VAS for scoring pain and as the primary means of determining the efficacy of the anesthetic gel. Although the VAS is reliable, sensitive, reproducible, simple, quantifiable, and amenable to statistical analysis[15] it is important to recognize the subjective nature of pain.

Conclusion

The anesthetic gel 2% lignocaine, provides a statistically significant reduction in patients reporting of pain on periodontal probing in patients with untreated periodontitis. It suggests that the gel may be used for those patients who find the full-mouth periodontal probing experience particularly painful.

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