Comparative evaluation of oxygen releasing formula (Blue-M Gel®) and chlorhexidine gel as an adjunct with scaling and root planing in the management of patients with chronic periodontitis –A clinico-microbiological study

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Abstract

Introduction: Phase I therapy is the first step in the treatment of periodontal diseases. However, Scaling and root planing (SRP) alone was found to be of limited efficacy especially in certain unapproachable areas, hence use of an adjunct to SRP has been advocated. In past, chlorhexidine has been used as an adjunct to SRP successfully and is considered as gold standard. Recently, use of commercially available BLUE –M® gel (high level oxygen releasing formula) has been advocated in the field of Periodontology.

Objective: The objective of the present study was to compare and evaluate the efficacy of Chlorhexidine gel and Blue-m® gel as an adjunct to non-surgical periodontal therapy (SRP) in ≤ 5 mm periodontal pockets, with regard to its clinical effectiveness and bactericidal properties.

Materials and Methods: A total of 20 Patients of chronic periodontitis with pocket probing depth ≤ 5 mm were divided into control group1: (SRP + chlorhexidine gel) and test group 2 (SRP + blue m® gel). Standardized periodontal parameters including Gingival index (GI), pocket probing depth (PPD), clinical attachment loss (CAL) were measured at baseline & 1 month respectively. Total bacterial count was assessed semi quantitatively at baseline and 1 month.

Result & Conclusion: Both the gels, chlorhexidine gel and blue m gel were equally effective and comparable in management of chronic periodontitis.

Keywords: Chlorhexidine, Scaling & root planning, Oxygen releasing gel, Periodontitis.

Introduction

Periodontitis describes a group of related diseases which out-turns in the desolation of the tissues that support the tooth structure. Oral microflora initiates most destructive diseases that lead to periodontal attachment loss.¹

Till date scaling and root planing (SRP) endures to be the “gold standard” for periodontal diseases compared to other treatment options and is still practised widely. The inflammatory changes in the periodontal tissue is instigated mainly by the microbial plaque and bacterial infection. A highly structured and complex biofilm is formed in the periodontal pocket by the bacteria. As this process continues, the biofilm reaches far subgingivally and it becomes inconvenient for the patient to reach it during oral hygiene practices.²

Traditional treatment options for such conditions such as chronic periodontitis include mechanical debridement aimed at disrupting the biofilm. However, as the anatomy of the root is complex the location of the lesion may hamper the treatment and prevent sufficient reduction of the bacterial load. Studies have assessed the value of various locally delivered antimicrobial systems either as monotherapy or as an alternative to the conventional scaling and root planing in management of the patients with chronic periodontitis³

Also, after nonsurgical therapy (SRP), thorough debridement is not fully achieved and several deep periodontal pockets are still believed to persist so, in cases like these, the patient has to undergo surgical procedures.⁴

Despite various advantages the systemic antibiotic therapy has various disadvantages too such there is the evolution and maturing of resistant bacteria and administration of higher dosages so as to attain required concentration of gingival crevicular fluid at the target sites led to the discovery of local drug delivery system.⁵

The flora associated to chronic periodontal diseases is dominated by the presence of Gram-negative anaerobic bacteria, such as *A. actinomycetemcomitans* and *P. gingivalis*.⁶

Chlorhexidine gel is an antiseptic that binds very strongly to the surface of teeth, inner cheeks and gums. It also kills the harmful microorganisms that cause swollen gums, tartar, bad odour from mouth, and other mouth infections.⁷

Over the past years, strong evidence has shown to compromise oxidative stress in pathogenesis and etiology of periodontitis as one of the cause. Also, Free radicals and reactive oxygen species (ROS) are very essential to biologic processes occurring normally. These free radicals can stimulate the growth of fibroblasts and epithelial cells at low concentrations, but it may result in tissue injury if subjected to higher concentrations.⁸

ROS encompasses reactive species such as singlet oxygen, hydrogen peroxide etc which are not true radicals but can however, transform to free radicals in both intra- and extra-cellular environments. ROS acts as intra cellular signal transducers resulting in autophagy, which plays a dual role in periodontitis by promoting cell death or blocking apoptosis in infected cell.⁹

Bluem® oral gel is specially recently developed formula by implantologists, oral surgeons and dentists for specific targeted problems in the mouth and is claimed to possess unique properties when compare to convention local drug delivery systems. It improves the healing of the wounds by intensifying the levels of oxygen in periodontal pockets, bleeding gum, wounds which results from traumatic extraction, in implant dentistry, chemotherapy. The use of this unique formula improves oral hygiene of an individual and also, reduces the risk of infections and inflammation.

Aim

The comparative evaluation of oxygen releasing formula (blue-m gel®) and chlorhexidine gel as an adjunct with scaling along with root planing in the management and treatment of patients with chronic periodontitis

Materials and Methods

The study was performed selecting thirty subjects who successfully fulfilled the inclusion criteria and those who did not, were excluded out of the study. All probable participants were explained the design of the study. Subjects who agreed to participate and consented by written informed approval were included.

Inclusion criteria

1. An age group of 20–50 years
2. Both sexes were included
3. Patients with Chronic periodontitis
4. Probing pocket depth less than or equal to 5mm (≤ 5 mm)
5. Gingival index (GI)
6. Plaque index (PI)

Exclusion criteria

1. Subjects who had priorly taken antibiotics or were on antibiotics during the trial
2. Medication taken by patient that would induce gingival enlargement
3. Pregnant women or lactating mothers.
4. Current Smokers
5. Patients with habit of Tobacco chewing.

Methodology

Clinical examination: The size of the samples for the present study was procured from the OPD or the outpatient Department of Periodontology and oral implantology ITS Dental College Muradnagar, Ghaziabad. After documenting of case history, proper clinical examinations were performed on a dental chair itself. After clinching inclusion and exclusion criteria patients with presence of localized or generalized chronic periodontitis were chosen for the study. Clinical parameters were taken such as PI, GI and pocket depth measurement were analysed at baseline (0 day) and at 30th day. Plaque samples were further stockpiled and evaluated for determining the colony forming units.

Study groups: The chosen thirty samples were arbitrarily divided into two groups using a split mouth design (flowchart 1) which were named as Group I (control) and Group II (experimental group). Left side was allocated for the control group (Group I) and other or the right side was allotted for the experimental group (Group II).

Group I (control group): 30 sites on the left side received SRP followed by local administration of chlorhexidine gel (hexigel) in the periodontal pocket with depth less than or equal to 5mm.

Group II (experimental group): Thirty sites on the right side were treated by SRP followed by blue m gel placement in the periodontal pocket.

Flowchart 1: Study allocation and procedure

Preparation of test materials: Chlohexidine gel (Fig. 1) in Group I (control group) 0.2% chlorhexidine gel (Cervitec Gel, Ivoclar Vivadent, Liechtenstein) was used. It is composed of chlorhexidine gel: with fluoride in conc of 900 ppm in combination with 0.2% chlorhexidinedi gluconate. Ingredients include: Aqua, hydroxyethyl cellulose, Laureth-23, sodium fluoride NaF, aroma, sodium saccharin.

Blue m gel (Fig. 2) in Group II (experimental group):

Blue m gel (15 ml): Composition: Aqua, Alcohol, Glycerin, Silica, Sodium Saccharin, Sodium Perborate, Citric Acid, PEG-32, Sodium Gluconate, Lactoferrin, Xanthan Gum, Cellulose Gum.

Fig. 1: Chlorhexidine gel

Fig. 2: Blue m gel

Procedure of periodontal therapy

Clinical examinations were carried out carefully and the values for evaluation at baseline were taken precedingly to the procedure and the recordings were made by one calibrated examiner also, values were taken on a standardized form which contained the analytical data of the patient, SRP was performed by ultrasonic scaler. After thorough SRP, the Pocket Probing Depth was re-determined by a probe followed by the local drug delivery of gels in both control and experimental sites.

In Group I, the area of interest was completely dried using air syringe, and then the isolation of the desired site was done with the help of cotton rolls that were made with the intention to prevent contamination from saliva. The local drug delivery consisting of 0.2% chlorhexidine gel (hexigel) was introduced into the periodontal pockets by means of a disposable syringe with a needle attached to it giving it a 90 degree bend so as to properly place the gel in position.

The pocket opening filled with the respective gels was then covered by Coe-Pak to retain the material or the gels in the periodontal pocket, as well as to prevent the ingress of oral fluids of the oral cavity.

With the same approach, in the experimental site (Group II) the local drug delivery system consisting of Blue m gel was put down in the periodontal pocket in similar manner. The pocket opening of the site was covered by Coe-Pak in an alike fashion. Both. The compared sites with there respective gels were then checked for the probing depth after a month that is at 30th day. As shown in fig. 3.

Fig. 3:(A)Initial pocket probing depth at baseline (B) insertion of chlorhexidine gel (C) pocket probing depth at 30 days (D) Initial pocket probing depth at baseline (E) insertion of Blue m gel (F) pocket probing depth at 30 days.

Microbiological analysis

The collection of plaque sample was performed in the Department of Periodontology, ITS Dental College, and Hospital, Ghaziabad. The collection of subgingival plaque samples was carried out by the same operator to standardize the sampling procedure and to avoid any bias. Before taking the samples, the neighbouring teeth were secluded with cotton rolls. Samples consisting of plaque were collected and scrapped from all the quadrants to achieve sufficient

sample volume and was pooled in “reduced trypticase soy agar” for microbiological analysis. Plaque samples that were contaminated with blood or saliva were repudiated. Immediately after taking out the samples, they were transferred for microbiological analysis of *Aa* and *Pg* which had to be separately vortexed and inoculated or grown in anaerobic jar to meet the requirement for culturing and quantification of anaerobic bacteria as shown in fig 4 A,B,C,D.

Fig. 4: (A) Plaque sample collected in test tubes (3ml) phosphate buffer saline (PBS); (B): Undiluted PBS containing plaque inoculated into trypticase soy agar plates; (C): Plates incubated in incubator with anaerobic gas pack at 37 degrees; (D): Colony counting under microscope; (E): Colonies on trypticase soy agar at baseline and at 30 days.

Statistical analysis

All entries of the data was formulated into a standardized format and examined to assess the efficacy of hexigel (Group I) and blue m gel (Group II) at baseline and at 30 days or 1 month using the statistical package for social sciences (SPSS 16.0 version). The Mean of standard deviation (SD) was calculated. Standardized periodontal parameters including Gingival index (GI), pocket probing depth (PPD), clinical attachment loss (CAL) were measured at baseline & 1 month respectively.

Total bacterial count (CFU) was assessed semi quantitatively at baseline and at 1 month. Statistical analysis was done using the unpaired t-test. Within-group comparison was done using paired t-test.

Test of significance i.e the P Value was set at - $P < 0.05$

Results

The value of PPD, GI decreased in SRP + Blue m gel from approx 4-5 mm at baseline to approx 2-3mm at 30 days as shown in (graph 1). and in the SRP +chlorhexidine gel from 3-4 mm at baseline to ≤ 5 mm at 30 days as shown in (Graph 2). Also at 30 days the bacterial colony count showed significant reduction in number as shown in (Graph 3) and values in (Table1 and Table 2).

Graph 1: Gingival index at baseline and at 30 days

Graph 2: Pocket probing depth (PPD) at baseline at 30 days

Graph 3: Colony forming units (CFU's) at baseline and at 30 days

Table 1: Gingival index mean values Inter group comparison

Groups	Group 1 (control)	Group2 (experimental)	values	
Mean GI +SD	50.63+0.67	50.43+0.72	t	0.838
Mean GI +SD	50.73+0.72	4.365	p	0.406

Table 2: Gingival index mean values and intra-group comparison of gingival index in Group I and Group II

Groups	Group 1 (control)	Group2 (experimental)	values	
Baseline 0 days	50.63+0.67	50.43+0.72	t	<0.001
At 30 days	40.73+0.72	4.365+0.56	p	<0.001

In the present study Blue m gel is found to be beneficial and encouraging when compared to chlorhexidine gel which is still considered the “Gold standard” to treat periodontal pockets with mild to moderate depth in patients diagnosed with chronic periodontitis, with noteworthy reduction in the indices scores and colony forming units scores compared to baseline values and at 30 days.

Discussion

Periodontitis expresses a group of concomitant inflammatory diseases resulting in the shattering of the tissues that provides support and strength to the tooth. Periodontitis is known to have composite etiology with the primary etiologic factor being pathogenic bacteria that is said to inhabit in the subgingival area.¹⁰

Based on the obtainable documentation, the introduction of local drug delivery into the periodontal pocket can enhance and improve the periodontal health, condition and status. However, these drugs sometimes fail

to completely replace the conventional scaling and root planing procedure.¹¹

Delivery of antimicrobial agents locally has been inquired into for defeating the restraints of conventional or traditional SRP therapy. Lately, the employing of sustained release formulations eg tetracycline fibers and metronidazole, gel chlorhexidine chip to deliver antimicrobial agents directly to the site with presence of infections within the periodontal pockets has become victorious therapy and many clinicians are widely accepting and using it.¹²

Chlorhexidine, as yet is said to be the most popular anti plaque agent and is considered as a ‘gold standard’ because of its potent antiplaque action, against which potency and benefit of other anti plaque and anti -gingivitis agents is appraised.

Its efficacy can be attributed to its potent bacteriostatic as well as bactericidal properties and its very well-known property of slow release i.e. substantivity within the oral cavity.¹³ It has exclusively and extensively been known as

an effective antimicrobial agent,¹⁴ however the use of chlorhexidine in any form for a prolonged period is limited by altered taste perception and staining of tooth.¹⁵

BlueM® oral gel formula is developed by a man on mission namely Peter Blijdrop for specific problems in the mouth with the following ingredients :Aqua, Alcohol, Glycerin, Silica, Sodium Saccharin, Sodium Perborate, Citric Acid, PEG-32, Sodium Gluconate, Lactoferrin, Xanthan Gum, Cellulose Gum with their specific functions.

The greater consequential abatement of Gingival index score in the experimental sites (Blue m gel) in our study could be owing to significant improvement in gingival inflammation, the high concentration of active oxygen, as it works fast and effective!

Significant reduction in pocket depth in sites treated with Blue M gel is because of release of more active oxygen of Blue m gel. This causes fast and progressive healing. The reduction in colony forming units was because of the fact that blue m gel is said to normalise and controls detrimental bacteria and thus, is analogous to chlorhexidine gel. Also, there were no complications or risks associated with performing the study with the Blue m gel.

However, Within the Limitation of the study: the substantivity of Blue m gel is not clear also the sample size and duration was less.

Conclusion

To summarise with, two of the gels i.e chlorhexidine gel and Blue m gel can be used as an reliable option or alternative to SRP, in the present study Blue m gel gel has shown to be fairly and coequally effective when compared to the chlorhexidine gel in treating periodontal pockets with mild to moderate depths

Source of funding

Nil.

Conflict of interest

None.

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