Comparative Evaluation of Oxygen Releasing Formula (Blue-M Gel®) and Metronidazole Gel as an Adjunct with Scaling and Root Planning in the Management of Patients with Chronic Periodontitis: A Pilot Study

Dr Sharmishtha Vijay, [1] Dr. Pavitra J, [2] Dr. Debopriya Chaterjee, [3] Dr. Rajeev Soangra, [4] Dr. Anjali Kapoor, [5] Dr. Jyoti Dad [6]

1. **Dr. Sharmishtha Vijay**
   Professor. & HOD , Department of Periodontics, RUHS College of Dental Science, Jaipur, Rajasthan, India
2. **Dr. Pavitra J.**
   Post Graduate Student, Department of Periodontics, RUHS College of Dental Science, Jaipur, Rajasthan, India
3. **Dr. Debopriya Chaterjee**
   Senior Demonstrator, Department of Periodontics, RUHS College of Dental Science, Jaipur, Rajasthan, India
4. **Dr. Rajeev Soangra**
   Senior demonstrator, Department of Periodontics, RUHS College of Dental Science, Jaipur, Rajasthan, India
5. **Dr. Anjali Kapoor**
   Sr. Professor, Department of Periodontics, RUHS College of Dental Science, Jaipur, Rajasthan, India
6. **Dr. Jyoti Dad**
   Post Graduate Student, Department of Periodontics, RUHS College of Dental Science, Jaipur, Rajasthan, India

CORRESPONDING AUTHOR
Dr. Rajeev Soangra
Senior Demonstrator,
Department of Periodontics, RUHS College of Dental Science, Jaipur, Rajasthan, India
Mobile - +917737323235
Email - rajeevsoangra@gmail.com

Abstract

Introduction: The first stage of treating periodontal disorders is called phase I therapy. Scaling and root planning (SRP) alone was found to be of limited efficacy especially in certain inaccessible areas, hence use of an adjunct to SRP has been advocated. Metronidazole has been effectively utilised in the past as an addition to SRP. In the discipline of periodontology, the use of commercially available BLUE -M® gel (high level oxygen releasing formula) has recently been encouraged.

Objective: The purpose of this study was to compare and assess the effectiveness of Blue-m® gel and Metronidazole gel as an adjuvant to non-surgical periodontal treatment (SRP), in terms of its clinical efficacy, in periodontal pockets ≥ 4 mm.

Materials and Methods: 20 patients with chronic periodontitis were randomly allocated into group A (SRP + blue m® gel) and group B (SRP + Metronidazole gel). Clinical parameters

such as Oral hygiene index simplified (OHI-S), Sulcus bleeding index (SBI), Probing pocket depth (PPD), Clinical attachment level (CAL)were measured at baseline & 6 week respectively.

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

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

INTRODUCTION

Periodontitis is a chronic inflammatory disease caused by microorganisms that have colonized the subgingival area. Despite the host's protective mechanisms these microorganisms are responsible for the connective tissue breakdown and alveolar bone loss.[1]

Scaling and root planning (SRP), is commonly used for treating periodontal diseases. Bacterial infection and microbial plaque are the main causes of the inflammatory alterations in periodontal tissue. The bacteria create a highly organised and intricate biofilm in the periodontal pocket. As the process goes on, the biofilm becomes difficult for the patient to access during oral hygiene procedures because it has spread far beneath the gingiva.[2]

Mechanical debridement, which disrupts the biofilm, is a traditional therapeutic option for disorders including chronic periodontitis. The location of the lesion, however, may make therapy more difficult and hinder a meaningful reduction in the bacterial burden due to the complex anatomy of the root. Numerous locally delivered antimicrobial solutions have been evaluated in studies as alternatives to traditional scaling and root planning or as monotherapy for the treatment of chronic periodontitis.[3]

Additionally, comprehensive debridement is not often obtained after SRP, and some deep periodontal pockets are thought to still exist. In these situations, the patient must undergo surgical therapy.[4]

Gram-negative anaerobic bacteria, such as A. actinomycetemcomitans and P. gingivalis, predominate in the flora of chronic periodontal diseases.[5]

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.[6]

Metronidazole gel has selective antimicrobial activity against obligate anaerobes has been used for the treatment of gingivitis and periodontitis. It significantly reduces the total bacterial count in gingival crevicular fluid.[7]

Strong evidence over the past few years has implicated oxidative stress as one of the factors contributing to the development and aetiology of periodontitis. Also, for biological processes to proceed normally, free radicals and reactive oxygen species (ROS) are crucial. At low concentrations, these free radicals can promote the development of fibroblasts and epithelial cells, but greater amounts could cause tissue damage.[8]

Blue m® oral gel is recently developed formula for specific targeted problems in the mouth and it claim's 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.[9]

Aim

To compare the effect of oxygen releasing oral gel (blue-m gel®) and metronidazole gel as an adjunct with scaling and root planning in the management of patients with chronic periodontitis.

Objective

To evaluate Clinical parameters like OHI-S, SBI, PPD, CAL at baseline & at 6 weeks.

Materials and Methods

20 participants were chosen for the study who successfully met the inclusion criteria. The study design was explained to all potential participants with their written informed consent.

Inclusion Criteria

1. Patients with chronic periodontitis with clinical attachment level >3mm and pocket depth ≥4mm (stage 2 and 3 periodontitis)
2. Age range between 20 and 65 years.
3. Systemically healthy subjects.

Exclusion Criteria

1. Patients With Systemic Diseases,
2. Patients under antibiotic and anti-inflammatory medication.
3. Smokers
4. Pregnant and lactating females.

METHODOLOGY

Clinical examination: The patients for the present study was procured from the outpatient Department of Periodontology and oral implantology, RUHS College of Dental sciences, Jaipur. Following the recording of the case history, clinical examinations were carried out. Patients with either localised or generalised chronic periodontitis were recruited for the study after meeting the inclusion and exclusion criteria. Clinical parameters were taken such as OHI-S, SBI, PPD, CAL were analysed at baseline (0 day) and at 6 weeks.

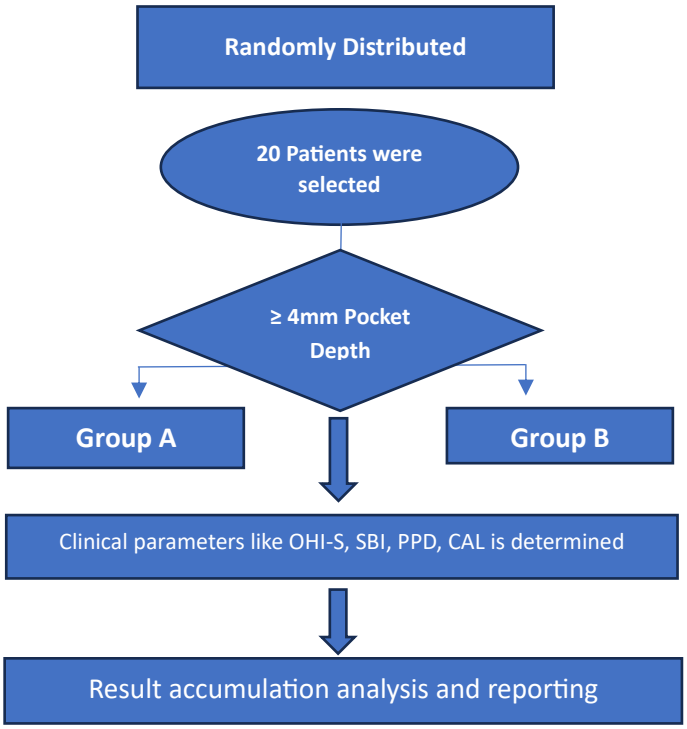
Study Groups

A total of 20 patients who fulfilled the inclusion criteria were enrolled in the study.

The Patient were randomly allotted into two groups by lottery method.

Group A: 10 Patients received SRP followed by local administration of blue m gel in the periodontal pocket with depth ≥ 4mm.

Group B: 10 Patients received SRP followed by local administration of metronidazole gel in the periodontal pocket with depth ≥4mm.



Flowchart 1: Study allocation and procedure

Preparation of Test Materials

Metronidazole gel(20g): Composition: Metronidazole Gel (1.5 %w/w)

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

Procedure of Periodontal Therapy

Clinical examinations were carefully performed, values for baseline evaluation were obtained prior to the procedure, and recordings were made by a single calibrated examiner as well. Values were obtained on a standardised form that contained the patient's analytical data, and SRP was carried out using an ultrasonic scaler. Following complete SRP, a probe was used to re-determine the Pocket Probing Depth, which was then followed by the local drug delivery of gels at both the control and experimental sites.

In Group A, the region of interest was thoroughly dried using an air syringe, and then the desired site was isolated using cotton rollers created specifically to guard against saliva contamination. Blue m gel, a local drug delivery, was injected into the periodontal pockets using a disposable syringe with a needle attached to it that had been bent at a 90-degree angle. The local drug delivery system composed of Metronidazole gel was placed in the periodontal pocket at the study site (Group B) using the same method. After 6 weeks, the comparable sites with their respective gels were tested for the probing depth.

Modified sulcular bleeding index by mombelli with scores 0,1,2,3 using periodontal probe to assess bleeding on probing and clinical attachment levels was assessed using periodontal probe with fixed point on the teeth (CEJ).

INITIAL PROBING DEPTH

INSERTION OF GEL

POCKET DEPTH AT 6 WEEKS

Statistical Analysis

To evaluate the effectiveness of blue m gel (Group A) and Metronidazole gel (Group B) data were organised into a uniform manner. Using the statistical tool, mean standard deviation (SD) was calculated. Clinical parameters like OHI, SBI, PPD, CAL were assessed, respectively, at baseline and at 6 weeks.

Paired t-tests were used for within-group comparison. Test of significance i.e the P Value was set at - $P < 0.05$

RESULTS

INTERGROUP COMPARISON OF OHI-S BETWEEN THE GROUPS

	Pre Treatment	Post Treatment	Mean Change	Percentage change	p value	P value
Group A	4.32±1.20	2.21±1.20	2.11±0.89	50.94±19.77	0.901	Non-Sig
Group B	4.49±1.08	2.20±0.84	2.29±0.63	51.84±10.78		

Independent t test with p value less than 0.05 as the significance level

INTRAGROUP COMPARISON OF OHI-S BETWEEN PRE AND POST TREATMENT LEVELS

	Pre Treatment	Post Treatment	Mean Change	p value
Group A	4.32±1.20	2.21±1.20	2.11±0.89	0.001 (Sig)
Group B	4.49±1.08	2.20±0.84	2.29±0.63	0.001 (Sig)

INTERGROUP COMPARISON OF PROBING DEPTH BETWEEN THE GROUPS

	Pre Treatment	Post Treatment	Mean Change	Percentage change	p value	P value
Group A	6.70±0.48	4.40±0.52	2.30±0.48	34.28±6.26	0.003	Non-Sig
Group B	6.60±0.52	5.10±0.73	1.50±0.53	22.81±8.26		

Independent t test with p value less than 0.05 as the significance level

INTRAGROUP COMPARISON OF PROBING DEPTH BETWEEN THE GROUPS

	Pre Treatment	Post Treatment	Mean Change	P value
Group A	6.70±0.48	4.40±0.52	2.30±0.48	0.001 (Sig)
Group B	6.60±0.52	5.10±0.73	1.50±0.53	0.001 (Sig)

INTERGROUP COMPARISON OF SULCULAR BLEEDING BETWEEN THE GROUPS

	Pre Treatment	Post Treatment	Mean Change	Percentage change	p value	P value
Group A	2.03±0.31	0.52±0.17	1.51±0.26	74.53±7.59	0.803	Non-Sig
Group B	1.81±0.42	0.46±0.16	1.35±0.42	73.90±8.38		

Independent t test with p value less than 0.05 as the significance level

INTRAGROUP COMPARISON OF SULCULAR BLEEDING BETWEEN THE PRE AND POST TREATMENT LEVELS IN BOTH THE GROUPS

	Pre Treatment	Post Treatment	Mean Change	Percentage change
Group A	2.03±0.31	0.52±0.17	1.51±0.26	0.001 (Sig)
Group B	1.81±0.42	0.46±0.16	1.35±0.42	0.001 (Sig)

INTERGROUP COMPARISON OF CAL BETWEEN THE GROUPS

	Pre Treatment	Post Treatment	Mean Change	Percentage change	p value	P value
Group A	5.00±1.05	3.50±0.85	1.50±0.85	28.66±14.90	0.724	Non-Sig
Group B	5.30±0.83	3.90±0.87	1.40±0.52	26.66±9.40		

Independent t test with p value less than 0.05 as the significance level

INTRAGROUP COMPARISON OF CAL FROM PRE TO POST TRATEMNET LEVELS IN BOTH THE GROUPS

	Pre Treatment	Post Treatment	Mean Change	Percentage change
Group A	5.00±1.05	3.50±0.85	1.50±0.85	0.001 (Sig)
Group B	5.30±0.83	3.90±0.87	1.40±0.52	0.001 (Sig)

From the results it is seen that there is a significant difference in reduction in probing pocket depth. The mean difference between the probing depth reduction in group A (Blue M gel) from baseline to 6 week was 2.3 and the mean difference probing depth reduction in group B (metronidazole gel) from baseline to 6 week was 1.5. Group A showed better potential in probing depth reduction.

Blue m gel is found to be helpful and encouraging in the current study. There was a notable decrease in the indices scores and colony forming unit scores compared to baseline values and at 6 weeks.

DISCUSSION

This is the first study according to our knowledge in which blue m gel and metronidazole is compared.

The Intra group comparison of clinical parameters like OHI-S, SBI, PPD, CAL was statistically significant in both the groups.

The mean probing depth at the day of drug delivery was for Blue M gel group was 6.70mm SD±0.48mm and the mean probing depth six week after drug delivery was 4.40 SD± 0.52mm .The mean probing depth at the day of drug delivery was for Metronidazole gel group was 6.60 mm SD±0.52mm and the mean probing depth six week after drug delivery was 5.10 SD± 0.73 mm.

From the results it is seen that there is a significant difference in reduction in probing pocket depth. The mean difference between the probing depth reduction in group A (Blue M) from baseline to 6 week was 2.3 and The mean difference probing depth reduction in group B (Metronidazole gel) from baseline to 6 week was 1.5. Group A showed better potential in probing depth reduction.

The mean clinical attachment levels at the day of drug delivery was for Blue M gel group was 5.0 mm SD±1.05 mm and the mean clinical attachment levels six week after drug delivery was 3.50 SD± 0.85 mm .The mean clinical attachment levels at the day of drug delivery was for Metronidazole gel group was 5.30 mm SD±0.83 mm and the mean clinical attachment levels six week after drug delivery was 3.90mm SD±0.87 mm

The mean bleeding on probing levels at the day of drug delivery was for Blue M gel group was 2.03 mm SD±0.31 mm and the mean bleeding on probing levels six week after drug delivery was 0.57SD± 0.17 mm .The mean bleeding on probing levels at the day of drug delivery was for Metronidazole gel group was 1.81 mm SD±0.42 mm and the mean bleeding on probing levels six week after drug delivery was 0.46 mm SD±0.16 mm

The Intergroup comparison of OHI-S, SBI, CAL between the Group A and Group B was statistically non-significant with almost similar average reduction .

According to the available evidence, the addition of local drug delivery into the periodontal pocket can increase and improve the status, condition, and health of the periodontal tissues.[10]

It has been investigated whether local delivery of antimicrobial drugs could overcome the limitations of conventional or standard SRP therapy. Utilising sustained release formulations of antibiotics like

tetracycline fibres, metronidazole gel, and chlorhexidine chips to deliver antimicrobial agents directly to the site of infections in periodontal pockets has recently proven to be a successful treatment, and many clinicians are now using it.[10]

Due to the release of more active oxygen by Blue M gel, pockets at areas treated with it have significantly less depth. Healing occurs quickly and effectively as a result. Because blue m gel is similar to Metronidazole gel in that it is believed to normalise and control harmful bacteria, the decrease in colony forming units was caused by this. Furthermore, using the Blue m gel to conduct the study had no drawbacks or hazards. The substantivity of Blue m gel is unclear, and the study's sample size and longevity were both smaller than expected.

CONCLUSION

Within the limitation of the study, we can say that SRP with blue m gel is as effective as SRP with metronidazole gel in the management of Chronic periodontitis.

Source of Funding

Nil.

Conflict of Interest

None.

BIBLIOGRAPHY

1. Oosterwaal PJ, Mikx FH, van't Hof MA, Renggli HH. Comparison of the antimicrobial effect of the application of chlorhexidine gel, amine fluoride gel and stannous fluoride gel in debrided periodontal pockets. J Clin Periodontol 1991;18:245-51.
2. Unsal E, Akkaya M, Walsh TF. Influence of a single application of subgingivalchlorhexidine gel or tetracycline paste on the clinical parameters of adult periodontitis patients. J Clin Periodontol 1994;21:351-5.
3. Rafiei M, Kiani F, Sayehmiri F, Sayehmiri K, Sheikhi A, Zamanian Azodi M. Study of Porphyromonasgingivalis in periodontal diseases: A systematic review and meta-analysis. Med J Islam Repub Iran 2017;31:62
4. Manthena S, Ramesh A, Srikanth A, Ramoji Rao MV, Preethi PL, Samatha YP. Comparative evaluation of subgingivally delivered chlorhexidine varnish and chlorhexidine gel in reducing microbial count after mechanical periodontal therapy. J Basic Clin Pharm 2014;6(1):24-8
5. Quirynen M, Teughels W, De Soete M, van Steenberghe D. Topical antiseptics and antibiotics in the initial therapy of chronic adult periodontitis: Microbiological aspects. Periodontol 2000.2002;28:72-90.
6. Kaldahl WB, Kalkwarf KL, Patil KD, Dyer JK, Bates RE Jr. Evaluation of four modalities of periodontal therapy: Mean probing depth, probing attachment level and recession changes. J Periodontol 1988;59:783-93
7. 7.P.K.Miani,C. do Nascimento ,S.Sato,A.V.Filho,M.J.da Fonseca,V.Pedrazzi,In vivo evaluation of a metronidazole-containing gel for the adjuvant treatment of chronic periodontitis: preliminary results, Eur.J.Clin.Microbiol. Infect.Dis.31(7) (2012) 1611-1618.
8. Dahiya P, Kamal R, Gupta R, Bhardwaj R, Chaudhary K, Kaur S. Reactive oxygen species in periodontitis. J Indian Soc Periodontol 2013;17(4):411-6.
9. 9 . Greenstein G, Polson A. The role of local drug delivery in the management of periodontal diseases: a comprehensive review. J Periodontol 1998;69(5):507-20.
10. 10. Magnusson I. Local delivery of antimicrobial agents for the treatment of periodontitis. Compend Contin Educ Dent 1998;19.