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Evaluation of Ornidazole and Metronidazole as Adjuncts to Non-Surgical Periodontal Therapy: A Clinical Evaluation

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KEYWORDS

metronidazole, ornidazole, non-surgical periodontal therapy, periodontitis, local drug delivery

ABSTRACT:

Introduction: Periodontal disease is agitating condition of periodontium involving both host immune system and pathogens and altering the unification of teeth supporting tissues. The removal of pathogenic flora with combination of SRP & LDD agents can be an effective approach.

Objectives: To appraise effectiveness of sub gingival application of ornidazole & metronidazole adjuvant to non-surgical periodontal therapy in managing periodontal disease.

Material & Methods: 70 patients splitted into 2 groups. Group 1 (35 subjects) were selected for subgingival placement of Ornidazole and Group 2 (35 subjects) were selected for subgingival placement of Metronidazole. Clinical parameters PI, GI, PD and CAL were assessed at baseline, one month and three months.

Results: Results showed significant betterment in clinical variables. The clinical variables showed substantial decrease in PI, GI, PD and gain in CAL from baseline to three months of time interval group 1 as compared to group 2.

Conclusion: within the limitations and based on the clinical variables, therapy with LDD both ornidazole and metronidazole enhances the benefits in non-surgical periodontal therapy.

1. Introduction

One of the most common chronic illnesses that impact directly on the people is dental diseases. Inflammatory disease such as periodontitis is preceded by gingivitis and spreads into the deeper areas of periodontal attachment apparatus. Nevertheless, gingivitis can continue without advancing to periodontitis resulting in the deterioration of the supporting attachment apparatus.[1] There is a diverse secondary microbial colonization associated within the ecosystem of periodontal pocket environment such as gram negative facultative and obligate anaerobes that include capnocytophaga species, Aggregatibacter actinomycetemcomitans, Bacteroides species and P. gingivalis. The secondary colonizers start gathering on the roots of compromised tooth and soft tissues as well.[2] If the inflammatory disease progresses it may result in tooth mobility and finally tooth loss. The primary key therapy for periodontitis is non-surgical periodontal therapy with basic therapy that includes SRP which is

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mechanical mode of treatment. NSPT included both mechanical and chemotherapeutical methods prevent and minimizes the microbial biofilm colonies which is the root cause of gingivitis and periodontitis. Local placement of antimicrobials is an effective method for the elimination of systemic adverse reaction without any adverse reactions in the body.[3]

The controlled use of local drug delivery antimicrobials has an advantageous effect by providing the drug at the local sites and without interfering with body immune system.[4] LDD agents based upon hypothesis that an antimicrobials agents applied instantly subgingivally and contribute high concentration of drug for a prolonged time period without any adverse reactions.[5] Local drug delivery is also known as site specific delivery as an advanced approach by placing a drug locally at the diseased site which was introduced by Goodson et al 1997. Basically, this concept gave a basis of LDD system in the treatment of periodontitis. LDD system helps to reduce or eliminate the multiplication of pathogenic microflora, decreased probing depth, stabilizes attachment and minimizes bleeding which eventually leads to controlling of the disease. Therefore, LDD has been used either alone or as an adjuvant to SRP. It can be used in maintenance phase (phase IV), post scaling and root planing cases to ensure that the disease does not occur. Various antimicrobials like tetracycline, doxycycline, minocycline, metronidazole, ornidazole and chlorhexidine assimilated locally in a controlled manner and marketed in the form of chips, gels, fibers and varnishes to the practitioner.[6]

Ornidazole is an antiprotozoal and antibacterial agent effective against anaerobic bacteria by reduces the nitro group into an amine group striking directly the microbial DNA which further inhibit their synthesis resulting in degradation of DNA. Metronidazole is a broad-spectrum antibiotic most commonly used for managing aggressive and chronic periodontitis. It is more efficacious against periodontal pathogens used as sole therapy or in combination with other antimicrobials for management of periodontitis.[7] Studies in the literature demonstrated the sub gingival application of both ornidazole and metronidazole as LDD agent as an adjuvant to SRP or as a sole therapy for the treatment for untreated periodontal lesions.[8,9]

Therefore, research was formulated to assess effectiveness of sub gingival application of ornidazole and metronidazole as an adjuvant to non-surgical periodontal therapy for management of periodontal diseases. Clinical parameters were evaluated for effectiveness of subgingival mode of therapy.

2. Objectives

To appraise effectiveness of sub gingival application of ornidazole & metronidazole adjuvant to non-surgical periodontal therapy in managing periodontal disease.

3. Methods

A total of 70 subjects, irrespective of gender, age group of 20-50 years, PPD between 5-6 mm diagnosed with chronic periodontitis were fixed from the outpatient department of Periodontics and Oral Implantology. Approval was obtained from ethical committee and an informed consent was taken from all participants before commencing of study.

Patients were allocated into 2 study groups:

Group 1- 35 subjects treated with Ornidazole (Ornigreat gel™) after SRP.

Group 2 – 35 subjects treated with Metronidazole (Metrohex plus gel™) after SRP.

Inclusion Criteria:

- Patient should have minimum of 20 teeth with age group of 20-50 years
- Patients diagnosed with chronic periodontitis with PPD in between 5-6 mm

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- No history of periodontal therapy/antibiotic therapy from past six months

Exclusion Criteria:

- Patients with known allergy to any component of metronidazole or ornidazole
- Patient with systemic disease
- Smoker and Chronic alcoholic patients
- Teeth with furcation involvement or presence of any oral pathologic lesion
- Pregnancy, lactation and use of contraceptives medication

METHODOLOGY

A total of 70 subjects, irrespective of gender, age group of 20-50 years, PPD between 5-6 mm diagnosed with chronic periodontitis were randomly spitted into 2 groups:

Group 1: 35 subjects treated with Ornidazole (Ornigreat gel™) into the deepest periodontal pocket with blunt cannula after scaling and root planing. Periodontal dressing was applied at on the treated area to block the escape of medicament from pocket area.

Group 2: 35 subjects treated with Metronidazole (Metrohex plus gel™) into the deepest periodontal pocket with blunt cannula after scaling and root planing. Periodontal dressing was applied at on the treated area to block the escape of medicament from pocket area.

Clinical Variables:

Clinical variables were taken which included Plaque index, Gingival index, Probing depth and Clinical attachment level (UNC-15 Probe) at baseline, one month and three months.

Statistical Analysis:

Numerical values were tabulated and analysed through Statistical Package SPSS 23.0 version. Different parameter was compared through One-way analysis of variance (ANOVA), Bonferroni post hoc ANOVA and Paired t test for intergroup and intragroup comparison.

4. Results

Table 1 showed intergroup and intragroup comparison of all the clinical parameters was compared in between two groups within different time period. The mean PI score at baseline, one month and three month time interval were 1.88±0.31, 1.26±0.35 and 1.08±0.29 for the Group 1. For the Group 2, it was 2.01±0.23, 1.44 ±0.39 and 1.13±0.30 at baseline, one month and three months' respectively. On intragroup comparison, mean PI score was found to be statistically significant (<0.001) while on intergroup comparison it was found to be statistically non-significant (Table 1)

The mean GI score at baseline, one month and three month time interval were 2.12±0.27, 1.62±0.31 and 0.81±0.26 for the Group 1. For the Group 2, it was 2.33±0.25, 1.43±0.36 and 0.76±0.35 at baseline, one month and three months' respectively. On intragroup comparison the mean GI score was substantially significant (<0.001) while on intergroup comparison it was substantially non-significant (Table 1).

Table 1: Intergroup and Intragroup comparison of clinical parameters value at baseline, 1 month and after 3 months of time interval

Parameters	Group	Baseline	1 month	3 months	Intragroup (p)
Plaque Index (PI)	**Group 1**	1.88±0.31	1.26±0.35	1.08±0.29	<0.001*
	Group 2	2.01±0.23	1.44±0.39	1.13±0.30	<0.001*

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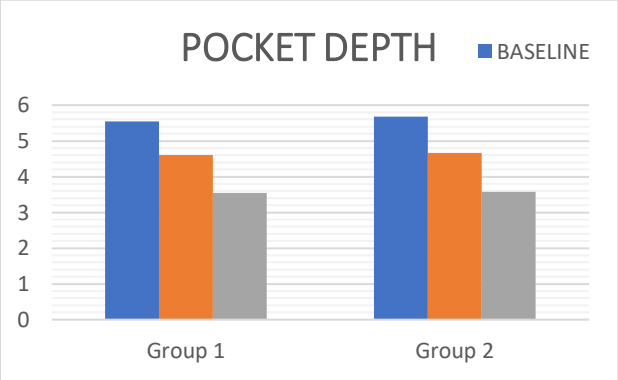
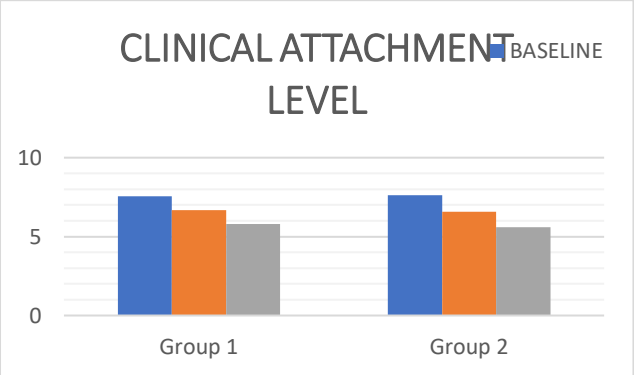
	Intergroup (p)	0.509**	0.404**	1.000**	
Gingival Index (GI)	**Group 1**	2.12±0.27	1.62±0.31	0.81±0.26	<0.001*
	Group 2	2.33±0.25	1.43±0.36	0.76±0.35	<0.001*
	Intergroup (p)	0.027**	0.197**	1.000**	
Probing Depth (PD)	**Group 1**	5.55±0.39	4.61±0.53	3.54±0.56	<0.001*
	Group 2	5.68±0.31	4.66±0.41	3.57±0.56	<0.001*
	Intergroup (p)	0.519**	1.000**	1.000**	
Clinical Attachment Level (CAL)	**Group 1**	7.54±0.39	6.66±0.38	5.80±0.50	<0.001*
	Group 2	7.62±0.33	6.58±0.48	5.60±0.55	<0.001*
	Intergroup (p)	1.000**	1.000**	0.623**	

* Statistically significant; ** statistically non-significant



Graph 1: Pocket depth in group 1 and group2 at different time interval



Graph 2: Clinical Attachment Level in group 1 and group2 at different time interval

The mean PPD value at baseline, one month and three month time interval were 5.55±0.39, 4.61±0.53 and 3.54±0.56 for the Group 1. For the Group 2, it was 5.68±0.31, 4.66±0.41 and 3.57±0.56 at the baseline, one month and three months' respectively. On intragroup comparison, mean PPD was found to be statistically significant (<0.001) while on intergroup comparison it was substantially non-significant (Table 1; Graph 1).

The mean CAL at the baseline, one month and three month time interval were 7.54±0.39, 6.66±0.38 and 5.80±0.50 for the group 1. For the group 2, it was 7.62±0.33, 6.58±0.48 and 5.60±0.55 at baseline, one month and three months' respectively. On intragroup comparison, mean CAL was substantially significant (<0.001) while on intergroup comparison, it was substantially non-significant (Table 1; Graph 2).

5. Discussion

To understand the etiology and pathogenesis of periodontitis the researchers are more focused towards the pharmaceutical modalities which can be supplemented or used as adjuvant to SRP. These pharmaceutical agents can be delivered or applied directly sub gingivally into the periodontal pocket

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areas to inhibit the number and quantity of periodontal pathogens and modify provoking result of soft and hard structures resulting into limit the amount of tissue destruction. The effectivity of the treatment depends upon important factors affecting LDD agent to periodontal pocket are Subgingival drug – microbial contact, Effective subgingival drug concentration, time period and substantivity as well as the type of pharmaceutical agent to be delivered. The site-specific local drug delivery agents reduce the microflora and their load from the periodontal pocket area that results in substantial changes in clinical variables.

Over the last three decades, locally delivered, antimicrobial pharmaceutical agents had been tested in the management of periodontal diseases. This approach to therapy is beneficial to the clinician as it enables site-specific elimination of residual bacteria, achieves greater drug concentrations at low therapeutic doses with lesser odds of adverse reactions and is easily applicable and less time-consuming with good patient compliance.[6] there was a speedy development in a variety of local periodontal treatment recently, metronidazole & ornidazole incorporated with chlorhexidine gel remains an efficacious antimicrobial agent and is solely employed to treat periodontitis.[10,11] Evidence have shown that there was decrease in inflammatory content associated with periodontal pathology when metronidazole gel used as adjuvant to treat chronic periodontitis.

The goal of research was to compare clinical efficacy of two LDD agents in gel forms. One is 1% ornidazole and second is 1% metronidazole along with 0.25% chlorhexidine di gluconate gel used adjuvant to NSPT in the treatment of periodontitis. The preferred form of drug is gel over other forms of local drug delivery forms such as solid formulation form. The primary advantage of gel is their biocompatibility and muco-adhesivity and elimination is by physiological metabolic pathways.[12] In the present study, clinical variables such as PI, GI, PD and CAL at baseline, 1 month and 3 months were recorded. On intragroup comparison the mean plaque index score, gingival index score, PPD and CAL were substantially improved while intergroup comparison mean score of clinical variables were substantially non-significant.

A substantial decrease in mean PI score were found in both groups which facilitates the patient's self-performed oral hygiene methods aided in improved plaque control status as well as better patient compliance following non-surgical periodontal therapy. Mechanical plaque control along with adjuvant local drug delivery agents disrupt the plaque microflora sub-gingivally and eliminate the pathogens from the inaccessible sites resulting in slow down the formation of new biofilm. Pardeep et al 2012 conducted a study 1% metronidazole and 0.25% CHX gluconate (Metrohex™ gel) employed adjuvant to NSPT in managing gingivitis with substantial improvement in PI score.[13] Similar association was found in a study conducted by Patel et al 2014 with ornidazole gel employed sub-gingivally after SRP.[14]

When mean gingival index score taken into account substantial improvement were observed in between groups. The decrease in mean score of GI is because of removal of local etiological factors (plaque and calculus) which further eliminate the inflammatory contents and use of antimicrobial agent locally resulting in shift of pathogenic microflora to a healthy state. Bhavin Patel et al 2014 evaluated effectiveness of Ornidazole containing gel as adjuvant to SRP and showed substantial improvement in gingival status. The study concluded as additional benefits were seen when antimicrobial gel used as adjuvant therapy.[14] Nagasree M et al 2016 evaluated antimicrobial agent locally as an adjunct with SRP and found that ornidazole has better potential to improve clinical parameters and shift of microbial pathogens when compared with SRP alone.[15]

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In 3 months follow of the present study local antimicrobial agents such as metronidazole and ornidazole both the gels when delivered into the periodontal pocket, both groups showed substantial improvement in PPD and CAL. Plaque and calculus are the local etiological factors which act as a niche for the development of colonies and release of endotoxins. The use of LDD agent into the pocket area disrupt the plaque biofilm and reduces the inflammation and because of mechanical therapy there is a shrinkage of the pocket wall. Jain et al 2013 and Nagasri et al 2015 hypothesize that LDD agents like metronidazole and tetracycline were more beneficial while delivered sub-gingivally in a sustained manner and effectively decreases probing depth and gain in CAL.[15,16] Nymphea et al 2013 assessed metronidazole gel and minocycline microsphere as an antimicrobial agent and proved that there was improvement in PPD and CAL in chronic periodontitis patients when compared with non-surgical periodontal therapy alone.[17]

Both antimicrobial gels metronidazole and ornidazole was delivered into the periodontal pocket in the present study with primary findings of improvement in clinical parameters (PI, GI, PD, CAL) however the regarding efficacious effect of local antimicrobial in case of periodontitis required long term investigation with follow up.

6.Conclusion

Based the clinical findings both the gels are effectively improved clinical variables in chronic periodontitis. The controlled-release antimicrobials are potential carrier to deliver an active agent which is suited for the site-specific area such as periodontal pocket. Both metronidazole and ornidazole based on the clinical aspects manifested an additional beneficial effect used adjuvant to no surgical periodontal therapy. Hence, future perspectives studies should be needed for further exploring this treatment modality.

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