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Research Protocol

Dentistry Section

Comparative Evaluation of Effectiveness of Triphala and Chlorhexidine in One Stage Full Mouth Disinfection Treatment of Stage-II and III Periodontitis in Type-II Diabetes Mellitus Patients- A Research Protocol

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ABSTRACT

Introduction: The idea of Full-Mouth Disinfection (FMD) was presented in the early 1990s, the traditional method of treating periodontal disease, quadrant by quadrant over several visits. The FMD method has been recommended with a number of changes over time. Triphala, Ayurvedic medicinal herbal formulations is also useful in dentistry as antiplaque, antimicrobial, antioxidant, analgesic, antipyretic and anti-inflammatory agent. As Chlorhexidine (CHX) is used from past years for full mouth disinfection, there is need to evaluate the efficacy of CHX as well as Triphala in diabetic mellitus patients.

Need of the study: As CHX has been used for years to disinfect the entire mouth, a study comparing the effectiveness of CHX and Triphala in individuals with Diabetes Mellitus (DM) for full mouth disinfection will be done.

Aim: To evaluate and compare the efficacy of triphala and CHX in the treatment of Stage-II and III periodontitis with one stage complete mouth disinfection in Type-IIDM patients.

Materials and Methods: This experimental study will be done in Sharad Pawar dental College, department of Periodontics after obtaining the ethical clearance during September 2021 to September 2022. About 24 type 2 diabetic subjects with Stage-II and Stage-III periodontitis, will be randomly divided into test Group-And control group with 12 in each group. In Group-A, Full mouth disinfection will be done using CHX and in Group-B full mouth disinfection will be done using Triphala. After full mouth subgingival scaling and root planing, patient will brush the dorsum of the tongue for one minute with gel, the mouth will be rinsed two times with mouthwash for one minute, the pharynx will be cleaned with a spray, and all periodontal pockets will be irrigated (thrice within 10 minutes) with a gel. Clinical parameters will be evaluated at baseline and six months. The clinical parameters are Probing Pocket Depth (PPD), Plaque Index (PI), Clinical Attachment Level (CAL), Papillary Bleeding Index (PBI). Paired t-test will be used to compare data within group for before and after treatment and unpaired t-test will be used to compare between the groups.

Keywords: Probing pocket depth, Root planing, Scaling

INTRODUCTION

Periodontal disorders (gingivitis and periodontitis) are inflammatory illnesses of the teeth's supporting components. The more severe of the two disorders is 'periodontitis'. If left untreated, it can destroy the periodontal ligament and alveolar bone, causing teeth to be loosen and eventually fall out [1].

Scaling and root planing in patients with periodontal disease improves microbiologic and clinical aspects, including decrease in pocket depth, periodontal inflammation, and the proportion of pathogenic bacterial species, as well as attachment level. However, at some regions and in some group of individual, this mechanical approach alone is insufficient to yield satisfactory clinical and microbiological results. This is especially important in patients who are at high risk of infection, such as diabetics. As a result, there is a keen interest in developing improved therapy for diabetic patients with periodontitis, in terms of both clinical and microbiological results. In this respect, numerous treatment techniques for diabetes patients have been proposed to overcome the limits of the standard quadrant-wise scaling and root planing, including Full-Mouth Scaling and Root Planning (FMSRP), FMD [2]. In 1995 Quirynen M et al., described FMD technique [3]. The rationale for one stage full mouth disinfection is to prevent reinfection by periodonto pathogens of the already treated periodontal sites from the remaining untreated pockets and intraoral bacterial reservoirs, such as the tonsils, tongue, and other mucous membranes, that could lead to a disease recurrence [4].

DM is a most common systemic condition that is a major risk factor for periodontitis, with the ability to alter the course of periodontitis. Diabetics have a three times higher chance of getting periodontitis compared to individuals who do not have the disease. Whereas current research does not indicate a distinct pathophysiology in people with DM and periodontitis, diabetes may significantly change the severity, prevalence, and responsiveness to periodontal therapy. As a result, DM was incorporated as a descriptor in the staging and grading procedure in the revised clinical classification of periodontitis [1].

CHX has antimicrobial properties. It is a cationic bisbiguanide with wide antimicrobial action, very less mammalian toxicity, and a high affinity for skin and mucous membrane binding [5]. It has a broad spectrum of activity against gram-positive and gram-negative bacteria, fungi like yeasts, dermatophytes, and some lipophilic viruses.

Ayurvedic medicines have been used to treat periodontal disorders. Triphala, according to the 20th Shloka of Sushruta Samhita, can be used as a gargling agent in dental problems due to its anti-inflammatory, antibacterial and antiseptic characteristics. As a result, rather than causing side-effects, it gives systemic advantages when ingested. Triphala has several possible systemic advantages and is highly recognised in Indian folk medicine. Ayurvedic practitioners have recommended it for a variety of systemic ailments due to its broad range of activities. As a result, it may be advantageous for impaired and immobile patients, as well as those who are unable to maintain proper oral hygiene [6].

CHX is a commonly used by dental practitioners, due to its antimicrobial effects. It is gold standard. There are lot of studies that have proved the effectiveness of CHX in periodontitis and gingivitis [5]. Triphala is one of the Ayurvedic medicinal herbal formulations prescribed by most healthcare practitioners but it is also useful in dentistry as antiplaque, antimicrobial, antioxidant, analgesic, antipyretic and anti-inflammatory agent [7]. It is used in stomatitis and halitosis cases. There is less research comparing CHX and Triphala for full mouth disinfection, and diabetes has two-way relations with periodontitis [8]. There are no clinical studies comparing CHX and Triphala in diabetic individuals, making this study unique. Thus, the aim of study is to evaluate and compare the efficacy of Triphala and CHX in the treatment of Stage-II and III periodontitis with one stage complete mouth disinfection in Type-II DM patients at baseline and after six months.

The main objectives of the study are:

1. To evaluate the efficacy of Triphala in one stage FMD treatment with Type-II DM in Stage-II and Stage-III periodontitis patients in terms of PPD, CAL, PI, and PBI.
2. To evaluate the effectiveness of CHX in one stage FMD treatment with Type-II DM in Stage-II and Stage-III periodontitis patients in terms of PPD, CAL, PI, and PBI.
3. To compare the efficacy of Triphala and CHX gel in One Stage FMD treatment with Type-II diabeties mellitus in Stage-II and Stage-III periodontitis patients in terms of PPD, CAL, PI, and PBI.

Null hypothesis: No difference will be observed in the efficacy between Triphala and CHX in the treatment of Stage-II and III periodontitis with one stage complete mouth disinfection in Type-II DM patients

Alternate hypothesis: Triphala will be as efficient as CHX in the treatment of Stage-II and III periodontitis with one stage complete mouth disinfection in Type-II DM patients.

Review of Literature

CHX is the most extensively researched and utilised oral product. Short-term studies show that CHX has a greater effectiveness on plaque removal and a variety of other outcome indicators. Based on the collection of favorable clinical research data, CHX rinses are frequently employed as a standard control, which is a product that is currently in use and/or being studied, providing information about the relative activity of another drug. CHX rinses are similarly employed as a positive control, which means they are recognised as efficient, highly efficient, or the "gold standard" [9].

Triphala has been widely utilised in Ayurvedic due to its diverse qualities and medicinal applications. Triphala, which means "three fruits" and is an Indian herbal plant, has been discovered to be a total body cleansing [10]. Triphala not only detoxifies and cleanses the intestines, but it also filters the blood and eliminates toxins from the liver. Other cleaning advantages of triphala are lowering levels of cholesterol and lowering blood pressure [11].

It can help with a wide range of stomach-related issues, including stomach acidity, abdominal discomfort, reduced appetite, and constipation. For example, this herb has been shown to be useful in treating common respiratory disorders such as cold and cough. Apart from its anti-inflammatory, analgesic, immunomodulatory, astringent, antimutagenic, antitumour, antispasmodic, and antimetastatic characteristics, it includes phenols, glycosides, and tannins which are responsible for its considerable antioxidant activity [12].

In a randomised clinical research, Naiktari RS et al., assessed and compared the efficacy of herbal mouthwash (Triphala) with CHX in patients with periodontal disorders who were being treated in hospitals [13]. The researcher concluded that herbal mouthwash is an effective antimicrobial agent, similar to CHX. It is quite beneficial in minimising plaque buildup and gingival irritation, and thereby regulating periodontal disorders in all patients. It is also inexpensive, easily accessible, as well as tolerated, with no documented negative effects.

In a randomised controlled trial, Baratakke SU et al., assessed the efficiency of triphala and CHX mouth rinse against plaque buildup and gingival inflammation in female undergraduates [14]. The study found that Triphala and CHX significantly reduced plaque and gingival scores. The authors found that Triphala mouthwash was helpful in decreasing plaque formation and gingival irritation, with no negative effects identified.

Bhor K et al., in their randomised controlled trial, assessed and compared the effect of Triphala and CHX mouthwash on gingival inflammation, plaque, and microbial count of *Streptococcus sanguinis*, *Streptococcus mutans*, and *Lactobacilli* from dental plaque samples of 14-15-year-old school children in Pune city over 90 days [15]. The findings showed that herbal mouthwash was effective in lowering plaque bacteria counts, plaque, and gingival irritation, and that it opens up new avenues in the fields of herbal dentistry and chemical plaque management.

Thus, the current study will compare and assess the efficacy of Triphala and CHX in one stage complete mouth disinfection therapy of Stage-II and III periodontitis in Type-II DM patients in terms of PPD decrease, and CAL gain at baseline, three months and six months.

MATERIALS AND METHODS

In this experimental study, total of 24 patients of Stage-II and Stage-III periodontitis according to new classification system of periodontitis by Caton JG et al., with Type-II DM will be selected from the Outpatient Department of Periodontics, Sharad Pawar Dental College, Sawangi (Meghe),Wardha [16]. The duration of the study will be one year (September 2021 to September 2022).

Before initial research, the goal and design of this clinical study will be presented to the patients, and each patient will sign an informed consent form. The research design has been approved by the DMIMS's Ethical Committee at Sawangi (Meghe), Wardha DMIMS(DU)/IEC/2020-21/267.

Inclusion criteria: Patient with ≥35 years of age having glycated haemoglobin levels ≥6.5% and fasting plasma glucose ≥126 mg/dL, Patients having a minimum number of 15 teeth, Patients with Stage-II periodontitis which have ≥2 interproximal sites with Attachment Loss (AL) 3 to 4 mm and PD ≤5 mm; and patient with Stage-III periodontitis which have ≥2 interproximal sites with AL ≥5 mm and PD ≥6 mm.

Exclusion criteria: Patients who have received periodontal therapy within the previous six months and patients with a known or suspected allergy, Patients with any systemic disease affecting periodontal health, excluding DM, those suffering from infectious diseases other than periodontitis. Patients who use tobacco, smokers, and chronic alcoholics. Patients with impaired immunity. Females who are pregnant or nursing. Substantial prosthesis rehabilitation in the patient; and patient who has significant complications of DM, including nephropathy, neuropathy, ulcers, gangrene, and amputation will be excluded.

Patients will be evaluated under adequate lighting using a mouth mirror and the UNC-15 probe. Primary outcome of the given study will be reduction in PPD and gain in CAL and secondary outcome will be reduction of PI, PBI. Comparison of the CAL, PI, PBI, PPD at baseline and six months will be done.

Clinical Measurements

I) Indices:

1) PI (Turesky S et al., Modification of Quigley-Hein 1970) [17]

2) PBI (Muhlemann HR 1977) [18]

II) Measurements of probing:

The following clinical aspects will be measured to extract the results. The PPD and CAL will be measured with a UNC-15 (Hu-Friedy). All the probing measurements will be recorded at maximum depth of pocket per tooth. These clinical aspects will be recorded only on the teeth to be treated.

Study design: A total of 24 patients will be chosen. In this study, the chosen patients will be allocated randomly into two groups Group-A and Group-B by flipping a coin. The control group (Group-A), and test group (Group-B). The control group will be treated with CHX gel (1% HEXIGEL, ICPA Health Product Ltd.,) while the test group will be treated with Triphala gel (Himalaya, HiOra-GA gel, Himalaya wellness Company) in patients with Stage-II and Stage-III periodontitis with Type-II DM.

Procedure

A FMD procedure described by Quirynen M et al., was used to treat all individuals (1995) [3]. Using hand curettes and an ultrasonic instrument, they obtained FMSRP in a single day.

Group-A

After 1 week of supragingival scaling, patient will be subjected to one stage full mouth disinfection. Under local anaesthesia full mouth subgingival scaling and root planing will be performed within 24 hours using curettes and ultrasonic scaler. Mechanical debridement will be augmented by the application of CHX to intra-oral niches with index figure and scraped with tongue cleaner. Immediately following each instrumentation session, the patient will brush the dorsum of the tongue for one minute with a 1% CHX gel, (1% HEXIGEL, ICPA Health Product Ltd.,) the mouth will be rinsed two times with a 0.2% CHX mouthwash for one minute, and all periodontal pockets will be irrigated (thrice within 10 minutes) with a 1% CHX gel, and the patient will be prescribed a 0.2% CHX mouthwash for one month. Spray was not used for pharynx.

Group-B

After one week of supragingival scaling, patient will be subjected to one stage full mouth disinfection. Under local anaesthesia full mouth subgingival scaling and root planning will be performed within 24 hours using curettes and ultrasonic scaler. Mechanical debridement will be augmented by the administration of Triphala gel to the intra-oral niches. Immediately following each instrumentation session, the patient will brush the dorsum of the tongue for one minute with a Triphala gel, the mouth will be rinsed two times with a Triphala mouthwash (Himalaya, Himalaya wellness company, Bengaluru) for one minute, and all pockets will be irrigated (thrice within 10 minutes) with a Triphala gel, and the patient will be prescribed Triphala mouthwash (Himalaya, Himalaya wellness company, Bengaluru) for one month.

Re-examination: Only the teeth to be treated (having PPD, CAL) will have all clinical data documented at baseline and 6 months following the treatment. All teeth will not be treated in all individuals.

STATISTICAL ANALYSIS

For all clinical parameters, the means and standard deviations (Mean SD) will be obtained. Comparison of the CAL, PI, PBI, PPD at baseline and six months will be made. If the probability value (p) will be >0.05, the difference observed will be considered non significant and if <0.05, it will be considered significant. Paired t-test will be used to compare data within group and unpaired t-test will be used to compare between the groups.

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