e - ISSN - 2349 - 8005

INTERNATIONAL JOURNAL OF ADVANCES IN CASE REPORTS

Journal homepage: www.mcmed.us/journal/ijacr

THE EFFICACY OF HYBENX® ORAL TISSUE DECONTAMINANT FOR PERIODONTAL DISEASE TREATMENT: A CASE SERIES STUDY

[1]Lauritano Dorina, [2]Girardi Ambra and [3*]Carinci Francesco

[1]Department of Translational medicine and surgery, Neuroscience Centre of Milan, NeuroMi, University of Milan-Bicocca, Milan, Italy.
[2]Department of Experimental, Diagnostic and Speciality Medicine, University of Bologna, Via Belmeloro 8, 40126 Bologna, Italy.
[3]Department of Morphology, Surgery and Experimental Medicine, University of Ferrara, Via Luigi Borsari, 46 - 44121 Ferrara, Italy.

Corresponding Author:- **Francesco Carinci**
E-mail: crc@unife.it

Article Info
Received 15/01/2015
Revised 27/02/2015
Accepted 02/03/2015

Key words:
Periodontitis, scaling, root planing, sulfates, drug, delivery

ABSTRACT
The objective of this study was to evaluate the efficacy of a chemical device HYBENX® Oral Tissue Decontaminant in the treatment of chronic periodontitis in adult patients. With the aim to identify the antibacterial property of HYBENX®, two samples of periodontal pocket microbiota were collected by paper probes, at two different time points. T0 represents the first sampling performed before treatment while T1 represents the second time point, 15 days after HYBENX® treatment. A total of 11 patients were enrolled. For each patient, at each time point, two paper probes were collected. Polymerase Chain Reaction methodology was used to detect microbial activity. After the treatment, a remarkable decrease in bacteria amount was observed, both for total bacteria and some specific periodontal pathogens representing the red complex bacteria (i.e. *Porphyromonas gingivalis*, *Treponema denticola* and *Tannerella forsythia*). The average reduction was about 99% for each of the red complex bacteria and about 96% for total Bacteria. This decrease was highly statistically significant based on *P*-values. HYBENX® solution is an effective adjunct to eradicate bacterial loading in the pockets of patients affected by periodontitis. It is an efficacious medical device for use in the management of moderate to severe chronic periodontitis

INTRODUCTION

Periodontitis is one of the most prevalent diseases affecting nearly one third of the adult population. Periodontitis is characterized by loss of connective tissue attachment to the tooth and pathological migration of the junctional epithelium apically, which leads to pocket formation, tooth mobility, and finally loss of the tooth. There are different types of periodontitis but the most common is adult periodontitis. There is ample evidence supporting the microbial etiology of periodontal disease [1]. The pathogenic bacteria that cause periodontitis are mainly gram-negative anaerobic or microaerophillic bacteria and the main organisms implicated are the red complex group: *Porphyromonas gingivalis*, *Tannerella forsythia*, and *Treponema denticola* [2].

Eliminating these infections, and thereby preventing disease progression, is a primary goal of periodontal therapy [3]. Studies have revealed that most forms of periodontal diseases are treated predictably by conventional non-surgical therapy like plaque control, scaling and root planing (SRP) and health can be

maintained for a long period of time with proper maintenance care programs [4]. Antimicrobial agents are used as local drug delivery agents including tetracycline, ofloxacin, clindamycin, chlorhexidine, etc. [5]. These local drug delivery devices have been used either alone or as an adjunct with SRP. These antimicrobial agents are placed directly into the site of infection, and therapeutic levels can be established and maintained for days to weeks using this approach (5). The use of these medications may improve periodontal maintenance results and help to extend the intervals between patients visit.

HYBENX® is a concentrated mixture of sulfates, which serve as a denaturing agent, consisting of 60% sulfonated phenolics and 28% sulfuric acid in a water-based gel solution. Porter et al. has demonstrated the effectiveness of HYBENX® in treating oral ulcers of recurrent aphthous stomatitis [6].

The aim of the present study is to evaluate the efficacy of a medical device for use in the management of moderate to severe chronic periodontitis.

MATERIALS AND METHODS

A cohort of 11 patients affected by moderate periodontal disease was enrolled in the present study.

Inclusion criteria were: age between 20 to 60 years, Bleeding on probing and at least one tooth with a pocket depth 6 mm or more. Exclusion criteria were systemic diseases, antibiotic or anti-inflammatory therapies in the last 30 days before admission to the clinic and pregnancy.

Two sample of periodontal pocket microbiota were collected by paper probes, at two different time points: admission before treatment (T0) and 15 days after HYBENX® treatment (T1). HYBENX® was used in the form of a gel in syringes of 1 ml each. For each patient, at each time point, two paper probes were collected.

After collection, paper probes were processed for bacterial and genomic DNA extraction, by using the GenEluteTM Bacterial Genomic DNA Kit (Sigma-Aldrich, St., St. Louis, MO, USA) and following the manufacturer's recommended procedures. Briefly, to isolate DNA, samples were incubated with lysozyme in a specific lysis buffer and, subsequently with proteinase K. Subsequently, DNA was purified by spin-column method.

Bacterial quantification was performed by Real-Time Polymerase Chain Reaction using the absolute quantification with the standard curve method. Primers and probes oligonucleotides were designed based on 16S rRNA gene sequences of the Human Oral Microbiome Database (HOMD 16S rRNA RefSeq Version 10.1). For the quantitative analysis, plasmid (Eurofin MWG Operon, Ebersberg Germany) containing the specific DNA target sequence was employed as standard. All reactions were performed in duplex, in 20ul final volumes, with 2X TaqMan Universal PCR master mix (Applied Biosystems, Foster City, CA, USA) and 50nM concentration of each primers and 200nM of the probes. Amplifications were carried out by using the ABI PRISM 7500 (Applied Biosystems, Foster City, CA, USA). To be more precise, two real-time PCR runs were carried out for each sample. With the first reaction the total amount of bacteria was quantified whereas with the second, in a multiplex PCR, the three red complex bacteria (*P.gingivalis, T.forsythia and T. denticola*) were quantified.

To evaluate if the difference in bacterial amount before and after the treatment wass statistically significant, Student's t-test was applied.

RESULTS

After the treatment, a remarkable decrease in bacteria amount, both for each species and for the amount of total bacteria (Fig. I upper), was observed. The average reduction was about 99% for each of the red complex bacteria (P. gingivalis, T. forsythia and T. denticola) and about 96% for Total Bacteria loading (Fig. II lower).

This decrease was highly statistically significant with *P*-value, 0,0015 to 0,038 respectively (Fig. II lower).

Fig. 1. Average values of bacterial absolute quantification, before (T0) and after (T1) the treatment with HYBENX.

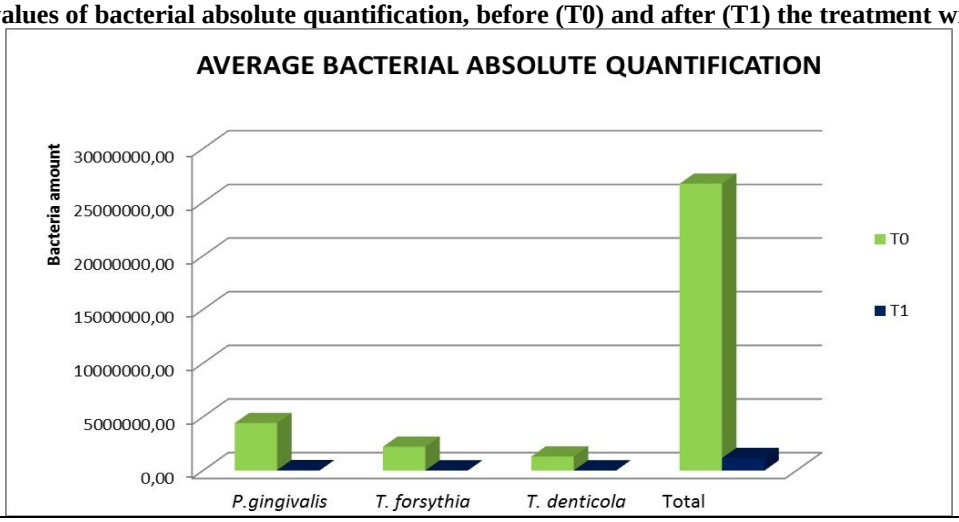
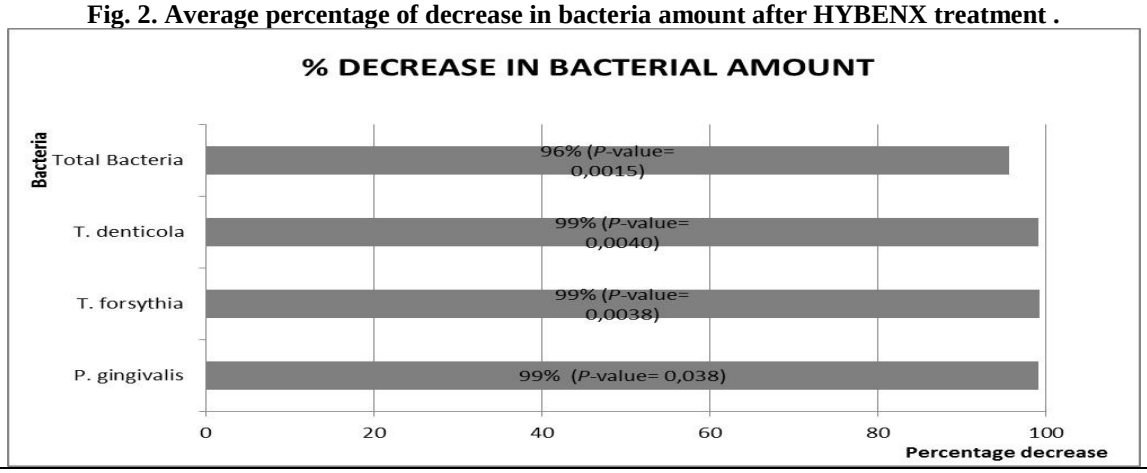


Fig. 2. Average percentage of decrease in bacteria amount after HYBENX treatment .



DISCUSSION

It is well understood that most destructive types of periodontal diseases occur due to the presence of pathogenic micro-organisms colonizing the sub-gingival area and that the suppression or eradication of these microbes results in improvement in periodontal health. Mechanical debridement is effective in both disturbing the biofilm and reducing the bacterial load. However, sometimes mechanical instrumentation may not be sufficient to control the disease due to tissue invasive pathogens, or other tooth-related anatomic factors. In such conditions, adjunctive use of a chemical device could provide an additional benefit in controlling the disease.

Supportive periodontal therapy is widely used, but a greater effectiveness is demonstrated by the associated administration of topical antimicrobials. The advantage of topical therapy involves the use of antimicrobical agents directly in the periodontal pocket, minimizing the adverse effects related to systemic therapy [5]. The potential benefits of local drug delivery include improved patient compliance, an easier access to periodontal pockets, and a lower dosage of antimicrobial agent. The most commonly used methods for local drug delivery are local gingival irrigations [1]. The antimicrobial agents used as local drug delivery agents include mainly tetracycline, ofloxacin, clindamycin, and chlorhexidine [5]. These local drug delivery devices have been used either alone or as adjunct with SRP. These local antimicrobials are administered directly into the periodontal pocket and the effectiveness of these chemical device is related to their bactericidal activity and the subsequent reduction of gingival inflammation [7-10].

The topical use of a chemical device along with mechanical therapy dramatically improves clinical results, and at the same time is free from adverse effects. Local delivery of chemical devices into the pocket achieves a greater localized concentration, proving bactericidal for most perio-pathogens, and at the same time, exhibiting negligible impact on the microflora residing in other parts of the body.

Our study evaluated the efficacy of HYBENX® in the management of moderate to severe chronic periodontitis. The results of this investigation demonstrate an overall improvement in total bacterial loading.

Microbiological testing was thought appropriate to evaluate the effect of HYBENX® on subgingival microbial population, the primary etiological factor for periodontitis. Several methods have been used for microbiological testing in periodontitis [12]. It is well known that both *P. gingivalis* and *T. denticola* occur concomitantly with the clinical signs of periodontal destruction [13-14]. They appear closely 'linked' topologically in the developing biofilm, showing an in vitro ability to produce a number of outer membrane-associated proteinases. They are considered the first pathogens involved in the clinical destruction of periodontal tissues. Moreover both they, and *T. forsythia*, show a higher prevalence in disease than in health suggesting that these bacterial are associated with the local development of periodontitis [15].

CONCLUSION

HYBENX® is an effective adjunct to eradicate bacterial loading in pockets of patients affected by periodontitis. It is an efficacious medical device for use in the management of moderate to severe chronic periodontitis.

REFERENCES

1. Haffajee AD, Socransky SS. (1994). Microbial Etiological agents of Destructive Periodontal Disease. *Periodontol*, 5, 78–111.
2. Consensus report for Periodontal Disease. (1996). Pathogenesis and Microbial Factors. *Ann Periodontol*, 926–32.
3. Socransky SS, Haffajee AD. (1993). Effect of Therapy in Periodontal Infections. *J Periodontol*, 64, 754–749.
4. Greenstein G. (2000). Non Surgical Periodontal Therapy in 2000: A literature Review. *J Am Dent Assoc*, 131, 1580–1592.

5. Rams TE, Slots J. (1996). Local Drug Delivery of Antimicrobial Agents in the Periodontal Pockets. *Periodontol 2000*, 10, 139–159.
6. Porter SR, Al-Johani K, Fedele S & Moles DR. (2009). Randomised controlled trial of the efficacy of HybenX in the symptomatic treatment of recurrent aphthous stomatitis. *Oral Diseases*, 15(2), 155–161.
7. Goodson JM. (1994). Antimicrobial strategies for treatment of Periodontal Diseases. *Periodontol 2000*, 5, 142–168.
8. Worthington RJ, Richards JJ, Melander C. (2012). Small molecule control of bacterial biofilms. *Org Biomol Chem*, 10(37), 7457-74.
9. Reise M, Wyrwa R, Müller U, Zylinski M, Völpel A, Schnabelrauch M, Berg A, Jandt KD, Watts DC, Sigusch BW. (2012). Release of metronidazole from electrospun poly (L-lactide-co-D/L-lactide) fibers for local periodontitis treatment. *Dent Mater*, 28(2), 179-188.
10. Varela VM, Heller D, Silva-Senem MX, Torres MC, Colombo AP, Feres-Filho EJ. (2011). Systemic antimicrobials adjunctive to a repeated mechanical and antiseptic therapy for aggressive periodontitis: a 6-month randomized controlled trial. *J Periodontol*, 82(8), 1121-1130.
11. Batoni G, Maisetta G, Brancatisano FL, Esin S, Campa M. (2011). Use of antimicrobial peptides against microbial biofilms: advantages and limits. *Curr Med Chem*., 18(2), 256-79.
12. Loomer PM. (2004). Microbiological diagnostic testing in the treatment of periodontal diseases. *Periodontology 2000*, 34, 49-56.
13. Mineoka T, Awano S, Rikimaru T, Kurata H, Yoshida A, Ansai T *et al*., (2008). Site-specific development of periodontal disease is associated with increased levels of Porphyromonas gingivalis, Treponema denticola, and Tannerella forsythia in subgingival plaque. *J Periodontol*, 79, 670-676.
14. Scapoli L, Girardi A, Palmieria, Testori T, Zuffetti F, Monguzzi R, Lauritano D, Carinci F. (2012). Microflora and periodontal desease. *Dental Research Journal*, 9(8), 202-206.
15. Carinci F, Girardi A, Palmieri A, Martinelli M, Scapoli L, Avantaggiato A, Nardi GM, Lauritano D. (2012). Lab-test 2: microflora and periodontal disease. *European Journal of Inflammation*, 10, 95-98.