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Original article

A prospective study of 0.2% Chlorhexidine varnish as an adjunct to the non-surgical treatment of Chronic Periodontitis

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Abstract:
Introduction: Treatment strategies using chemotherapeutic agents in conjunction with scaling and root planning (SRP) have evolved, assuming that chemical aids would compensate for the technical shortcomings of mechanical debridement. The aim and objective of the study were to assess the efficacy of 0.2% chlorhexidine in the treatment of chronic periodontitis.
Methodology: The present study was designed as a split-mouth, single-blind, randomized clinical trial and was conducted over a 18-month period. After screening 73 patients, 50 patients were enrolled who satisfied the inclusion and exclusion criteria. Each patient site selected was randomly assigned to one of the three study groups: Group A (Control group), scaling and root planing alone; Group B (Test group 1), scaling and root planing with local Cervitec application; and Group C (Test Group 2), Cervitec application alone. Study outcome variables were Plaque Index (PI), Gingival Index (GI), Probing Pocket Depth (PPD), and Clinical Attachment Level (CAL). Study parameters were recorded at baseline, at 1 month, and 3 months.
Result: In Groups A and B, a significant improvement in periodontal indices was observed after 1 month from baseline, which was maintained over 3 months ($p < 0.001$). In Group C, at 1 and 3 months, compared to the baseline, the results revealed a statistically significant difference ($p<0.001$) for PI and GI but no improvement in PPD and CAL.
Conclusion: From the current study it could be concluded that chlorhexidine varnish (Cervitec ®) when applied as an adjunct to SRP, demonstrated significant improvement of periodontal health parameters after 3 months.
Keywords: conservative approach, pocket depth, scaling and root planing

Introduction:

Chronic periodontitis (CP) is a prevalent condition, affecting 47.2% of the adult US population aged 30 years or older [1]. Chronic periodontitis results in the loss of tooth-supporting connective tissue and alveolar bone and, if left untreated, is a significant cause of tooth loss in adults [2]. Dental plaque plays a key role in the progression of CP and mechanical debridement alone has limited efficacy. Therefore, treatment strategies using chemotherapeutic agents in conjunction with scaling and root planing have evolved, assuming that chemical aids would compensate for technical shortcomings [3].

Not surprisingly, a large number of chemical agents have been tested for their ability to reduce plaque accumulation. Although many antimicrobial agents would appear to be suitable for plaque control, only few have been found to possess clinical efficacy. This is because many of the antimicrobial agents do lack property of substantivity and lacks efficacy against oral microorganisms. Currently formulated antimicrobial agents include essential oils, metals (zinc, stannous, copper), phenols (triclosan), plant extracts, (Terminalia chebula Extract, garlic extract. occimum sanctum, triphala, aloe vera enzymes etc [4-7].

Chlorhexidine is a bisbiguanide formulation with cationic properties. Its antimicrobial spectrum includes most of the microbes, such as gram-positive and gram-negative organisms, including bacterial spores, lipophilic viruses, yeasts, and dermatophytes [8-11]. Chlorhexidine varnishes are an easy-to-use and affordable vehicle, notably highly concentrated, which can be injected into the periodontal pocket. Hence, this comparative study was designed to make a clinical assessment of the efficacy and safety of 0.2% chlorhexidine as an adjunct to

scaling and root planning or alone in the treatment of chronic periodontitis.

Materials and Method:

The study was designed as a split-mouth, single-blind, randomized clinical trial and conducted for 18 months from May 1, 2017, to November 30, 2018. The study was conducted after obtaining clearance from the Institutional Ethics Committee. Subjects suffering from generalized chronic periodontitis who presented to the outpatient clinic in the study institute were screened for recruitment in the study as per the inclusion and exclusion criteria, and their consent.

The sample size was calculated to ensure adequate power to detect a statistically significant difference in the study parameters under investigation. Considering an expected significance level (α) of 0.05 and a statistical power (1-β) of 80%, 28 subjects were required to enrol for the study. Due to the long and multiple follow-ups, a multiplication factor of 1.5 was applied to account for potential dropouts, resulting in a sample size of 42. The sample size was adjusted to account for missing data, and a sample size of 50 was finalized.

Systemically healthy or with controlled medical diseases of age range 25 to 60 years, of either sex with at least 20 teeth with minimum of four multi-rooted teeth and four teeth per quadrant, at least four non adjacent sites with periodontal pocket depth 4-7 mm and clinical attachment loss of 3-4mm in each quadrant were included in the study, after obtaining written consents. However, pregnant patients, smokers, tobacco chewers, those with known allergy to chlorhexidine, and patients with a history of consumption of antimicrobial drugs in the last 3 months were excluded.

The patient site was randomly assigned to one of the three groups: Group A (Control group), scaling and root planing alone; Group B, scaling and root planing with local Cervitec application; and Group C, Cervitec alone. Test Product used in study was Cervitec® (Ivaclar Vivadent AG, Bendererstrasse 2, 9494 Schaan, Liechtenstein). Cervitec is a combination of 0.2 % chlorhexidine plus 900 ppm fluoride, plus provitamin D-panthenol + xylitol. It contains 0.2% chlorhexidine di-acetate as an active antimicrobial ingredient. Once the gel has been applied and dried, it contains approximately 2% of chlorhexidine [12].

The study included parameters such as Silness and Loe's Plaque Index (PI) (1964), Loe and Silness's Gingival Index (GI) (1963), Probing Pocket Depth (PPD), and Clinical Attachment Level (CAL) [13]. The Standard Parallelism Technique was used for measurements in the facial, buccal-lingual, and palatal areas. Probing depth measurements are recorded for six specific sites on each tooth: dentofacial, facial, mesiofacial, distolingual, lingual, and mesiolingual. Plaque Index System categorizes plaques into four types, where score zero is given to no plaque present, and thereafter, 1, 2 and 3 respectively for a film of plaque adhering to the free gingival margin and adjacent area of the tooth, moderate accumulation of soft deposits within the gingival pocket, or the tooth and gingival margin which can be seen with the naked eye, abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin. Similarly, the Gingival Index is also categorized into four severity scores: zero, 1, 2, and 3. Zero represents healthy gingivae, one stands for gingivae that look inflamed, but don’t bleed when probed, two for gingivae that look inflamed and bleed when probed, and three represents ulceration and spontaneous bleeding

Interventions were conducted according to the study protocol. After recording baseline parameters, the dental quadrants of group A received Scaling and Root Planning (SRP) therapy with ultrasonic scalers and curettes. Group B quadrants were performed upon Scaling and Root Planing (SRP) on the same setting.

Patients were called for a visit after seven days to application for Cervitec. On the 2nd visit, i.e., after 7 days, these quadrants received a supra-gingival and sub-gingival Cervitec application with the help of an applicator syringe. Thereafter, the coe-pak was applied. The patients were asked not to eat or drink for 1 hour after the application of Cervitec and were called after seven days for the removal of the Coe-Pak. Group C study quadrants received supra-gingival scaling before Cervitec application. After drying with cotton rolls and an air syringe, gel was applied supra- and subgingivally with an applicator syringe. Thereafter, the coe- pak was applied. The patients were asked not to eat or drink for 1 hour after the application of Cervitec and were called after seven days for the removal of the Coe-Pak.

Participants were instructed to carry out routine oral hygiene maintenance protocol throughout the study period. Patients were asked to return after one month from the recording of the baseline parameters. A visit was scheduled thereafter, 3 months after the recording of baseline parameters. Patients were advised to avoiduching the treated area and refrain from using any mouth rinses or oral irrigation devices.

The latest available version of SPSS (Statistical Package for Social Sciences) software was used for statistical analysis. The data obtained were analyzed using appropriate tests to yield results in the form of mean ± SD (standard deviation). Groups were compared using one-way analysis of variance (ANOVA), and to compare the means of two groups, an independent t-test was applied. A two-tailed $P<0.05$ was considered statistically significant.

TABLE 1: Baseline Comparison of Periodontal Parameters using ANOVA.
Group A: Scaling and Root Planning only; Group B: Scaling and Root Planning followed by Cervitec application after seven days; Group C: Supragingival scaling and Cervitec application in the same setting.

S. No.	Parameter	Group A		Group B		Group C		Significance of difference	
		Mean	SD	Mean	SD	Mean	SD	F (ANOVA)	p
1	Plaque Index	2.34	0.42	2.26	0.43	2.24	0.41	0.885	0.41
2	Gingival Index	1.58	0.46	1.63	0.38	1.52	0.26	1.128	0.32
3	Pocket Depth (in mm)	3.98	0.79	4.19	1.07	3.9	0.92	1.296	0.27
4	Clinical Attachment Level (in mm)	4.46	0.54	4.35	0.47	4.23	0.58	2.234	0.11

TABLE 2: Intragroup comparison of parameters at different time points in Group A using paired t- Test.

Parameters	Comparison between baseline and at 1 month		Comparison between baseline and at 3 month		Comparison between 1 month and at 3 month	
	t	p	t	P	t	P
Plaque Index	13.36	0	14.65	0	1.3	0.19
Gingival Index	12.09	0	13.57	0	1.47	0.14
Probing pocket Depth (in mm)	8.62	0	8.27	0	0.34	0.73
Clinical attachment level (in mm)	4.29	0	4.79	0	0.5	0.14

TABLE 3: Intragroup comparison of parameters at different time points in Group B using paired t-Test.

Parameters	Comparison between baseline and at 1 month		Comparison between baseline and at 3 month		Comparison between 1 month and at 3 month	
	T	p	T	P	T	P
Plaque Index	13.51	0	13.84	0	0.33	0.74
Gingival Index	11.12	0	10.57	0	-0.55	0.58
Probing pocket Depth (in mm)	7.26	0	7.48	0	0.22	0.82
Clinical attachment level (in mm)	3.7	0	3.8	0	0.1	0.92

TABLE 4: Intragroup comparison of parameters at different time points in Group C using Paired t- Test.

S. No.	Parameter	Group A vs Group B		Group A vs Group C		Group B vs Group C	
		"t"	"p"	"t"	"p"	"t"	"p"
1	Plaque index	2.233	0.02	0.272	0.08	2.246	0.02
2	Gingival index	2.185	0.03	1.566	0.12	4.244	0
3	Pocket depth (in mm)	1.783	0.02	7.792	0	11.101	0
4	Clinical attachment level (in mm)	3.95	0	11.675	0	18.001	0

TABLE 5: Multiple Group wise Comparison of Post-treatment Periodontal Parameters status at 1 Month using Student t-Test.

S. No.	Parameter	Group A vs Group B		Group A vs Group C		Group B vs Group C	
		"t"	"p"	"t"	"p"	"t"	"p"
1	Plaque index	2.88	0.01	0.585	0.56	2.246	0.02
2	Gingival index	4.065	0	2.955	0.004	6.41	0
3	Pocket depth (in mm)	2.713	0.008	9.949	0	11.648	0
4	Clinical attachment level (in mm)	8.519	0	15.663	0	20.956	0

TABLE 6: Multiple Group wise Comparison of Post-treatment Periodontal Parameters status at 3 Month using Student t-Test.

Parameters	Comparison between baseline and at 1 month		Comparison between baseline and at 3 month		Comparison between 1 month and at 3 month	
	t	p	t	p	t	P
Plaque Index	12.39	0	12.24	0	-0.15	0.87
Gingival Index	10.12	0	10.44	0	0.32	0.75
Probing pocket Depth (in mm)	0.26	0.79	0.44	0.66	0.17	0.86
Clinical attachment level (in mm)	0.42	0.68	0.32	0.68	0.26	0.87

Results:

Seventy-three patients of either sex suffering from generalized chronic periodontitis were screened for recruitment in the study. As the follow-up period was a little more extended, seven patients could not be followed up through all time points. Therefore, seven more patients were recruited to complete the study. Finally, a total of 50 patients were enrolled in the study, meeting the inclusion and exclusion criteria, whose complete data could be collected for statistical analysis. Three different quadrants were selected in each patient, which were treated by three different treatment modalities and were accordingly divided into three groups, viz. Group A- Scaling and root planing alone (Control Group), Group B- Scaling and root planing + Cervitec, and Group C- Cervitec alone.

In the age ranges of 25-35, 36-45, and 46-60 years, there were 17, 24, and 9 patients, respectively. Gender- wise, there were 22 male patients and 28 female patients. At baseline, the three groups were matched for all periodontal parameters, plaque index, gingival index, pocket depth, and clinical attachment level (Table 1). Table 2 presents a comparison of study parameters at three different time points in Group A. The table shows a statistically significant decrease in all 4 study parameters from baseline at 1 and 3 months. However, the changes from 1 month to 3 months were statistically nonsignificant. Instead, there was an increase in the Gingival Index from 1 month to 3 months.

Table 4 presents a comparison of study parameters at three different time points in Group C. It shows a statistically significant decrease in Plaque Index and Gingival Index from baseline at 1 and 3 months. However, the changes from 1 month to 3 months were statistically nonsignificant. Instead, there was an increase in the Plaque Index from 1 month to 3 months. Probing Pocket Depth and Clinical Attachment level showed only nominal, statistically non-significant changes from baseline to 1-month and 3-month intervals.

At a 1-month interval, an intergroup comparison of post-treatment periodontal parameters revealed that Group B had significantly lower mean plaque index, gingival index, probing pocket depth, and Clinical Attachment loss compared to Group A, as well as Group C ($p < 0.01$). However, no significant difference was observed between Group A and C for Plaque Index and Gingival Index after I month of intervention. Statistically significant differences were observed for Probing Pocket Depth and Clinical Attachment Loss compared to Group A and Group C (Table 5).

Likewise, at 3 3-month intervals, intergroup comparison of post-treatment periodontal parameters for soft tissue parameters revealed that Group B had significantly lower mean plaque index,

gingival index, and probing depth as compared to Group A, as well as Group C ($p<0.001$). It also had a significantly lower mean clinical attachment level compared to Groups A and C ($p < 0.001$). A statistically significant difference was observed between Group A and Group C for all parameters, with Group A showing significantly lower mean values compared to Group C ($p < 0.05$), except for the Plaque Index, where no statistical difference was observed (Table *6*).

Discussion:

The present study was conducted to evaluate the clinical efficacy of chlorhexidine varnish (Cervitec) as an adjunct to scaling and root planing in patients with chronic periodontitis.

The study's results show a significant improvement in periodontal indices in group A after 1 month from baseline, which was maintained over 3 months ($p < 0.001$). There was an observed, non-significant increase in the Gingival Index and Clinical Attachment Level, and a non-significant decrease in the Plaque Index and Probing Pocket Depth between 1 and 3 months.

These findings are consistent with various studies that have demonstrated improvements in periodontal parameters after scaling and root planing [14-16]. However, other studies have shown that periodontal probing depth and gain in attachment level do not improve significantly following root planing and scaling for patients with shallow initial periodontal probing depths [15, 17]. This may be attributed to the good oral hygiene maintained by the patients, resulting from constant patient motivation and reinforcement of oral hygiene measures.

In Group B, statistically significant differences ($p < 0.001$) were found for all four clinical parameters at both 1 month and 3 months. Other studies have reported similar findings regarding the use of chlorhexidine irrigation as an adjunct to scaling and root planning to reduce microbial load [18]. Jan Cosyn et al. found significant reductions in probing pocket depth and clinical attachment level at 1, 3, and 9 months with subgingival chlorhexidine [3, 19, 20].

In Group C, at 1 and 3 months, compared to the baseline, the results revealed a statistically significant difference ($p<0.001$) for Plaque Index and Gingival Index, documenting the antiplaque effect of chlorhexidine-thymol varnish. However, no change was observed for Probing Pocket Depth and Clinical Attachment level at either 1 month or 3 months. This is in line with the fact that the effect of chlorhexidine on mature plaque or biofilms is minimal due to the exopolymer matrix, bacterial enzymes, and low growth rate, which hinder the action of chlorhexidine [21]. However, a recent in vitro study has shown that 0.12% chlorhexidine exhibits the most excellent antibacterial activity against both planktonic and biofilm-grown organisms [22].

The findings of the current study were in agreement with those of Valente et al., who first demonstrated evidence of a beneficial effect of chlorhexidine varnish treatment on gingival health, stating that the application of a chlorhexidine varnish significantly improved the gingival health of subjects for up to three months [23]. However, this result was not in agreement with Javier Clavero et al., who found no significant differences between the plaque and bleeding indices of the control group and the group treated with Cervitec [24]. However, it was assumed that this lack of results was owing to various factors such as a lack of oral hygiene or the subjects wearing removable dentures. Similarly, Weiger et al. did not detect any significant difference between plaque index scores recorded at 3 days and 12 weeks after a single one-hour varnish application and no varnish application [25]. However, Anand V et al. had contrasting observations, revealing short-term advantages in clinical parameters in subjects receiving scaling and root planing and an adjunct, chlorhexidine-thymol varnish (Cervitec Plus(®)), who showed the most significant improvement in periodontal parameters at 3 months [26]. They concluded that Subjects with chronic periodontitis significantly benefit from scaling and root planing when used with an adjunct, chlorhexidine-thymol varnish (Cervitec Plus(®)).

When intergroup differences were compared at 1 month and after 3 months, it was found that Group B exhibited significantly better results, followed by Group A and then Group C in terms of improvement of the clinical parameters. Contrasting results were obtained by Jan Cosyn et al., who were unable to detect inter- group differences at any time in terms of plaque index, gingival index, or bleeding on probing. However, these parameters decreased significantly over time, irrespective of the treatment strategy (Scaling and root planing + Cervitec and scaling and root

planing)[19].

Even though the outcome of mechanical debridement usually satisfies in terms of reduction in probing depth and bleeding on probing, difficulties reaching the bottom of the pocket can lead to its failure. As a consequence, supplementary treatment becomes inevitable. The idea of subgingivally applying a concentrated antiseptic as an adjunct to scaling and root planing was the result of an increased consciousness of the limitations of the former. The objective was to compensate for these shortcomings, thereby improving treatment outcome [19].

To summarize, when comparing post-treatment periodontal health parameters between Group B and Group C at 1 and 3 months after baseline, Group B showed significantly lower mean values for all periodontal parameters compared to Group C ($p < 0.001$). Similarly, between 1 and 3 months, the mean proportional change in Group B compared to Group C was found to be significantly higher for plaque index, gingival index, pocket depth, and clinical attachment level.

The limitation of this study lies in the fact that cases were followed for only 3 months. A longer follow-up might have suggested the utility of chlorhexidine varnish for long-term remission from generalized chronic periodontitis. Further studies are also needed to assess these effects over the long term, to determine the optimal number of applications and the interval between them that yield the best results over time.

Conclusion:

In conclusion, this study demonstrates that Cervitec as an adjunct to scaling and root planing is efficacious in improving periodontal parameters in periodontitis patients. Thus present study reveals that when Cervitec is used as an adjunct to scaling and root planning, better results are obtained when compared to scaling and root planing alone or Cervitec alone. Further studies need to be conducted to assess these effects over the long term, in order to establish the number of applications and the interval between them that offer the best results over time.

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