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EVALUATION OF ACHYRANTHES ASPERA CHIP AS A LOCAL DRUG DELIVERY AGENT IN THE MANAGEMENT OF CHRONIC PERIODONTITIS: A CLINICAL TRIAL

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ABSTRACT

BACKGROUND: Plant based formulations such as Achyranthes aspera have gained rapid interest recently as they are safer to use with minimal side effects. Aim of the present study to evaluate the efficacy of Achyranthes Aspera chip in periodontal pockets along with SRP to treat chronic periodontitis.

METHODS: Based on the inclusion and exclusion criteria, the study was conducted on 60 sites on 30 patients diagnosed with chronic periodontitis with pocket depth of 5-8mm and were randomly allocated into two groups as control and test groups. Clinical indices (Gingival index, Probing pocket depth and Relative attachment level), objective and subjective parameters were assessed on baseline and at 3 months for both the groups.

RESULTS: In Group A, significant improvement in the mean GI ($p \leq 0.001$), PPD ($p \leq 0.001$) and RAL ($p \leq 0.001$) scores were observed from baseline to 3 Months. Similarly, significant decrease in the mean GI ($p \leq 0.001$), scores were observed in group B. However, no significant difference in PPD($p < 0.071$) and RAL ($p=0.288$) scores were seen in Group B.

CONCLUSION: The adjunctive use of Achyranthes aspera chip is an effective therapy to scaling and root planing in the treatment of chronic periodontitis. Results revealed a significant improvement for all the clinical parameters in Group A after application of Achyranthes aspera chip

KEYWORDS: Achyranthes aspera chip, Scaling and root planning, gingival index, probing pocket depth, relative attachment level, Local drug delivery.

INTRODUCTION

The most important goal of periodontal therapy is to reduce or eliminate the diseased pockets, number of pathogenic bacteria and to alter host immune-inflammatory response in periodontal tissues.[1] Conventional periodontal treatment consists of mechanical debridement to eliminate the subgingival microbiota and infected tissue in the inflamed pocket, usually performed by scaling and root planning. Although scaling and root planning are moderately successful, the rate of recurrence of periodontitis is high due to limited visibility of the operating site, restricted access, tissue invasion of certain microbes, and inaccessible biofilm retained in surface irregularities such as furcations, grooves, concavities, and deep pockets. Therefore, it is important to use adjunctive antimicrobial chemotherapeutic agents to eliminate or inactivate pathogenic microflora in sites where mechanical instrumentation is invidious.

Various antimicrobial agents being incorporated in delivery vehicles have been used and investigated as local drug in treatment of periodontal disease like Tetracycline, doxycycline, Chlorhexidine, minocycline and metronidazole. Devices may release the active drug in less than 24 hrs (sustained release) or for more than 24 hrs (controlled release). One such natural product is Achyranthes aspera which is a medicinal plant.

Research is being conducted for the use of the natural products instead of chemical agents. With the growing interest and increasing knowledge about medicinal value of natural products, various formulations like Eucalyptus extract, blood root, chamomile, green tea catechin, aloe vera, tulsi, and turmeric are available in the drug delivery systems. One such natural product is Achyranthes aspera which is a medicinal plant and many traditional healers used it for the management of fever, asthma, hypertension, dysentery, diabetes, cough, bronchitis, and rheumatism. It has various pharmacological properties such as antimicrobial, analgesic, antipyretic, anti-inflammatory, immunostimulant, antioxidant.[11]

According to Ayurveda, it is bitter, pungent, laxative, stomachic, carminative and useful for the treatment of vomiting, bronchitis, heart disease, piles, itching, abdominal pain, ascites, dysentery, blood disease etc. Different parts of the plant are used as ingredient in many native prescriptions in combination with more active remedies.

Achyranthes aspera has been used as an oral rinse against salivary streptococcus mutans in 8-12 years old children.[12] It has also been used in the form of mouth wash in comparison between ayurvedic drugs that is neem, apamarga, khadiradi over chlorhexidine in treating chronic periodontitis patient.[13] Though the agent has been tested for its anti inflammatory[14], antioxidant [15] and antibacterial properties [16] in vitro or in animals, limited studies are published to evaluate the effectiveness of Achyranthes aspera in humans as a local drug delivery agent used for treatment of periodontal disease.

Literature search reveals only one similar publication that has tested the efficacy of Achyranthes aspera as a local drug delivery agent in gel form.[2] Thus, the purpose of this study was to evaluate the efficacy of Achyranths aspera used in a chip form as an adjunct to SRP in the treatment of chronic periodontitis.

MATERIALS AND METHOD

This study is a randomized controlled clinical trial, in which a total of 60 sites diagnosed with chronic periodontitis were selected from department of Periodontics and department of Oral medicine at Triveni Institute of Dental Sciences, Hospital and Research Centre, Bilaspur, Chhattisgarh. The study was reviewed by the Scientific and Ethical Committee of Triveni Institute of Dental Sciences and clearance was obtained. An informed consent was obtained from each subject before conducting the trial.

A total of 60 sites diagnosed with chronic periodontitis with pocket depth of 5-8mm were chosen for the study based upon inclusion and exclusion criteria.

Inclusion criteria included Patients diagnosed with chronic periodontitis with age ≥ 30 years, Subjects having at least 1 periodontal site with pocket depth 5mm to 8mm, systemically healthy subjects, Patients not using any medicated toothpaste/ antibacterial mouthwash/ antibiotics or any anti-inflammatory drug before the commencement of the study for at least the past 3 months. Exclusion criteria included **Patients** having Aggressive periodontitis, Subjects with any systemic diseases, Smokers and other tobacco product consumers, Pregnant/ lactating mother, Patients with a history of any kind of periodontal therapy within past 6 months.

A stent was made for each tooth for subjects to measure the probing pocket depth before and after the treatment, subjects were recalled for the non-surgical phase. Two groups were formed for the study: Group A comprised of 30 sites who were treated with scaling and root planning (SRP) followed by Achyranthes aspera chip.

Group B comprised of 30 sites who were treated with only SRP.

All the subjects were chosen for the study using the inclusion and exclusion criteria mentioned before. For each patient, the screening visit was scheduled 7 days before the baseline visit. At the screening visit, after complete history taking and clinical examination, gingival index was recorded and supragingival scaling was performed with piezoelectric ultrasonic scaler. Alginate impression was made to prepare customised acrylic stents which would act as a reference guide for recording probing pocket depths and relative attachment level of the experimental sites. At baseline, clinical parameters (probing pocket depth and relative attachment level) were recorded at all the study sites. All measurements were made using the UNC-15 probe and the data obtained was noted as baseline scores. All data was recorded on a proforma. After this subgingival scaling was performed for the both the groups and Achyranthes aspera chip was placed only in Group A sites, which were first isolated and dried with compressed air for the placement of the chips. The chips were carried using sterile tweezers and were inserted into the respective pockets until the resistance was felt. Periodontal dressing (Coe-pack) was placed at sites A to prevent the dislodgement of the drug and to prevent the ingress of oral fluids.

Patients were recalled after 7 days for Coe-pack removal and to evaluate for any inflammatory response. The clinical parameters (GI, PPD and RAL) were assessed at baseline and 3 months.Also all the subjective parameters (pain and taste alteration) were recorded for all study sites for Group A and Group B. All the data thus obtained was subjected to statistical analysis. The data recorded was subjected to statistical analysis,carried out using IBM SPSS (Statistical package for Social Sciences) statistical version 21. All quantatitive variables were estimated using measures of central location “mean” and measures of dispersion (standard deviation). For normally distributed data, mean was compared using independent t- test (for two groups).For not normality distribution data ,median was compared using Mann Whitney U test (for two groups).For relationship pearson correlation method was used using chi square

test. Data analysis was done in IBM SPSS 20.0.Level of significance ,p>0.05 Not significant (ns), p<0.05 significant(*),p<0.01 highly significant (***).

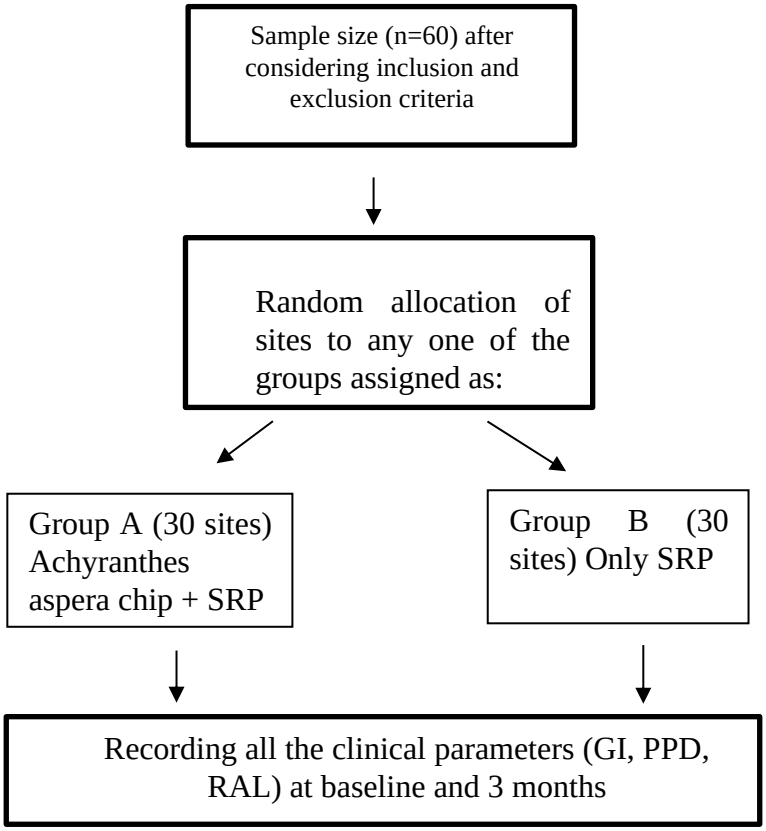

Figure 1: Flowchart depicting the study design

RESULTS

Table 1 shows the distribution of age in group A and Group B which shows mean age in group A 32.67 years and Group B 32.70 years respectively. There was no significant difference in tha age for both the study groups.

Group	N	Mean	SD	P value
Group A	30	32.67	7.62	.987
Group B	30	32.70	7.95	

Table 2 shows comparison of gender between the groups. Results showed out of the 60 subjects, 27 were males (45%) and 33 (55%) were females, Group A consisted of 30 subjects of which 14 were males (46.7%) and 16 were females (53.3%), similarly Group B showed 30 subjects where in 13 were males (43.3%) and 17 were females (56.7%) respectively.

Groups		Gender		Total	P value
		Male	Female		
Group A	N	14	16	30	0.795
	%	46.7%	53.3%	100.0%	
Group B	N	13	17	30	
	%	43.3%	56.7%	100.0%	
Total	N	27	33	60	
	%	45.0%	55.0%	100.0%	

Table 3 shows intragroup comparison of Group A for clinical parameters from baseline to 3 months. Result showed high significant improvement **(p<0.001)** in gingival index scores, probing pocket depth and relative attachment level after the placement of Achyranthes aspera chip

	Parameters	Baseline	3 Months	P value
Group A	GI	1.53±0.39	1.20±0.22	<0.001*
	PPD	4.39±0.92	3.47±1.05	
	RAL	4.43±0.90	3.62±0.99	

Table 4 shows intragroup comparisons of Group B for clinical parameters from baseline to 3 months. While significant improvement observed for gingival index scores **(p<0.001)** from baseline (1.63) to 3 months (1.31). PPD and RAL showed no significant difference.

	Parameters	Baseline	3 Months	P value
Group B	GI	1.63±0.52	1.31±0.40	<0.001*
	PPD	4.65±1.26	4.49±1.25	0.071
	RAL	4.72±1.29	4.60±1.19	0.288

Table 5 shows intergroup comparison in change in difference between clinical parameters from baseline to 3 months. Group A and Group B both showed highly significant difference in PPD **(p<0.001)** and RAL **(p<0.001)** when compared to baseline, while GI score for both Group A and Group B showed no significant change in difference from baseline to 3 months.

Parameters	**Group**	**Mean**	**P value**
GI	Group A	0.33±0.29	0.851
	Group B	0.31±0.41	
PPD	Group A	0.92±0.77	<0.001*
	Group B	0.15±0.46	
RAL	Group A	0.81±0.49	<0.001*
	Group B	0.11±0.56	

DISCUSSION

The Aim of the present study was to clinically evaluate the adjuvant benefit of Achyranthes Aspera chip in the form of a local drug delivery agent in treating chronic periodontitis patients. The most widely used approach has been scaling and root planning (SRP) that effectively decreases the microbial load but recolonization of the same can occur as early as 60 days after SRP.[3] Consequently, this has led to the adjunctive use of antimicrobials, assuming that chemicals would compensate for technical limitations, prevent early microbial recolonization and provide a chance for clinical improvements. Anti-infective agents can be administered locally or systemically.

Recently, many herbal products and their component are being used as an adjunct agent in the treatment of periodontitis in the form of local drug delivery such as neem, aloevera, lemon grass, curcumin, pomegranate etc. However, these agents have an advantage of cost effectiveness, minimal side effect and good patient compliance. Presently a large number of herbal products are researched for oral use in form of mouth rinses, gels etc. Among them one

of the herbal products is Achyranthes aspera. It is a perenial medicinal plant belonging to family Amaranthaceae that contains alkaloids, flavonoids, saponins, steriods, terpenoids and ecdysterone found as a weed throughout India. It has various pharmacological properties such as antimicrobial, analgesic, antipyretic, anti-inflammatory, immunostimulant, antioxidant, antifertility, hypoglycemic, diuretic, hypolipidemic, cardiac stimulant, antihypertensive, antinoiceptive, prothyrodic, antispasmodic, and hepatoprotective properties.[11]

The decrease in gingival inflammation could be achieved owing to the anti-inflammatory action of Achyranthes aspera in augmenting gingival health leading to reduced edema of the gingival margin along with enhanced collagen quantity and reduction in penetration of the tissue on probing.[1]

The reduction of probing depth and or improvement in the relative attachment levels could be attributed to the antioxidant property of A. aspera which results in terminating the radical chain reaction by inhibiting free-radical quenching and by inhibiting lipid peroxidation and increase in super oxide dismutase and catalase activity, thus, prevent the damage of cells caused by free radicals as quoted by **Edwin et al**.[15] Further the author also states the immunostimulant action of Achyranthes aspera by the promotion of T- lymphocyte proliferative response thus reducing inflammation.

Researchers having studied other LDD agents against only SRP have found similar results in accordance to the results of the present study. **Tyagi et al**[18] showed clinically significant reduction in PPD and gain in RAL in Group I (Pomegranate chip + SRP) when compared to Group II (SRP) at 3 months. **Sastravaha et al**[19] found significant improvement in pocket depth and attachment level after placing Centella asiatica and Punica granatum extracts following scaling and root planning when compared to placebo at 6 months. Result obtained by **Jain et al**[8] also demonstrated better PPD Reduction and RAL gain for Group I (*neem* chip + SRP) on comparison to Group II (SRP) at 12 weeks. **Garrett et al**[6] showed that doxycycline delivered sub gingivally in a bioresorbable polymer, at baseline and 4 months, produced significantly better CAL, PPD, and bleeding on probing (BOP) results than a placebo polymer over a six-month period. **Bogren et al**[20] used doxy gel along with SRP which showed significantly improved clinical conditions when compared to SRP alone at 3 months.

Improved CAL gain in the present study might be associated with the controlled release of the Achyranthes aspera chip; this in turn results in higher local concentration of the drug that might be responsible for the greater effect.

On the contrary to present study results, **Singh et al**[7] showed after a 1-month interval GI have no significant difference in all three groups Periochip + SRP, curcumin chip + SRP, and SRP. **Mehta et al**[17] in 2015 used *neem* extract as an LDD agent and found it to be marginally better than SRP at 3 months but not significant. Few authors in their study showed the change was significant in the first month but not significant from 1 month to 3 months. The authors attributed this to differences in study design and sample size. Further the authors attribute the reason to the thoroughness of SRP when effectively performed by a skilled clinician with no time limit, under anesthesia and in multiple visits shall yield excellent results. Nevertheless, in the present study A aspera has shown a clear and greater beneficial effect as local drug delivery agent providing substantivity of this drug at an effective concentration over time.[21]

In a systematic review by **Kalsi et al**[3] subgingival insertion of sustained-release antimicrobial systems alone was as effective as SRP alone in producing PD reduction. Therefore, placement of drug along with an effective SRP may have provided synergistic effect on the treatment outcomes. This was reflected in the present study wherein change in differences for clinical outcomes from baseline to 3 months was statistically significant for PPD ($P<0.001$) and RAL ($p<0.001$) in Group A subjects.

Overall, the result of the present study favours the use of Achyranthes aspera as an effective adjunctive therapy to scaling and root planning in treatment of chronic periodontitis. The possible shortcomings of the present study are the modest sample size, shorter follow up period for evaluation of clinical parameters and lack of microbiological assessment.

Future research taking a larger sample size with longer follow up period and along with microbiological assessment is required to deduce the clear benefits of A aspera as an LDD agent. Furthermore, Minimal Inhibitory concentration (MIC) of A aspera needs to be evaluated to know the exact concentration of the drug that needs to be incorporated for its better antibacterial action.

CONCLUSION:

The adjunctive use of Achyranthes aspera chip is an effective therapy to scaling and root planning in the treatment of chronic periodontitis. Moreover, A aspera can also be used in treatment of residual pockets as supportive periodontal therapy to prevent recolonization of the treated pockets. Although LDD systems do not replace time tested periodontal therapies, they definitely prove to be a strategic interventional modality with an important place in the treatment of periodontal disease.

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