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Comparison of 1% alendronate gel versus 1.5% chlorhexidine gel (chlosite) as an adjunct to the scaling and root planning in treating chronic periodontitis - A randomized controlled trial

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Abstract:
Local drug delivery is a promising non-surgical alternative to SRP for treating chronic periodontitis patients. Therefore, it is of interest to analyse the effectiveness of 1% Alendronate gel, 1.5% Chlorhexidine gel as an adjunct to scaling and root planing. Twenty participants were enrolled and distributed among three groups: Test Group A treated with SRP+1% alendronate gel, Test Group B treated with SRP+1.5% chlorhexidine gel and Control Group C treated with SRP alone. Periodontal parameters like PI, GI, SBI, CAL and PPD were noted at baseline, 3 and 6 months postoperatively. Remarkable reduction of all parameters was observed in all 3 groups from the beginning of treatment to 3-month to 6-month interval, whereas, no difference was observed in control Group C for PD scores and CAL gain. On intergroup comparison of PI, GI, SBI scores test, group B shows highly significant differences in comparison to test Group A and control Group C at 3 and 6-month intervals ($P < 0.001$). Thus, data shows the chlorhexidine gel as LDD is efficacious in treating periodontal pocket, whereas 1% alendronate gel, along with SRP, can be used as an alternative for treating chronic periodontitis.

Keywords: Periodontitis, local drug delivery (LDD), chlosite, alendronate, bisphosphonates

Background:
The sub-optimal clinical result of periodontal therapy is often associated with the presence of periodontopathogens persisting or re-established after treatment **[1]**. A routine mechanical removal of plaque from all non-shedding oral surfaces remains the cornerstone of prevention and control of gingivitis and periodontitis, the primary therapeutic goal in managing periodontal disease is to diminish bacterial load and prevent the advancement of inflammation **[2]**. Scaling and root planning are intended to remove subgingival irritants and reduce root surface roughness, which may promote plaque accumulation. However, mechanical debridement alone does not guarantee complete eradication of pathogenic microorganisms residing within the subgingival environment **[3]**. This limitation is especially evident in sites presenting with deep periodontal pockets, where access and efficacy of non-surgical interventions are significantly compromised. Studies have indicated that in areas with probing depths exceeding 4 mm, up to 66% of treated root surfaces may still exhibit residual plaque and calculus **[4, 5]**. This poses a need for adjunctive therapies such as locally administered antibiotics. The use of locally delivered antimicrobial agents has been associated with improved patient compliance. The subgingival application allows for the attainment of antimicrobial concentrations up to 100 times greater than those achieved through systemic administration **[6]**. Chlorhexidine (CHX), an antiseptic agent with broad-spectrum antimicrobial efficacy, has been recognized for its substantivity, safety profile and minimal toxicity **[6]**. It remains the most extensively utilized locally delivered drug in the management of periodontitis. In addition to liquid and solid carriers, gel-based delivery systems have been developed, typically containing CHX at concentrations up to 1.5 times higher than liquid carriers. The increased viscosity of gel-based systems reduces the clearance of the active compound from periodontal pockets. Compared to solid carriers, gels offer ease and speed of administration, reduce the risk of iatrogenic tissue trauma, avoid revisits for device removal and ensure compliance. Sustained release delivery of chlorhexidine 1.5 % has shown a significant reduction in microbial colony counts when used in higher concentrations **[7]**. A novel delivery system incorporating 2.5% xanthan gum was formulated to enhance the retention of chlorhexidine gels within periodontal pockets. Xanthan gum increases the viscosity of liquids and remains stable across varied temperatures and pH. Bioadhesive properties of xanthan gum are responsible for its use in gel carriers and viscosity may prevent CHX clearance from subgingival sites **[8]**. Alendronate (ALN), an amino bisphosphonate, is a potent inhibitor of bone resorption. Once incorporated into bone, it shows prolonged retention and may be released during the resorptive process, potentially contributing to the preservation of alveolar bone **[9]**. Bisphosphonates, due to their high affinity for osseous tissue, suppress osteoclastic activity, thereby inhibiting bone resorption **[9]**. Evidence indicates that bisphosphonates may stimulate osteoblastic activity, thereby facilitating early bone formation. Moreover, bisphosphonates antagonize the activity of various matrix metalloproteinases which work by breaking periodontal

connective tissue elements **[10]**. In light of these therapeutic benefits, bisphosphonates have been proposed to be used as an adjunct to scaling and root planing for treating periodontitis. In 2021, Hedvicakova *et al.* reported that during hard tissue repair, alendronate predominantly inhibits two pathways *i.e.* RANKL signalling pathway and macrophage colony stimulating factor expression. This mechanism contributes to the effects of alendronate on wound healing of periodontal defects **[11]**. Alendronate has been reported to act as a wound-healing enhancer by exerting both anti-inflammatory and antimicrobial effects. A reduction in neutrophil infiltration within inflamed gingival tissues, along with the suppression of proinflammatory mediators such as interleukin-6 and matrix metalloproteinases, has been observed, which may contribute to the limitation of soft tissue damage **[12]**. Therefore, it is of interest to assess the efficacy of 1% alendronate gel, 1.5 % chlorhexidine gel along with scaling and root planing and in comparison, to scaling and root planing alone in chronic periodontitis.

Methodology:

Single-blind, split-mouth study was performed after obtaining written informed consent of all participants and institutional ethical approval obtained from IECSMBT dental college, hospital and postgraduate research center, Sangamner, Maharashtra. (SMBT/DC/1329/2017 dated on 16th Jan 2017). The sample size was calculated using SPSS software version 16 with α = 5%, power = 80%, SD = 1.0 mm. Twenty subjects, both male and female (25–55 years), having periodontitis with moderate to severe severity were enrolled having pocket depth ≥5 mm in at least one site in three different quadrants, willing to undergo treatment and had not received periodontal treatment in the last six months. Participants with systemic illness, immunocompromised, pregnant or lactating females, allergic to alendronate, bisphosphonates or chlorhexidine, subjects undergoing bisphosphonate therapy and those who voluntarily withdrew and have experienced adverse reactions were excluded from this study. Following full-mouth SRP, eligible sites were randomly assigned using computer-generated tables into 3 groups (20 sites each, a total of 60 sites across three groups). Test Group A received SRP + 1% alendronate gel**,** Test Group B received SRP + 1.5% chlorhexidine gel (CHLO-SITE) and Control Group C received SRP alone. Patients were completely blinded about the treatment and clinical parameters like Plaque Index (PI), Gingival Index (GI), Sulcus Bleeding Index (SBI), Clinical Attachment Level (CAL) and Probing Pocket Depth (PPD) were documented using UNC-15 probe ensuring high inter-examiner reliability at baseline (prior to SRP), at 3- and 6-month intervals. CHLO-SITE gel was obtained from GHIMAS, Italy. Following the method prescribed by Reddy *et al.* (2005), **[13]** 1% alendronate gel was prepared under aseptic conditions using sterilized equipment. After SRP, selected sites were isolated and dried using compressed air or paper points. Through a blunt cannula fitted to a syringe, the 1% alendronate gel and 1.5% chlorhexidine gel were delivered into the pocket base till gingival margin is reached. A periodontal dressing was used to hold the gel in place for 8 days before being removed. Control sites received SRP alone. Oral hygiene instructions were reinforced at each follow-up visit. Postoperative probing depths were measured after 6 months.

Results:

The study was completed by analysing 60 sites from 20 participants with a mean age of 38.95 ± 3.69 years (range: 32**–**48 years) **(Table 1)** without any complications or adverse effects. Among the 20 participants, 9 (45%) were males, 11 (55%) were females and there was no significant difference observed among the genders ($p > 0.05$) **(Table 2)**. The clinical parameters for all three groups were presented **(Table 3)** at baseline, 3 and 6 months, which include PI, GI, SBI, PPD and CAL. Intergroup comparison resealed significant reductions in PI, GI, SBI and PPD scores from baseline to 3 and 6 months in both test groups, whereas the control group showed less improvement particularly for PPD and CAL parameters **(Table 4)**. For inter-group analysis of Plaque Index scores, Test Group B achieved significantly greater reductions at 3- and 6-month intervals ($p < 0.001$) compared to both Test Group A and the control Group C, which does not show any significant difference. Comparing Gingival scores, at 3 months there was a significant difference found between test group A and B ($p < 0.05$) and test Group B and control Group C ($p < 0.05$), compared to test Group A and control Group C showing, no significant difference ($p = 0.887$). GI score at 6 months reveals significant difference between Test Group B and the control group C ($p<0.001$), when compared Test Group A to Control Group C show, no significant difference ($p>0.05$) **(Table 5)**. Findings disclose that for sulcus bleeding scores; Test Group B showed a highly significant reduction compared to the control group at both time points ($p < 0.001$) and there was significant difference between group A and group B ($p < 0.05$) as well as group A and group C ($p < 0.05$) at 3- and 6-months intervals. Regarding PPD reduction and CAL gain, both test groups reveal significant difference ($p < 0.05$) and when test Group B is compared to group C at both time points ($p < 0.001$) shows highly significant results. Comparing results between group A and group C reveals significant reductions at 3 months ($p < 0.05$) and highly significant difference at 6 months ($p < 0.001$) **(Table 5)**.

Table 1: Age distribution in study population

	MEAN	S.D.	S.E. MEAN	MINIMUM	MAXIMUM
AGE (in years)	38.95	3.69	0.82	32.0	48.0

Table2: Gender distribution in study population

	MALE N (%)	FEMALE N (%)	CHI-SQUARE TEST	P value
GENDER	9 (45%)	11 (55%)	Chi = 0.20	P = 0.665

Table 3: Mean and SD of PI, GI, SBI, PPD and CAL at baseline, 3 months and 6 months among test group A (SRP + 1 % Alendronate gel), test group B (SRP + 1.5% Chlorhexidine gel) and control group C (SRP)

Parameter	Group A (alendronate gel)			Group B (chlorhexidine) gel			Group C (SRP-control)		
	Baseline	3 months	6months	Baseline	3months	6 months	Baseline	3months	6 months

Plaque index	3.0 ±0.84	1.79±0.35	1.06±0.24	3.07±0.86	0.99±0.18	0.60±0.12	3.20±0.90	1.87±0.43	1.02±0.26
Gingival index	1.65±0.38	1.09±0.22	0.83±0.16	1.72±0.33	0.80±0.28	0.62±0.06	1.70±0.31	1.13±0.29	0.91±0.22
Sulcus bleeding index	3.11±0.57	1.53±0.32	1.1±0.28	3.41±0.57	1.14±0.24	0.70±0.15	3.08±0.51	1.87±0.43	1.48 ±0.44
Pocket probing depth	7.1±1.16	5.75±0.96	4.7 ±1.03	7.0 ±0.97	4.85±1.08	3.95±0.88	6.95±1.09	6.5 ±1.31	6.2±1.28
Clinical attachment loss	7.45±1.19	5.65±1.03	5.3±1.38	7.65±1.08	4.85±1.03	4.25±1.01	7.3±1.12	6.95±1.76	6.65±1.49

Table 4: Intragroup comparison of PI, GI, SBI, PPD and CAL among test Group A (SRP + 1 % Alendronate gel), test group B (SRP + 1.5% Chlorhexidine gel) & control Group C (SRP) at baseline, 3 months and 6-months

Parameter	Group	Anova f-test	Baseline Vs 3 months	Baseline Vs 6 months	3 months vs 6 months	P value, significance
Plaque index	Group A (alendronate gel)	F = 64.03	p <0.001**	p <0.001**	p <0.001**	P <0.001**
	Group B (chlorhexidine) gel	F= 133.59	p <0.001**	p <0.001**	p =0.048*	P <0.001**
	Group C (SRP-control)	F= 66.67	p <0.001**	p <0.001**	p <0.001**	P <0.001**
Gingival index	Group A (alendronate gel)	F =46.765	p <0.001**	p <0.001**	p=0.013*	P <0.001**
	Group B (chlorhexidine) gel	F= 106.33	p <0.001**	p <0.001**	p =0.043*	P <0.001**
	Group C (SRP-control)	F= 41.675	p <0.001**	p <0.001**	p 0.045*	P <0.001**
Sulcus bleeding index	Group A (alendronate gel)	F =131.385	p <0.001**	p <0.001**	p=0.004*	P <0.001**
	Group B (chlorhexidine) gel	F= 305.75	p <0.001**	p <0.001**	p =0.001*	P <0.001**
	Group C (SRP-control)	F= 64.570	p <0.001**	p <0.001**	p=0.030*	P <0.001**
Pocket probing depth	Group A (alendronate gel)	F =25.885	p <0.001**	p <0.001**	p = 0.007*	P <0.001**
	Group B (chlorhexidine) gel	F= 50.44	p <0.001**	p <0.001**	p =0.015*	P <0.001**
	Group C (SRP-control)	F= 1.864	p=0.487	p=0.143	p=0.724	p =0.164
Clinical attachment loss	Group A (alendronate gel)	F =18.126	p <0.001**	p <0.001**	p=0.634	P <0.001**
	Group B (chlorhexidine) gel	F= 59.73	p <0.001**	p <0.001**	p=0.176	P <0.001**
	Group C (SRP-control)	F= 0.960	p=0.738	p=0.356	p=0.799	p =0.389

p >0.05 – not significant; p <0.05 – significant; p <0.001 – highly significant; #p value calculated using Anova F test, ^ p value calculated using Turkey's post hoc test

Table 5: Intergroup comparison of plaque index, gingival index, sulcus bleeding index, pocket probing depth & clinical attachment level among test Group A (SRP+1% Alendronate gel), test Group B (SRP+1.5% Chlorhexidine gel) & control Group C (SRP)

Parameter	Group	Anova f test #	A vs B	A vs C	B vs C	P value significance
Plaque index	Baseline	F =0.269	p = 0.960	p=0.750	p=0.893	P = 0.765
	3 months	F=40.312	p <0.001**	P=0.742	p <0.001**	P <0.001**
	6 months	F= 26.82	p <0.001**	P=0.834	p <0.001**	P <0.001**
Gingival index	Baseline	F = 0.193	P=0.824	P=0.892	P=0.990	P = 0.825
	3 months	F = 8.845	P = 004*	P =0.887	P =001*	P<0.001**
	6 months	F=15.541	P=0.001*	P=0.340	P<0.001**	P<0.001**
Sulcus bleeding index	Baseline	F = 2.143	P=0.208	P=0.989	P=0.160	P=0.127
	3 months	F =22.734	p=0.002*	P=0.09*	P<0.001**	P<0.001**
	6 months	F =30.255	P =0.001*	P =0.001*	P<0.001**	P<0.001**
Pocket probing depth	Baseline	F = 0.10	p=0.954	p=0.900	p=0.988	P=0.905
	3 months	F = 10.615	p= 0.039*	p =0.049*	p <0.001**	P <0.001**
	6 months	F = 22.551	p= 0.041*	p <0.001**	p <0.001**	P <0.001**
Clinical attachment loss	Baseline	F = 0.477	p= 0.844	p=0.909	p=0.597	P = 0.623
	3 months	F = 12.80	p = 0.047*	p=0.008*	p<0.001**	P <0.001**
	6 months	F = 16.75	p = 0.038*	p = 0.005*	p<0.001**	P <0.001**

p >0.05 – not significant; p <0.05 – significant; p <0.001 – highly significant; #p value calculated using Anova F test, ^ p value calculated using Turkey's post hoc test

Discussion:

The study determines the efficacy of drugs delivered locally such as 1% alendronate gel, 1.5% chlorhexidine gel for patients suffering from chronic periodontitis in addition to scaling and root planing at an interval of 3 and 6 months as chlorhexidine delivered locally is productive for 11 weeks, with 3 months representing the standard periodontal recall interval and 6 months allowing evaluation of sustained long-term effects. Chlosite contains xanthan gum that sustains bacteriostatic and bactericidal levels of chlorhexidine, thereby preventing bacterial recolonization **[7]**. Additionally, Sajna *et al.* and colleagues reported that incorporating chlorhexidine into xanthan gum enhances the gel's bioadhesive qualities, improving its structural integrity and prolonging its substantivity **[8]**. Bisphosphonates are resistant to hydrolysis as they contain a phosphate-carbon-phosphate bond. In addition to its structural stability, alendronate easily adheres to hydroxyapatite crystals present in bone, thereby reducing active osteoclastic bone resorption **[14]**. Increasing the frequency and dose of bisphosphonate will improve periodontal parameters according to Shetty *et al.* **[15]**. The study showed significant reduction in plaque scores, resulting from supragingival and subgingival scaling, the patient's compliance and proper oral hygiene maintenance. Among the groups, sites treated with Chlosite gel showed a greater reduction in plaque levels compared to ALN gel or SRP alone due to the synergistic effect of combining chlorhexidine digluconate and dihydrochloride which results in enhanced antimicrobial action and prolongs the duration of its antibacterial action. These results align with findings reported by Verma *et al.* who observed a greater reduction in PI in patients treated with SRP+Chlosite gel when compared with SRP alone **[16]**. 1% alendronate gel showed no significant difference in plaque reduction compared to SRP, suggesting that its additional use has no cumulative effect over SRP for plaque reduction. Similar findings were observed in study conducted by Phassang *et al.* **[14]** which showed improvements in both site-

specific and overall Plaque Index (PI) scores; however, the differences observed between the groups at various time points did not show statistical significance. Individually, all the treatment modalities have equal effectiveness in reducing bleeding on probing and gingival inflammation from baseline to 3 and 6 month intervals; however, test group B exhibited superior. Similar findings were observed by Gautam *et al.* **[17]** who reported a marked reduction in bleeding on probing in patients treated with chlosite gel. In contrast, the adjunctive use of 1% alendronate gel did not result in any improvement in GI scores beyond what was achieved with SRP alone. However, significant reduction in SBI was recorded at both the 3 and 6 month evaluations, possibly due to modulating inflammatory response. According to Mitra *et al.*, alendronate exhibits wound healing properties, anti-inflammatory and antimicrobial effects. Its mechanism involves decreasing neutrophil influx in inflamed tissues and suppressing proinflammatory mediators, thereby limiting soft tissue damage **[12]**. We found similar results to a study which found decreased SBI scores in alendronate groups compared with placebo groups at 6 and 12 months. After the application of Chlosite gel, PPD and CAL scores reduced due to its potential to minimize microbial recolonization during wound healing post SRP. In a similar study by Shergill *et al.* **[18]** the additional use of chlorhexidine gel along with SRP led to greater reduction in PPD and improved CAL at 3-month follow-up. Study by Zhou *et al.* **[19]** suggested that the efficacy of xanthan-based chlorhexidine gel is increased, facilitating oral hygiene maintenance in patients. Using 1% alendronate gel demonstrated a reduction in PPD and CAL in contrast to scaling and root planing alone. Alendronate has been discovered to modulate both hard and soft tissue healing in periodontal disease over time. The observed decrease in pocket depth and the antibacterial properties of alendronate contribute to its therapeutic effects, thereby enhancing wound healing within periodontal defects, as reported by Arena *et al.* **[20]**. According to Reddy *et al.* **[13]**, osteoclast suppression is likely responsible for the observed pocket depth reduction and improvement in clinical attachment. While the study was carefully planned and executed, certain limitations should be considered. To evaluate the regeneration dynamics of periodontal healing, radiographic evaluation and microbiological analyses are further required.

Conclusion:

We show that additional use of subgingival 1.5% chlorhexidine gel and 1% alendronate gel lead to better outcomes of initial periodontal therapy. The use of chlosite gel as a drug delivered locally demonstrated greater efficacy in removing subgingival biofilm and reducing probing depth of periodontal pockets in contrast to scaling and root planing alone and 1% alendronate gel. The adjunct use of 1% alendronate gel with SRP appears to be a beneficial alternative in the treatment of chronic periodontitis.

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