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ADJUNCTIVE EFFECT OF LOCALLY DELIVERED MINOCYCLINE MICROSPHERES IN CHRONIC PERIODONTITIS: A SYSTEMATIC REVIEW

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Keywords:

Chronic periodontitis, Local drug delivery, Minocycline microspheres, Probing depth, scaling, and root planing

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ABSTRACT: Objective: Chronic periodontitis, an inflammatory disease of the supporting tissues of teeth, is usually treated non-surgically by scaling and root planing. Minocycline is used as a local drug delivery and can be used as an adjunctive agent. The study aims to determine the efficacy of minocycline microspheres as a local drug delivery agent in treating chronic periodontitis. **Methods:** Randomized controlled trials investigating the efficacy of minocycline microspheres as local drug delivery agents in chronic periodontitis were included. Articles were retrieved from MEDLINE, EBSCO, Cochrane database, PUBMED, and Google Scholar in the English language from January 2000 up to January 2023. Articles retrieved were screened using specific inclusion criteria by four independent reviewers and analyzed using Rev Man 5.0 software. The measured outcomes were Probing Pocket Depth, Clinical Attachment Level, Plaque Index, and Gingival Index. **Results:** About 1288 patients aged above 30 were studied. In all the studies, the control group was treated with scaling and root planing alone, whereas the test group was treated with scaling and root planing followed by subgingival administration of minocycline microspheres. Scaling and root planing plus minocycline microspheres demonstrated better clinical outcomes than scaling and root planing alone. **Conclusion:** The present study shows that local delivery of minocycline microspheres significantly improves the clinical outcomes of traditional treatment and should be considered as an adjunct to scaling and root planing in chronic periodontitis.

INTRODUCTION: Chronic periodontitis is the most frequently occurring form of periodontitis characterized by loss of clinical attachment and loss of the adjacent supporting bone [1]. Scaling and root planing (SRP) is the Gold Standard treatment regimen for periodontitis and acts by reducing bacterial load by meticulous removal of plaque [2]. Significant reduction in the bacterial load results in improvements in all clinical parameters of periodontitis [3].

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Mechanical therapy alone may fail to eliminate invasive, pathogenic bacteria as they are located deep within the gingiva and thus can be inaccessible to periodontal instruments. These are mostly gram-negative microorganisms [4]. Systemic antibiotics are discouraged due to increasing concerns over the development of resistant organisms. An alternative is the local delivery of antibiotics into periodontal pockets.

This can avoid side effects associated with systemic antibiotic therapy by localizing and limiting the agent to the periodontal pocket. Minocycline hydrochloride is a semi synthetic derivative of tetracycline that acts by interfering with protein synthesis in the bacterial cell wall. Minocycline microsphere is a controlled-release bioabsorbable polymer [1].

Active drugs dissolve and diffuse out of the microspheres through the channels into the surrounding tissues and after 10 days, the microspheres are fragmented and continue to release minocycline for 14 days or longer, and eventually these microspheres completely bio resorb [4]. Thus, from both a biological and clinical point of view, it is important to evaluate the combination of SRP and locally administered minocycline microspheres as a treatment of chronic periodontitis.

Rationale: Rationales behind the use of minocycline in the eradication of periodontal pathogens implicated in periodontitis are:

- Broad spectrum antibiotic [5].
- Drug substantivity [5].
- Anti-collagenase activity against *P. gingivalis* [5].
- Increased lipid solubility prevents protein synthesis and ensures quick passage through the bacterial cell wall [5].

An ideal formulation of minocycline as a local drug delivery agent should exhibit ease of delivery, good retention at the application site, and a controlled release of the drug [5]. Thus, through this systematic review, the effectiveness of minocycline microsphere as an adjunct to scaling and root planing is assessed as compared to scaling and root planing alone.

Focused Question: Is minocycline microsphere as an adjunct to scaling and root planing more effective as compared to scaling and root planing alone for pocket reduction in subjects with chronic periodontitis?

Primary Objective: To evaluate the effect of minocycline hydrochloride as an adjunct to scaling and root planing as compared to scaling and root planing alone in subjects with chronic periodontitis with respect to probing pocket depth (PPD).

MATERIALS AND METHODS: A systematic review was undertaken as per the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) checklist. The systematic review is registered at the PROSPERO website: CRD42024503462.

Search Strategy and Study Selection: A literature search was performed in MEDLINE, Pub Med, Embase, Google Scholar, and EBSCO host databases for papers published from January 2000 up to January 2023. Randomized controlled trials published in the English language were selected for analysis.

Search Terms: Keywords used for study identification in all databases were "(local minocycline) and (scaling) and (periodontitis)" and "(minocycline microspheres) and (scaling) and (periodontitis)" and "((arestin or minocycline microsphere) and (scaling) and (periodontitis)".

Inclusion Criteria:

1. Randomized controlled trials interventional study.
2. Randomized Clinical Trials (RCT) comparing minocycline microspheres with SRP + SRP alone.
3. Controlled Clinical Trials (CCT) comparing minocycline microspheres with SRP + SRP alone.
4. Studies reporting one or more clinical parameters including probing pocket depth (PPD), Clinical Attachment Level (CAL), Plaque Index (PI), and Gingival Index (GI)
5. Full-text articles.
6. Studies on human subjects.
7. Studies published in English language only from the year January 2000 to January 2023.
8. Patients with chronic periodontitis.

Exclusion Criteria:

1. Case reports and case series.
2. Animal model studies, in-vitro studies, commentaries, and interviews.
3. Studies where local and/or systemic antimicrobials were used with non-surgical therapy as a control group.
4. Unpublished research.

Data Collection Process: Quality and risk of bias of the randomized controlled trials were assessed using Rev Man 5.0. A data extraction sheet was prepared based on variables associated and the articles were analysed. Risk of bias assessment was conducted by using the recommended approach for assessing the risk of bias in studies included in Cochrane Reviews (Higgins 2011) using the tool RevMan 5.0.Using a data extraction sheet, the following data were collected: Authors, year of publication, country, aim, tissue assessed, type of study, sample size, comparison group and control group, methodology, and conclusion **Fig. 1.**

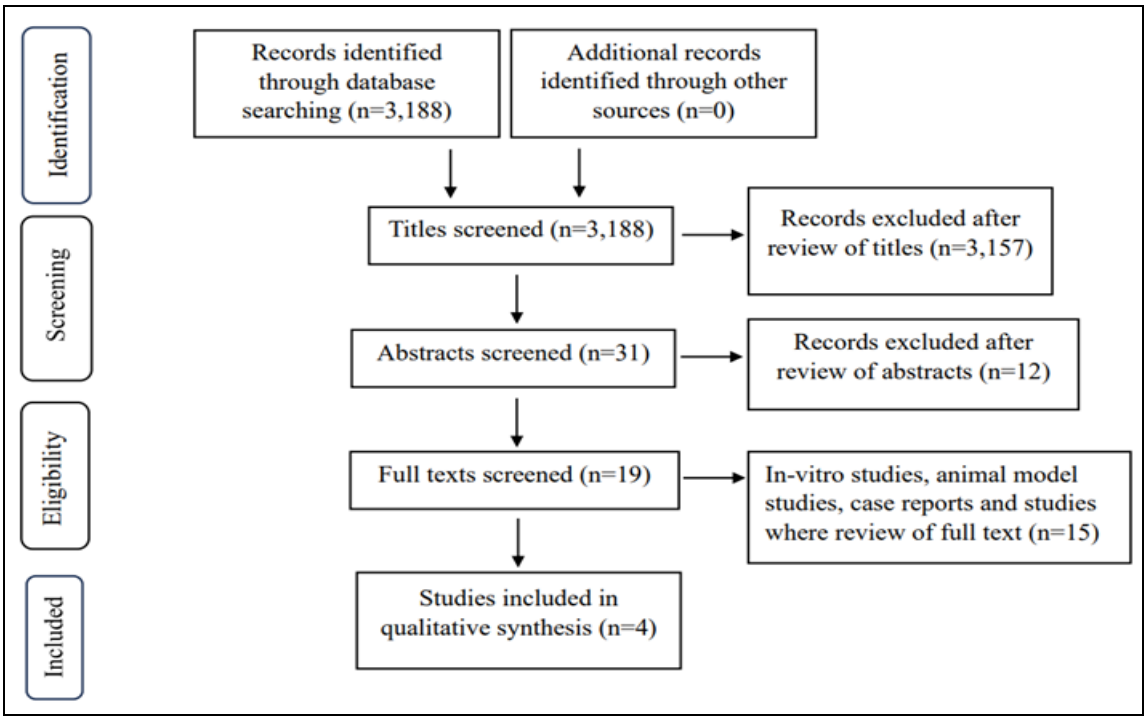

FIG. 1: FLOW CHART OF LITERATURE SEARCH RESULTS AND STUDY SELECTION

RESULTS:

Study Characteristics: Four randomized controlled trial studies were included for the qualitative synthesis. All 4 studies suggest that minocycline microspheres used as an adjunct to scaling and root planing yield significant results when compared to scaling and root planing alone. An overview of the included studies for the analysis is presented in **Table 1.**

TABLE 1: STUDIES INCLUDED IN THE REVIEW

Sr. no.	Author, Year	Title	Test Group	Control Group	Study Design	Follow Up	Result
1.	Bland PS et al, 2010	Association of Antimicrobial and Clinical Efficacy: Periodontitis Therapy with Minocycline Microspheres	Moderate-to-advanced chronic periodontitis patients treated with scaling and root planing (SRP) plus minocycline microspheres.	Moderate-to-advanced chronic periodontitis patients treated with scaling and root planing (SRP) alone	RCT	1 month	The addition of minocycline microspheres to scaling and root planing led to a greater reduction in pocket depth was significantly correlated with the reduction of the proportions and numbers of red complex bacteria.
2.	Cortelli JR et al, 2006	Longitudinal Clinical Evaluation of Adjunct Minocycline in the Treatment of Chronic Periodontitis	Chronic periodontitis patients treated with scaling and root planing (SRP) plus minocycline microspheres.	Chronic periodontitis patients treated with scaling and root planing (SRP) alone.	RCT	3, 6, 9, 12 and 24 months	SRP combined with subgingival minocycline showed a higher reduction at 6- and 9-months following therapy.

3.	Gopinath V. et al, 2009	Effect of a controlled release device containing minocycline microspheres on the treatment of chronic periodontitis: A comparative study	Chronic periodontitis patients treated with scaling and root planing (SRP) plus minocycline microspheres	Chronic periodontitis patients treated with scaling and root planing (SRP) alone,	RCT	3 and 6 months	Minocycline microspheres plus scaling and root planing showed better results than control group to reduce probing depth.
4.	William RC et al,2001	Treatment of Periodontitis by Local Administration of Minocycline Microspheres: A Controlled Trial	Moderate-to-advanced chronic periodontitis patients treated with scaling and root planing (SRP) plus minocycline microspheres.	Moderate-to-advanced chronic periodontitis patients treated with scaling and root planing (SRP) alone	RCT	9 Months	Minocycline microspheres plus scaling and root planing provided substantially more probing depth reduction than SRP alone.

TABLE 2: QUALITY ASSESSMENT OF THE STUDIES INCLUDED BY JUDGING THE RISK OF APPLICABILITY USING COCHRANE RISK OF BIAS TOOL FOR RANDOMIZED CONTROLLED TRIAL

Sr. no.	Author /Year	Type of study	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome	Incomplete outcome data	Selective reporting	Other Bias
1.	Bland PS et al, 2010	RCT	Low Risk	Unclear Risk	High Risk	Low Risk	Low Risk	Unclear Risk	Unclear Risk
2.	Cortelli JR et al, 2006	RCT	Low Risk	Unclear Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
3.	Gopinath V. et al, 2009	RCT	Low Risk	Unclear Risk	High Risk	Unclear Risk	Low Risk	Unclear Risk	Low Risk
4.	William RC et al, 2001	RCT	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Unclear Risk

The risk of bias of the included studies is presented in **Fig. 2**, and **Fig. 3**.

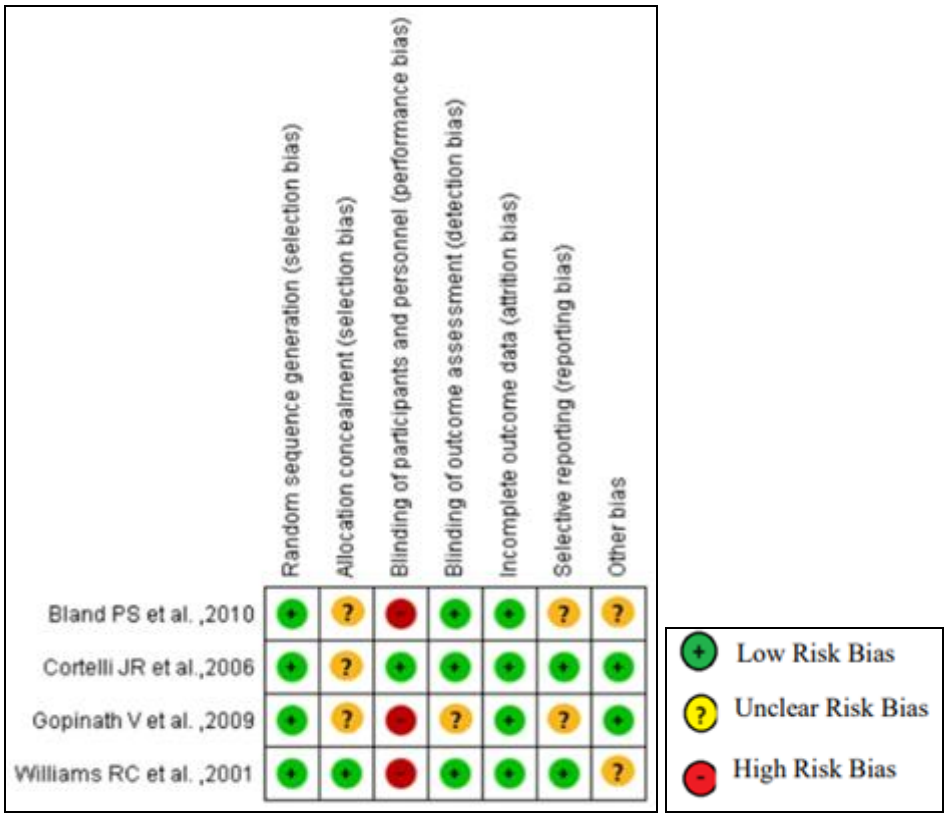

FIG. 2: RISK OF BIAS IN INDIVIDUAL STUDIES

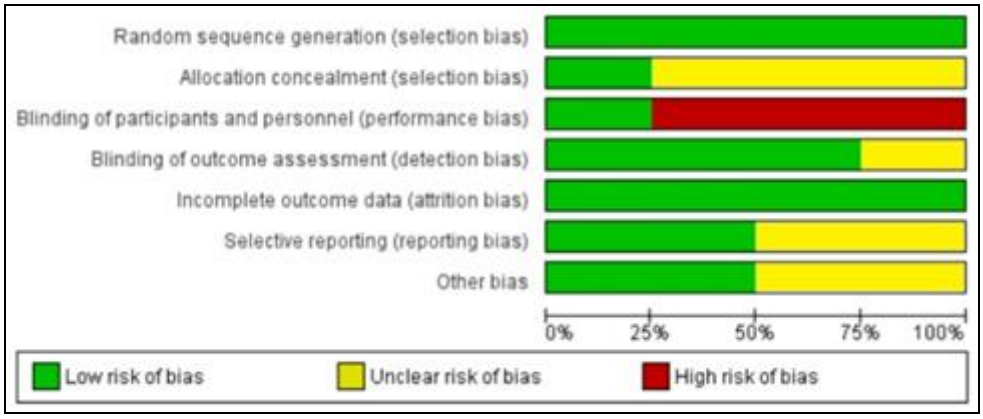

FIG 3: SUMMARY OF RISK OF BIAS ASSESSMENT OF INDIVIDUAL STUDIES

Primary objective of all the studies depicting the mean probing pocket depth at baseline and different follow-up intervals are explained in **Table 3.** Secondary objective of all the studies depicting the PI, GI and CAL at baseline and different follow-up intervals are explained in **Table 4.**

TABLE 3: MEAN PROBING POCKET DEPTH AT BASELINE AND VARIOUS FOLLOW-UP INTERVALS

Study	Test	Control
Bland PS et al, 2010	Baseline- ≥ 5 mm Change in PD: 1 Month-1.38	Baseline- ≥ 5 mm Change in PD: 1 Month-1.01
Cortelli JR et al, 2006	Baseline-7.45 Change in PD: 3 Months-3.14 6 Months-3.40 9 Months-3.54 12 Months-3.58 24 Months-2.27	Baseline-7.73 Change in PD: 3 Months-2.66 6 Months-2.80 9 Months-2.66 12 Months-2.53 24 Months-1.80
Gopinath V. et al, 2009	Baseline- 5.33mm Change in PD: 3 Months-1.73mm 6 Months-1.66 mm	Baseline-5.57mm Change in PD: 3 Months-0.24mm 6 Months-0.37 mm
Williams RC. et al, 2001	Baseline- 5.8mm Change in PD: 9 Months-1.32 mm	Baseline-5.8mm Change in PD: 9 Months-1.08 m

Statistically significant difference (P <0.05)

TABLE 4: MEAN PLAQUE INDEX (PI), GINGIVAL INDEX (GI), AND CLINICAL ATTACHMENT LEVEL (CAL) AT BASELINE AND VARIOUS FOLLOW-UP INTERVALS

Study	Plaque Index (PI)		Gingival Index (GI)		CAL Gain
Williams RC. et al, 2001	NA		NA		NA
Study	Plaque Index (PI)		Gingival Index (GI)		CAL Gain
Bland PS et al, 2010	NA		NA		Control Group: 0.80 mm Test Group: 1.16 mm
Cortelli JR et al, 2006	Control Group		Control Group		NA
	Baseline 1.08	1.13	Baseline 0.88	0.82	
	3 Months 0.88	0.77	3 Months 0.25	0.27	
	6 Months 0.70	0.73	6 Months 0.25	0.13	
	9 Months 0.57	0.63	9 Months 0.25	0.17	
	12 Months 0.48	0.60	12 Months 0.25	0.20	
	24 Months 1.28	1.28	24 Months 1.72	1.30	
Gopinath V. et al, 2009	Control Group		Control Group		NA
	Baseline 1.05	1.05	Baseline 1.16	1.21	
	1 Month 0.59	0.49	1 Month 0.93	0.49	
	3 Months 0.63	0.33	3 Months 0.88	0.41	
	6 Months 0.52	0.28	6 Months 0.78	0.26	

DISCUSSION: Instrumentation of the subgingival area aims at eliminating the bacterial biofilm and subgingival calculus. However, as subgingival SRP is technically demanding since access and visibility of the area are limited, complete subgingival plaque and calculus removal is rarely achieved. Non-surgical scaling and root planing cannot ensure the complete removal of subgingival calculus in sites with probing depths exceeding 5 mm. Therefore, it is necessary to use additional adjuncts in the form of antimicrobial agents to achieve effective clinical results [6]. Although results from all 4 studies showed that minocycline microspheres as an adjunct to scaling and root planing resulted in the reduction of probing pocket depth from baseline to investigated time points, investigators in only 1 of the 4 studies evaluated the Clinical Attachment Gain [6]. Thus, there is insufficient evidence that it produces any additional benefit. The studies available were low in numbers and, with one exception, were small-scale clinical trials without adequate controls, which presents a high risk of bias. Williams RC *et al.* have reported that periodontitis patients treated with SRP plus minocycline microspheres were 60% more likely to improve with an overall mean probing depth [7].

In a study by Bland PS *et al,* the safety of minocycline microspheres was confirmed by the low incidence of adverse events recorded. A total of 73 adverse events were reported, mostly associated with headaches and teeth and gum pain. Both groups exhibited adverse events at equal frequencies, except oral pain, which was reported three times more subjects in the control group [6]. The study also reported a greater reduction in the proportions and numbers of red complex bacteria. The reduction in pocket depth was significantly correlated with the reduction of the proportions and numbers of red complex bacteria [6]. According to Gopinath V. *et al,* the gingival status showed a significant improvement in the test sites and this was consistent with the findings of the studies conducted by Muller *et al.,* Vansteenberghe *et al.,* Saito *et al.,* Jones *et al.,* Timmerman *et al.,* Radvar *et al.,* Hagiwara *et al.,* Vansteenberghe *et al.,* and Kinane *et al* [4]. According to a pharmacokinetic study by Paquette D *et al,* minocycline has minimal absorption through the periodontal pocket into serum and stays concentrated in saliva. Levels of minocycline in saliva were found to be longer than 14 days, which suggested a sustained release of minocycline from the local delivery system [8]. The effectiveness of minocycline microspheres as an adjunct to scaling and root planing was greater than scaling and root planing alone in patients with chronic periodontitis. However, its effectiveness compared to other forms of minocycline as well as other local drug delivery agents needs to be evaluated to obtain a local drug delivery agent that produces significant clinical benefits in nonsurgical periodontal management.

Limitations: Studies should have longer follow-up periods to assess the changes in probing depth and the long-term effectiveness of non-surgical therapy. Method of mechanical debridement and minocycline microspheres administration should be standardized. Clinical Attachment Level gain and microbiological effects of minocycline can be considered as additional parameters for assessing the effectiveness of minocycline microspheres after non-surgical therapy. Articles of languages other than English were not included.

CONCLUSION: The systematic appraisal of the evidence on the efficacy of minocycline microsphere confirms that a degradable, subgingivally placed drug delivery system containing 1 mg Minocycline spheres, is a safe and efficient adjunct to scaling and root planing in the treatment of chronic periodontitis.

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