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Research Article

Adjunctive Homecare Sub-Gingival Water Irrigation versus Conventional Oral Hygiene in Type 2 Diabetic Patients with Chronic Periodontitis: A Randomized Controlled Trial from Yamuna Nagar, Haryana, India

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Abstract

Background: Type 2 diabetes mellitus (T2DM) and chronic periodontitis share a well-documented bidirectional relationship in which hyperglycaemia predisposes to periodontal breakdown and periodontal inflammation, in turn, worsens glycaemic control. Whether the addition of homecare sub-gingival water irrigation to non-surgical periodontal therapy (NSPT) provides an incremental clinical, glycaemic, and inflammatory benefit over conventional oral hygiene alone in this population remains inadequately defined.

Objective: To comparatively evaluate the effect of homecare sub-gingival irrigation versus standard tooth-brushing and flossing, both delivered after NSPT, on periodontal, glycaemic, and inflammatory parameters in adults with T2DM and chronic periodontitis.

Methods: A single-blind, randomized controlled trial was conducted over eighteen months at the Department of Periodontology and Oral Implantology, Yamuna Institute of Dental Sciences and Research, Yamuna Nagar, Haryana, India. A total of 140 patients with T2DM (HbA1c below 7%) and generalized chronic periodontitis were randomized, using research randomizer software, into two equal groups of 70. Group 1 used a powered sub-gingival water irrigator twice daily in addition to brushing; Group 2 performed conventional brushing and flossing twice daily. Gingival Index (GI), Plaque Index (PI), Oral Hygiene Index-Simplified (OHI-S), Gingival Bleeding Index (GBI), probing depth (PD), and clinical attachment loss (CAL) were recorded at baseline, one, three, and six months. HbA1c and C-reactive protein (CRP) were recorded at baseline and six months. Repeated-measures ANOVA with post-hoc Bonferroni correction and independent-sample t-tests were used, with significance set at $p<0.05$. Results: Both groups improved significantly across all clinical indices over six months. Inter-group comparison favoured

Group 1: mean GI at six months was 0.48±0.36 versus 0.78±0.32 (p=0.009), PD was 2.24±0.48 mm versus 3.60±0.51 mm ($p<0.001$), and CAL was 0.63±0.60 mm versus 1.01±0.57 mm (p=0.049). CRP fell from 17.06±2.42 mg/L to 6.96±1.21 mg/L in Group 1 compared with 18.27±2.38 mg/L to 10.17±1.90 mg/L in Group 2 ($p<0.001$ at six months).

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HbA1c declined in both groups (Group 1: 6.69% to 6.44%; **Group 2:** 6.76% to 6.52%) without a statistically significant inter-group difference (p=0.182). Conclusion: Adjunctive homecare sub-gingival irrigation produced significantly greater improvement in periodontal clinical parameters and systemic inflammatory status than conventional oral hygiene alone in diabetic patients with chronic periodontitis, although the two protocols did not differ significantly in their effect on glycaemic control at six months.

KEYWORDS: type 2 diabetes mellitus; chronic periodontitis; sub-gingival irrigation; HbA1c; C-reactive protein; non-surgical periodontal therapy; randomised controlled trial; Yamuna Nagar.

1. INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder arising from defective insulin secretion, defective insulin action, or a combination of both. Type 2 diabetes mellitus (T2DM), the more prevalent form, results from the body's ineffective use of insulin and currently affects an estimated 463 million people worldwide. Periodontitis, a chronic multifactorial inflammatory disease of the tooth-supporting tissues, is now widely recognized as the sixth complication of diabetes. The relationship between the two conditions is bidirectional: hyperglycaemia impairs neutrophil function, alters collagen metabolism, and promotes an inflammatory phenotype that accelerates periodontal tissue destruction, while the systemic dissemination of pro-inflammatory cytokines originating in inflamed periodontal tissue, such as interleukin-1beta and tumour necrosis factor-alpha, aggravates insulin resistance and worsens glycaemic control.Non-surgical periodontal therapy (NSPT), consisting of scaling and root planing, remains the cornerstone of periodontal management in diabetic patients and has repeatedly been shown to produce modest but consistent reductions in glycated haemoglobin (HbA1c). However, the literature offers no consensus on the ideal homecare maintenance regimen that should follow NSPT in this high-risk group. Mechanical plaque control through tooth-brushing and flossing is standard practice, but incomplete access to sub-gingival biofilm, particularly in periodontal pockets, limits its effectiveness. Powered sub-gingival water irrigation has been proposed as an adjunct capable of disrupting sub-gingival biofilm through pulsatile compression-decompression forces, and several trials have reported improved periodontal indices with its use, although its incremental effect on systemic glycaemic and inflammatory markers in diabetic patients has been less consistently demonstrated.Given this gap, the present study was designed to prospectively and comparatively evaluate two homecare maintenance protocols, namely sub-gingival water irrigation combined with brushing versus brushing and flossing alone, in type 2 diabetic patients with chronic periodontitis undergoing NSPT, with assessment of clinical periodontal, glycaemic, and inflammatory outcomes over a six-month follow-up period.

1.1 Objectives of the Study

(1) To comparatively evaluate clinical periodontal parameters in type 2 diabetic patients with chronic periodontitis maintained on homecare sub-gingival irrigation versus conventional homecare alone, following NSPT. (2) To evaluate changes in probing depth, clinical attachment loss, and gingival bleeding index in both groups over six months. (3) To evaluate changes in glycated haemoglobin (HbA1c) and the inflammatory marker C-reactive protein (CRP) in both groups. (4) To compare the relative efficacy of the two maintenance protocols in improving periodontal health and metabolic-inflammatory status in this population.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This was a single-blind, parallel-group randomized controlled trial conducted at the Post-Graduate Department of Periodontology and Oral Implantology, Yamuna Institute of Dental Sciences and Research, Yamuna Nagar, Haryana, India. The total study duration, from patient recruitment to the final recall appointment, was eighteen months. The study protocol was approved by the institutional ethical committee of Pandit B. D. Sharma University of Health Sciences, Rohtak, and written informed consent was obtained from all participants prior to enrolment.

2.2 Study Population and Sample Size

Patients were recruited from those reporting to the outpatient department of Periodontology and Oral Implantology. With type I error set at 0.05 and study power at 80%, the sample size required to detect a 12.4% difference in bleeding on probing between the experimental and control groups was estimated at a minimum of 19 patients per group. To allow for a more robust comparison, the final study population comprised 140 patients with type 2 diabetes and chronic periodontitis, randomly divided into two equal groups of 70 patients each. Inclusion criteria required patients to have type 2 diabetes with HbA1c below 7%, to have generalized chronic periodontitis diagnosed according to the 1999 Armitage classification (probing depth of at least 5 mm and clinical attachment loss of at least 2 mm in more than 30% of teeth present), to be on a stable dose and type of anti-diabetic medication (oral hypoglycaemic agents, insulin, or diet, alone or in combination) for the preceding six months, to be otherwise systemically healthy, and to provide informed consent. Patients were excluded if they had used systemic antibiotics in the preceding six months, had received non-surgical periodontal treatment within the preceding six months, were pregnant or lactating, were on immunosuppressive medication, were taking supplemental ascorbic acid or anticoagulant medication that could interfere with clinical measurements, had a history of severe cardiovascular,

haematological, renal, hepatic, or immunological disease, or were smokers or alcohol users.

2.3 Randomization, Blinding, and Intervention

Eligible patients were randomly allocated to Group 1 or Group 2 using research randomizer software. Single blinding was employed, such that patients were unaware of their group allocation. All 140 patients first underwent Phase I therapy consisting of supra-gingival scaling and root planing. Baseline clinical parameters were recorded one week after Phase I therapy. Group 1 (n=70; sub-gingival irrigation protocol) patients were instructed to use a powered oral irrigator with a sub-gingival tip, following brushing, twice daily (morning and evening), using a full reservoir of water in accordance with manufacturer instructions. Supervised demonstration was provided at baseline, and correct technique was reinforced at every recall visit. Group 2 (n=70; conventional homecare protocol) patients were instructed to brush twice daily and to floss using commercially available dental floss, with no irrigation. Both groups used regular, commercially available dentifrices throughout the study period.

2.4 Outcome Variables and Measurement Time-Points

Primary outcome variables were Gingival Bleeding Index (GBI), probing depth (PD), clinical attachment loss (CAL), CRP, and HbA1c. Secondary outcome variables were Gingival Index (GI), Plaque Index (PI), and Oral Hygiene Index-Simplified (OHI-S). GI was scored using the Loe and Silness (1963) index, PI using the Silness and Loe (1964) index, OHI-S using the Greene and Vermillion (1964) index, and GBI using the Ainamo and Bay (1975) index. PD and CAL were measured in millimetres using a calibrated Michigan probe with William's markings, at a standardized probing force of approximately 0.25 N. GI, PI, OHI-S, GBI, PD, and CAL were assessed at baseline (one week after Phase I therapy), and at one, three, and six months thereafter. HbA1c and CRP, whose biological half-lives make short-interval re-testing uninformative, were assessed only at baseline and at six months. HbA1c was measured by liquid chromatography and CRP by a latex agglutination-based assay, both performed in a certified laboratory.

2.5 Statistical Analysis

Data were analysed using SPSS version 25.0 and MedCalc software. Descriptive statistics were expressed as mean and standard deviation for continuous variables and as absolute numbers and percentages for categorical variables. Repeated-measures ANOVA was used to compare mean values of each parameter across the four time-points within each group, followed by post-hoc Bonferroni-corrected pairwise comparisons to localize the source of within-group differences. Independent (unpaired) Student's t-tests were used to compare mean values between the two groups at each time-point and for the magnitude of change from baseline. A p-value below 0.05 was considered statistically significant, and a two-sided 95% confidence interval was applied throughout.

3. RESULTS

3.1 Sample Characteristics

Of the140 type 2 diabetic patients with chronic periodontitis enrolled, 70 were randomized to Group 1 (sub-gingival irrigation plus brushing) and 70 to Group 2 (brushing and flossing alone). All enrolled patients completed the six-month follow-up, and no adverse events attributable to either homecare protocol were reported during the study period.

3.2 Gingival Index (GI)

In Group 1, mean GI fell from 1.09±0.51 at baseline to 0.60±0.41 at one month, 0.51±0.47 at three months, and 0.48±0.36 at six months (repeated-measures ANOVA, F=7.766, p=0.001). In Group 2, mean GI fell from 1.30±0.49 at baseline to 0.92±0.52, 0.85±0.38, and 0.78±0.32 at the same intervals (F=119.279, p=0.001). Post-hoc analysis confirmed that in both groups the reduction from baseline to each follow-up point was significant, with no further significant change between the one-, three-, and six-month recalls. On inter-group comparison, GI was significantly lower in Group 1 than Group 2 at one month (0.60 vs 0.92, p=0.042), three months (0.51 vs 0.85, p=0.048), and six months (0.48 vs 0.78, p=0.009), and the magnitude of reduction from baseline was significantly greater in Group 1 at every follow-up interval (Table 1)

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Table 1: Inter-group comparison of Gingival Index across follow-up (*p<0.05)

Time-point	Group 1 Mean±SD	Group 2 Mean±SD	Mean Difference	p-value
Baseline	1.09 ± 0.51	1.30 ± 0.49	-0.21	0.103
1 month	0.60 ± 0.41	0.92 ± 0.52	-0.31	0.042*
3 months	0.51 ± 0.47	0.85 ± 0.38	-0.13	0.048*
6 months	0.48 ± 0.36	0.78 ± 0.32	-0.30	0.009*

3.3 Plaque Index (PI) and Oral Hygiene Index-Simplified (OHI-S)

Mean PI in Group 1 declined from 0.72±0.47 at baseline to 0.34±0.24 at six months (F=12.953, p=0.001), and in Group 2 from 0.84±0.52 to 0.55±0.31 (F=48.648, p=0.001). Between-group comparison reached statistical significance only at six months (0.34 vs 0.55, p=0.022) and for the overall baseline-to-six-month change (p=0.049), whereas differences at the earlier time-points did not reach significance (Table 2). A comparable pattern was observed for OHI-S, which decreased significantly within both groups across the six-month period, with the six-month inter-group difference favouring Group 1.

Table 2: Inter-group comparison of Plaque Index across follow-up (*$p<0.05$)

Time-point	Group 1 Mean±SD	Group 2 Mean±SD	Mean Difference	p-value
Baseline	0.72 ± 0.47	0.84 ± 0.52	-0.11	0.469
1 month	0.50 ± 0.24	0.68 ± 0.54	-0.17	0.197
3 months	0.39 ± 0.21	0.58 ± 0.41	-0.19	0.080
6 months	0.34 ± 0.24	0.55 ± 0.31	-0.21	0.022*

3.4 Probing Depth (PD) and Clinical Attachment Loss (CAL)

Probing depth decreased progressively in both groups. Group 1 fell from 5.05±0.21 mm at baseline to 3.80±0.54 mm at one month, 2.44±0.46 mm at three months, and 2.24±0.48 mm at six months. Group 2 fell from 4.95±0.81 mm to 3.99±0.68 mm, 3.73±0.53 mm, and 3.60±0.51 mm over the same intervals. While the two groups were comparable at baseline (p=0.614) and at one month (p=0.320), Group 1 showed significantly shallower probing depths than Group 2 at three months (2.44 vs 3.73 mm, p<0.001) and six months (2.24 vs 3.60 mm, p<0.001), with a significantly greater baseline-to-six-month reduction in Group 1 (-2.80 mm vs -1.35 mm, p<0.001) (Table 3).

Table 3: Inter-group comparison of probing depth across follow-up (*p<0.05)

Time-point	Group 1 Mean ± SD (mm)	Group 2 Mean ± SD (mm)	Mean Difference (mm)	p-value
Baseline	5.05 ± 0.21	4.95 ± 0.81	0.10	0.614
1 month	3.80 ± 0.54	3.99 ± 0.68	−0.20	0.320
3 months	2.44 ± 0.46	3.73 ± 0.53	−1.29	0.001*
6 months	2.24 ± 0.48	3.60 ± 0.51	−1.36	0.001*

Clinical attachment loss followed a similar trajectory. Group 1 improved from 2.08±0.25 mm at baseline to 0.63±0.60 mm at six months (F=44.057, p=0.001), and Group 2 from 2.00±0.67 mm to 1.01±0.57 mm (F=19.632, p=0.001). Inter-group comparison showed significantly less residual attachment loss in Group 1 at three months (0.78 vs 1.27 mm, p=0.045) and six months (0.63 vs 1.01 mm, p=0.049), with a significantly greater overall gain in attachment in Group 1 (baseline-to-six-month change of -1.45 mm versus -0.99 mm, p=0.026).

3.5 Gingival Bleeding Index (GBI)

GBI decreased significantly from baseline to six months within both groups (post-hoc Bonferroni, p<0.05 at every interval). On inter-group comparison, GBI was significantly lower in Group 1 than Group 2 at three and six months, and the reduction from baseline was significantly greater in Group 1 over the same intervals, indicating superior resolution of gingival inflammation with the addition of sub-gingival irrigation.

3.6 Glycated Haemoglobin (HbA1c)

Mean HbA1c fell from 6.69%±0.20 at baseline to 6.44%±0.19 at six months in Group 1 (a reduction of 0.25 percentage points), and from 6.76%±0.19 to 6.52%±0.17 in Group 2 (a reduction of 0.24 percentage points). Neither the between-group difference at baseline (p=0.081) nor at six months (p=0.192) reached statistical significance, and the magnitude of HbA1c reduction did not differ significantly between the two protocols (p=0.182) (Table 4).

Table 4: Inter-group comparison of HbA1c across follow-up

Time-point	Group 1 Mean±SD (%)	Group 2 Mean±SD (%)	Mean Difference	p-value
Baseline	6.69 ± 0.20	6.76 ± 0.19	-0.11	0.081
6 months	6.44 ± 0.19	6.52 ± 0.17	-0.08	0.192
Baseline-6-month change	0.25 ± 0.16	0.24 ± 0.24	-0.21	0.182

3.7 C-Reactive Protein (CRP)

Mean CRP fell markedly in Group 1, from 17.06±2.42 mg/L at baseline to 6.96±1.21 mg/L at six months, a mean reduction of 9.10 mg/L (t=16.810, p=0.001). Group 2 also showed improvement, from 18.27±2.38 mg/L to 10.17±1.90 mg/L, a mean reduction of 8.10 mg/L. Inter-group comparison showed no significant baseline difference (p=0.096), but CRP was significantly lower in Group 1 than Group 2 at six months (6.96 vs 10.17 mg/L, p<0.001), and the reduction from baseline was significantly greater in Group 1 than Group 2 (p=0.048), indicating a superior anti-inflammatory effect associated with the sub-gingival irrigation protocol (Table 5).

Table 5. Inter-group comparison of CRP across follow-up (*p<0.05*)*

Time-point	Group 1 Mean ± SD (mg/L)	Group 2 Mean ± SD (mg/L)	Mean Difference (mg/L)	p-value
Baseline	17.06 ± 2.42	18.27 ± 2.38	−1.21	0.096
6 months	6.96 ± 1.21	10.17 ± 1.90	−3.21	0.001*
Baseline–6-month change	9.10 ± 2.42	8.10 ± 2.24	1.00	0.048*

4. DISCUSSION

This randomized controlled trial compared two homecare maintenance protocols following non-surgical periodontal therapy in 140 type 2 diabetic patients with chronic periodontitis, recruited from the outpatient department of Periodontology and Oral Implantology at Yamuna Institute of Dental Sciences and Research, Yamuna Nagar, Haryana. Both protocols produced statistically significant within-group improvement in every clinical periodontal index measured, consistent with the well-established observation that meticulous mechanical plaque control, whether achieved through irrigation-assisted or conventional means, is fundamental to resolving periodontal inflammation. However, the addition of homecare sub-gingival water irrigation to twice-daily brushing conferred a clear incremental benefit over brushing and flossing alone, with significantly greater reductions in GI, PI, OHI-S, GBI, PD, and CAL evident from the three-month recall onward and sustained to six months. These findings align with the proposed mechanism of action of sub-gingival irrigation, in which a pulsating stream of water generates alternating compression and decompression forces within the periodontal pocket, disrupting bacterial biofilm to a depth that toothbrushing and flossing cannot reach. The results are consistent with earlier evaluations of adjunctive irrigation therapy, which similarly reported superior resolution of gingival inflammation and pocket depth when irrigation was added to standard oral hygiene, although the literature has not been unanimous, and some trials have found no enhanced effect from single in-office irrigation delivered by the clinician. The present results suggest that self-administered, twice-daily homecare irrigation may be more effective than episodic professional irrigation, since it permits sustained bacterial load reduction over the entire maintenance period rather than a single application. With respect to systemic markers, CRP fell significantly more in the irrigation group, supporting the concept that a reduction in localized periodontal inflammation is reflected in a corresponding reduction in systemic inflammatory burden, consistent with the established role of CRP as a sensitive, non-specific acute-phase marker that rises in both diabetes and periodontitis owing to their shared inflammatory pathophysiology. This finding is in line with previous work reporting reductions in serum inflammatory markers following successful periodontal therapy in diabetic populations. In contrast to the clinical and inflammatory findings, HbA1c improved to a similar, modest extent in both groups, without a significant inter-group difference at six months. This is broadly consistent with several meta-analyses reporting that periodontal therapy produces only a modest reduction in HbA1c, generally in the range of 0.3 to 0.4 percentage points, and that this effect appears to derive predominantly from the periodontal therapy itself (scaling and root planing) rather than from the specific homecare maintenance regimen that follows it. Because HbA1c reflects average glycaemia over the preceding two to three months and is influenced by numerous factors outside periodontal status, including diet, physical activity, medication adherence, and psychosocial stress, none of which were controlled for in this trial, it is plausible that any incremental glycaemic benefit attributable to superior plaque control in Group 1 was diluted by these unmeasured variables. It is also relevant that patients were included only if their baseline HbA1c was already below 7%, a threshold at which further reduction is inherently more difficult to demonstrate statistically. Both study groups were drawn from a homogeneous local population of type 2 diabetic patients attending a single dental institution in Yamuna Nagar, Haryana, which strengthens internal comparability between groups but limits the generalizability of the findings to diabetic populations with different genetic, dietary, and healthcare-access profiles. The recall period of six months, while sufficient to capture early and intermediate healing responses, as periodontal pocket depth changes are known to occur predominantly within the first four to five months of therapy, does not permit conclusions about the durability of the observed benefits beyond this interval. Furthermore, several biologically plausible mediators of the diabetes-periodontitis relationship, such as interleukin-1beta and tumour necrosis factor-alpha, were not measured in this study and would be valuable additions to future work exploring the mechanistic basis of the clinical findings reported here.

5. CONCLUSION

In this randomized controlled trial of 140 type 2 diabetic patients with chronic periodontitis treated at Yamuna Institute of Dental Sciences and Research, Yamuna Nagar, Haryana, the addition of homecare sub-gingival water irrigation to twice-daily brushing produced significantly greater improvements in gingival index, plaque control, probing depth, clinical attachment level, gingival bleeding, and serum CRP than conventional brushing and flossing alone, when both regimens followed non-surgical periodontal therapy. Both maintenance protocols produced comparable, modest reductions in HbA1c, indicating that periodontal therapy itself, rather than the specific homecare regimen, may be the principal driver of glycaemic benefit in well-controlled type 2 diabetic patients. These findings support the clinical recommendation that homecare sub-gingival irrigation be considered as a beneficial adjunct to conventional oral hygiene in the periodontal maintenance of diabetic patients, while underscoring the need for larger, multi-centric trials with longer follow-up and broader panels of inflammatory biomarkers to further define its role in the integrated management of diabetes and periodontal disease.

5.1 Limitations

The study population, though adequately powered for the primary periodontal outcome, was drawn from a single centre and a single geographic region, limiting generalizability. The six-month follow-up period precluded assessment of long-term durability of the observed benefits. Confounding systemic variables potentially influencing HbA1c and CRP, including diet, physical activity, and other comorbidities, were not controlled for or measured. Additional inflammatory cytokines implicated in the diabetes-periodontitis axis were not assessed.

5.2 Scope for Future Research

Future studies should incorporate larger, multi-centric samples, extended follow-up beyond six months, and a broader panel of inflammatory biomarkers, including interleukin-1beta and tumour necrosis factor-alpha, to more comprehensively characterize the mechanistic pathways linking adjunctive homecare irrigation, periodontal healing, and glycaemic outcomes in patients with type 2 diabetes mellitus.

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