



Effect of nonsurgical periodontal treatment on clinical response and glycemic control in type 2 diabetic patients with periodontitis: Controlled clinical trial

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ABSTRACT:

Background: Type 2 diabetes mellitus (type 2 DM) and chronic periodontitis are common chronic diseases in adults in the world population. Once periodontal disease is established, the chronic nature of this infection may contribute to worsening of diabetic status leading to more severe diabetes-related complications. It has been proposed that the relation of periodontitis and diabetes is bidirectional. **Objectives:** The objective was to compare the clinical response and glycemic control in type 2 DM patients with periodontitis, before and after the nonsurgical periodontal treatment with controls. **Materials and Methods:** A total 70 type 2 DM patients with chronic generalized moderate periodontitis was divided into 2 groups. Treatment group (35) received one stage full mouth scaling and root planning plus oral hygiene instructions; the control group (35) received only oral hygiene instructions. At baseline, 1st month and 3rd month, the clinical periodontal parameters (plaque index [PI], gingival index [GI], pocket depth [PD], clinical attachment loss [CAL], gingival recession [GR], and bleeding on probing [BOP]) and glycemic parameters (fasting blood sugar [FBS], and postprandial blood sugar [PPBS]) were recorded, whereas the glycated hemoglobin (HbA1c) was recorded only at baseline and 3rd month. The collected data were subjected to statistical analysis. **Results:** When comparing the mean scores of clinical parameters for both the groups, there was a significant difference in all clinical parameters, that is, mean PI, GI, BOP, PD, CAL scores except mean GR, whereas for the glycemic parameters, there was a significant difference in mean FBS; PPBS values and no significant difference in mean percentage of HbA1c for treatment group at 3rd month follow-up. **Conclusion:** Findings of the present study showed that nonsurgical periodontal treatment resulted in lower glycemic levels and the reduction of clinical parameters of periodontal infection, confirming the existing relation between type 2 DM and periodontal disease.

Key words:

Glycemic control, nonsurgical periodontal treatment, oral hygiene, periodontitis, type 2 diabetes mellitus

INTRODUCTION

Oral health is an integral part of general health.^[1] Oral health is strongly associated with the life circumstances and general health of an individual.^[1] Varieties of medical conditions have associations with oral health and influence quality-of-life. Diabetes mellitus (DM) is one such systemic condition which is commonly associated with deteriorating oral health.^[2]

Diabetes mellitus is a complex disease with both metabolic and vascular components, characterized by hyperglycemia resulting from an absolute or relative insulin deficit.^[3] Type 2 DM is also called as noninsulin-dependent DM which occurs mainly in the middle-aged and elderly persons.^[1,2] In type 2 DM there is increased production of glucose by the liver in the

fasting state, altered cell receptors for insulin as well as resistance to insulin actions in target (liver, muscle, fat) tissue.^[4] This group of patients is managed with weight reduction, a low-calorie diet, increased exercise, oral hypoglycemic medication, and exogenous insulin.^[4]

Type 2 diabetes and chronic periodontitis are common chronic diseases in adults in the world

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population.^[3] According to WHO, 90% of the Indian population suffers from periodontitis. This is recognized as the 6th complication of diabetic patients.^[4-6]

It has been proposed that the relation of periodontitis and diabetes is bi-directional.^[7] Periodontitis in adults is a bacterial infection caused by Gram-negative anaerobes, these organisms specially bacteroids species, may affect the endocrine-metabolic status of the diabetic patients.^[4,7] Once periodontal disease is established, the chronic nature of this infection may contribute to worsening of diabetic status leading to more severe diabetes-related complications.^[1] If successful periodontal treatment is carried out it results in a reduction in levels of proinflammatory cytokines which in turn improve insulin sensitivity and glycemic control in diabetic patients.^[7,8]

To explore further, the present study aims to investigate whether there is an effect of nonsurgical periodontal treatment on clinical response and glycemic control in type 2 diabetic patients with periodontitis.

Objectives

- To compare the clinical response in type 2 diabetic patients with periodontitis, before and after the nonsurgical periodontal treatment with controls
- To monitor the glycemic control in type 2 diabetic patients with periodontitis, before and after the nonsurgical periodontal treatment with controls.

MATERIALS AND METHODS

A controlled clinical trial with double blinding was conducted in type 2 diabetic patients with periodontitis spread over a period of 6 months from June 2009 to November 2009.

Study population

The list of diabetic clinics was obtained from the yellow pages of the telephone directory of Bangalore city, India. Five diabetic clinics agreed to co-operate. Hence, these clinics were enrolled in the study. The diabetic clinic authorities were approached; the purpose of the study explained and their permission were obtained from the diabetic clinics to recruit the subjects for the study. Diabetic patients were selected for the study based on the inclusion and exclusion criteria. Each clinic was surveyed for a period of 2 months on a rotation basis till the required sample size of 70 was obtained.

Study sample

Considering power of the study as 90% and based on the mean difference 0.50 (standard deviation: 0.26) of glycated hemoglobin value between the groups from the previous literature.^[4] with the significance level of 0.05, sample size was estimated to be 30 in each group.

Inclusion criteria

- Diagnosed type 2 diabetic patients without modification of diabetes treatment from the past 2 months
- Age-35-55 years
- The diabetic patients should be only on oral hypoglycemic drugs
- Individuals having >14 teeth present
- Individuals with generalized moderate periodontitis (pocket depth [PD] 4-6 mm involving >30% sites)
- Patients should not have received periodontal treatment for the past 6 months
- Patients should follow dietary instructions strictly as prescribed by their physician
- Patients should come under category of nonobese.

Exclusion criteria

- Other systemic diseases and any history of diabetic complications
- Patients using antibiotics or anti-inflammatory drugs for the previous 4 weeks
- Smokers
- Pregnancy and lactation
- Any changes in drug regime during the study period.

Ethical clearance was obtained from the Ethical Committee of the Institution. Informed consent was obtained from each patient. The script was given in both English and Kannada. Calibration of the examiners was done before the start of the intervention. The correlation coefficient values for intra and inter examiner variability (0.7) reflected high degree of conformity in observations. A pilot study was undertaken on 15% of the study population to check the feasibility.

Method of obtaining data

After the selection of diabetic patients, they were divided into treatment group and control group (depending on the willingness to participate for the periodontal treatment or not). A specially prepared proforma, designed for collecting all required and relevant general information, oral hygiene practices, blood sugar levels, and clinical findings was used for recording data. At baseline, venous blood samples were taken for each diabetic patient to measure the fasting blood sugar (FBS) value at the Dept of Oral pathology, The Oxford Dental College and Hospital. Following this, clinical examinations (Loe and Silness gingival index [GI], Ainamo and Bay bleeding on probing [BOP] index, probing PD, clinical attachment loss [CAL], gingival recession [GR], Turesky, Gilmore, Glickman modification of Quigley Hein plaque index [PI] using the prescribed scores and criteria) were carried out on dental chair by precalibrated examiner who was blinded to the study with the appropriate armamentarium.

Venous blood samples were taken again for each diabetic patient to measure the postprandial blood sugar (PPBS) value and HbA1c value. Following this, a nonsurgical

periodontal treatment was carried out for only the treatment group by performing the supra and subgingival scaling using ultrasonic scaler and root planning using Hu friedy curettes. Then specific posttreatment oral hygiene instructions were given to the treatment group. For control group, oral hygiene instructions were given though the periodontal treatment was not carried out. The reinforcement of these instructions was carried out once in a month. The same baseline clinical examinations were carried out, and glycemic values were obtained at 1st and 3rd month after the treatment.

Control group patients were advised and motivated to take a full nonsurgical and supportive periodontal treatment after completion of the study. Any oral observations requiring further treatment were informed to the diabetic patients, and they were advised to seek treatment for the same for both the groups.

Statistical analysis

Data were analyzed using SPSS 15.0, INC (Chicago), and Microsoft word and Excel. Student's *t*-test (two-tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Intergroup analysis) and Student's *t*-test (two-tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Mann-Whitney U-test has been used to find the significance of nonparametric parameters BOP between two groups and Wilcoxon signed rank test has been used find the significance of BOP (nonparametric) in paired condition.

RESULTS

Of 35 patients in the control group, 3 of them were excluded from the study because they needed to change their medication for diabetic control, and 4 of them were lost to follow-up. In the treatment group, out of 35 patients 7 of them were lost to follow-up. Hence, at the end of the study, there were 28 patients from the treatment group and 28 from the control group. Hence, the dropouts from baseline data were excluded for analysis.

Table 1 shows the demographic information of the patients in both groups. At baseline, both groups had similar mean values for age, sex, duration of diabetes, body mass index (BMI) of diabetic patients, medications, and oral hygiene practices.

The clinical parameters of the both groups at baseline, at 1-month and 3 months are shown in Table 2. At baseline the mean PI, GI, BOP, PD, CAL, GR scores for both groups were not statistically significant. The results showed that there was a significant reduction in all clinical parameters that is, mean PI, GI, BOP, PD, CAL scores

except mean GR after a month of the treatment in both the groups. However, there was a significant reduction in all clinical parameters, that is, mean PI, GI, BOP, PD, CAL scores except mean GR at 3rd month follow-up in both the groups.

The levels of FBS, PPBS, and HbA1c of the both groups at baseline are shown in Table 3. At baseline, mean FBS, PPBS, HbA1c values for both groups were not statistically significant. The results showed that there was no significant reduction in mean FBS; PPBS values after

Table 1: Demographic information of diabetic patients at baseline

	Treatment group (n=28)	Control group (n=28)	P
Age (years)			
Mean±SD	47.14±5.28	48.86±3.81	0.169
Range	40-55	40-55	
Gender (%)			
Male	19 (33.9)	21 (37.5)	0.554
Female	9 (16.1)	7 (12.5)	
Duration of diabetes mellitus (years)			
Range	1-15 years	1-15	0.821
BMI of diabetic patients			
Mean±SD	23.34±3.76	23.71±2.64	0.634

BMI – Body mass index, SD – Standard deviation

Table 2: Comparison of clinical parameters at baseline, at 1-month and 3 months between two groups

Clinical parameters	Treatment group	Control group	Significance
At baseline			
PI	3.67±0.41	3.51±0.43	<i>t</i> =1.556; <i>P</i> =0.124
GI	1.82±0.43	1.76±0.21	<i>t</i> =0.744; <i>P</i> =0.460
BOP (%)	75.74±19.44	76.57±14.91	<i>Z</i> =0.254; <i>P</i> =0.799
PD (mm)	3.11±0.47	3.18±0.26	<i>t</i> =0.772; <i>P</i> =0.443
CAL (mm)	4.48±1.09	4.68±0.89	<i>t</i> =0.832; <i>P</i> =0.408
GR (mm)	1.71±0.79	1.60±0.49	<i>t</i> =0.719; <i>P</i> =0.475
At 1-month			
PI	2.71±0.4	2.94±0.39	<i>t</i> =2.322; <i>P</i> =0.024*
GI	1.28±0.37	1.80±0.31	<i>t</i> =5.877; <i>P</i> <0.001**
BOP (%)	29.78±13.19	85.43±20.68	<i>Z</i> =6.114; <i>P</i> <0.001**
PD (mm)	2.54±0.43	3.70±0.45	<i>t</i> =10.325; <i>P</i> <0.001**
CAL (mm)	4.21±1.23	4.89±0.57	<i>t</i> =2.768; <i>P</i> =0.007**
GR (mm)	1.75±0.81	1.80±0.59	<i>t</i> =0.259; <i>P</i> =0.796
At 3 rd month			
PI	1.91±0.38	2.26±0.35	<i>t</i> =3.578; <i>P</i> =0.001**
GI	0.98±0.34	1.97±0.22	<i>t</i> =12.836; <i>P</i> <0.001**
BOP (%)	9.74±16.49	90.25±19.11	<i>Z</i> =6.170; <i>P</i> <0.001**
PD (mm)	2.13±0.45	4.02±0.56	<i>t</i> =13.865; <i>P</i> <0.001**
CAL (mm)	3.58±0.87	5.16±0.80	<i>t</i> =7.026; <i>P</i> <0.001**
GR (mm)	1.63±0.72	1.75±0.61	<i>t</i> =0.702; <i>P</i> =0.486

*Moderate significant difference at *P*<0.05, **Strong significant difference at *P*<0.01. PI – Plaque index, GI – Gingival index, BOP – Bleeding on probing, PD – Pocket depth, CAL – Clinical attachment loss, GR – Gingival recession

Table 3: Comparison of glycemic parameters at baseline, at 1-month and 3 months between two groups

Glycemic parameters	Treatment group	Control group	Significance
At baseline			
FBS (mg/dl)	131.31±21.48	127.34±19.89	$t=0.803$; $P=0.425$
PPBS (mg/dl)	218.91±34.93	215.37±28.17	$t=0.467$; $P=0.642$
HbA1c (%)	8.49±1.50	8.04±0.70	$t=1.601$; $P=0.114$
At 1-month			
FBS (mg/dl)	121.41±23.31	123.90±16.51	$t=0.483$; $P=0.631$
PPBS (mg/dl)	196.16±29.52	202.93±34.75	$t=0.829$; $P=0.410$
HbA1c	-	-	-
At 3 rd month			
FBS (mg/dl)	122.64±17.81	136.57±15.07	$t=3.159$; $P=0.003^{**}$
PPBS (mg/dl)	178.43±19.71	220.11±31.46	$t=5.941$; $P<0.001^{**}$
HbA1c (%)	8.47±0.89	8.27±0.63	$t=0.948$; $P=0.347$

*Moderate significant difference at $P<0.05$, **Strong significant difference at $P<0.01$. FBS – Fasting blood sugar, PPBS – Postprandial blood sugar

a month of the treatment in both the groups. However, there was a significant reduction in mean FBS; PPBS values and no significant reduction in mean % of HbA1c in both the groups at 3rd month follow-up.

DISCUSSION

In order to better understand the relationship between periodontal disease and DM, the present study aimed to investigate the effect of nonsurgical periodontal therapy on clinical response and glycemic control without systemic antibiotics in adult patients with both chronic periodontitis and DM, in the absence of any changes in medical therapy during the study period.

Adult patients aged 35-55 years were chosen for the study because healing response will be better when compared to elder patients. Furthermore, the age is a risk factor for increased insulin resistance and periodontal disease. Thus the age may have influence on glycemic control and clinical response.^[7] One of the inclusion criteria for this study was that patients should come under category of nonobese because obesity may influence the clinical response and glycemic control of the study.^[9,10] But other studies have not taken this into consideration. Hence, these criteria were the advantage of this study. Furthermore, patients taking only oral hypoglycemic drugs were included in this study because the mechanism of action of drug varies for oral hypoglycemic drugs and insulin, so as to influence the glycemic control of the study.^[11,12]

Apart from periodontal treatment there are many other factors influencing the short-term blood glucose level of a diabetic patient, and one of these is diabetic medical care.^[4] Hence, the present study was designed to include such patients who did not receive any change in their diabetic control regimen during the 3 months study

period. Even though long-term study would have been preferable, the ethical dilemma of withholding any change in medical treatment for a period significantly longer than 3 months in patients with diabetes made such a longer term study impossible.^[7,13]

This study included one stage nonsurgical supra and subgingival scaling and root planning treatment which was similar to a study conducted by Kiran *et al.* 2005, Rodrigues *et al.* 2003, Stewart *et al.* 2001. One of the advantages to include this could be due to additional clinical benefits, demonstrating clinical improvement superior to conventional periodontal therapy, mainly by preventing bacterial recolonization of the sites by microorganisms that remained in the nontreated areas.^[13-15]

The blood investigations carried out in this study to monitor glycemic control were HbA1c, FBS and PPBS. Blood glucose measurements show the level at a given moment in time. In contrast, HbA1c measurements yield data on the glucose in the blood over a period (30-90 days). Because glucose in the blood is irreversibly bound to hemoglobin. Therefore, higher the concentration of glucose in blood, the larger amount of binding between the glucose and hemoglobin molecule, and glycosylated hemoglobin indicates the glucose status during at least half of the life of these cells (30-90 days) because the half-life of blood cells is 120 days. The A1C fraction of hemoglobin is elevated in diabetic patients and is used to monitor their glycemic control.^[13] Similar investigations were carried out by Kiran *et al.* 2005, Promsudthi *et al.* 2005, O'Connell *et al.* 2008, Rodrigues *et al.* 2003, Stewart *et al.* 2001.^[3,4,7,13,16]

At the beginning of the present study, no statistical significant difference was observed between the treatment group and control group in age, gender, duration of diabetes, BMI of the patients, and Clinical parameters.

In the present study, both the groups showed a significant reduction ($P < 0.001$, significant) after 3 months in the percentage of mean plaque scores (PI: Treatment group 47.9%, control group 34.8%). This reduction was more when compared to studies done by Promsudthi *et al.* 2005 (1.83% increase), Kiran *et al.* 2005 (5.52% reduction) Rodrigues *et al.* 2003 (25% reduction), O'Connell *et al.* 2008 (37.1% reduction). This could be due to oral hygiene instructions and their reinforcement which were given to the both groups.^[7,3,13,16]

Significant changes ($P < 0.001$, significant) in mean GI score and mean percentage of sites with BOP were found in the both groups (GI: Treatment group 46.2%, control group 13.2%) (percentage of sites with BOP: Treatment group 87.1% reduction, control group 19.1% increase) after 3 months. This observation in the control group was opposite when compared to study done by Promsudthi *et al.* 2005 (0.02% increase), Kiran *et al.* 2005 (treatment

group 3.4% reduction, control group 2.83% increase) this could be due to nonintervention in this group. Hence, no reduction in inflammation was observed.^[3,7]

The percentage changes in mean PD (treatment group 31.06%, control group 26.8%) and CAL (treatment group 18.8%, control group 11.9%) were significant ($P < 0.001$, significant) in this study after 3 months. This observation in the treatment group and control group was more when compared to studies done by Promsudthi *et al.* 2005 (PD, CAL: 29.1%, 11.6% reduction), Kiran *et al.* 2005 (PD, CAL: 21.3%, 12.2% reduction), Rodrigues *et al.* 2003 (PD, CAL: 28.1% reduction, no % change), O'Connell *et al.* 2008 (PD, CAL: 27.5%, 5% reduction), Westfelt *et al.* 1996 (31.5% reduction) Promsudthi *et al.* 2005 (0.30% increase), and Kiran *et al.* 2005 (0.89% increase) with respect to the mean PD and CAL.^[3,7,13,16,17] This confirms the favorable response of type 2 diabetic

patients to periodontal therapy. This is because of epithelial attachment starts taking place after 1-2 weeks of supra and subgingival scaling and root planning.^[18] Thus, the duration of the study was sufficient to assess the changes and found improvement in CAL in the treatment group.

There was no percentage change of mean GR 3 months following the treatment. In contrast, Kiran *et al.* 2005 and Navarro-Sanchez *et al.* 2007 have reported a 10.6% and 37.5% increase, respectively [Figure 1].^[3,19,20] This could be due to by the adoption of treatment strategy and oral hygiene instructions. Whereas the percentage was increased 18.24% ($P < 0.003$, significant) at the end of 3rd month in the control group. This observation was more when compared to studies done by Kiran *et al.* 2005 (4.10% reduction) in mean GR. This could be due to the fact that no treatment strategy employed for this

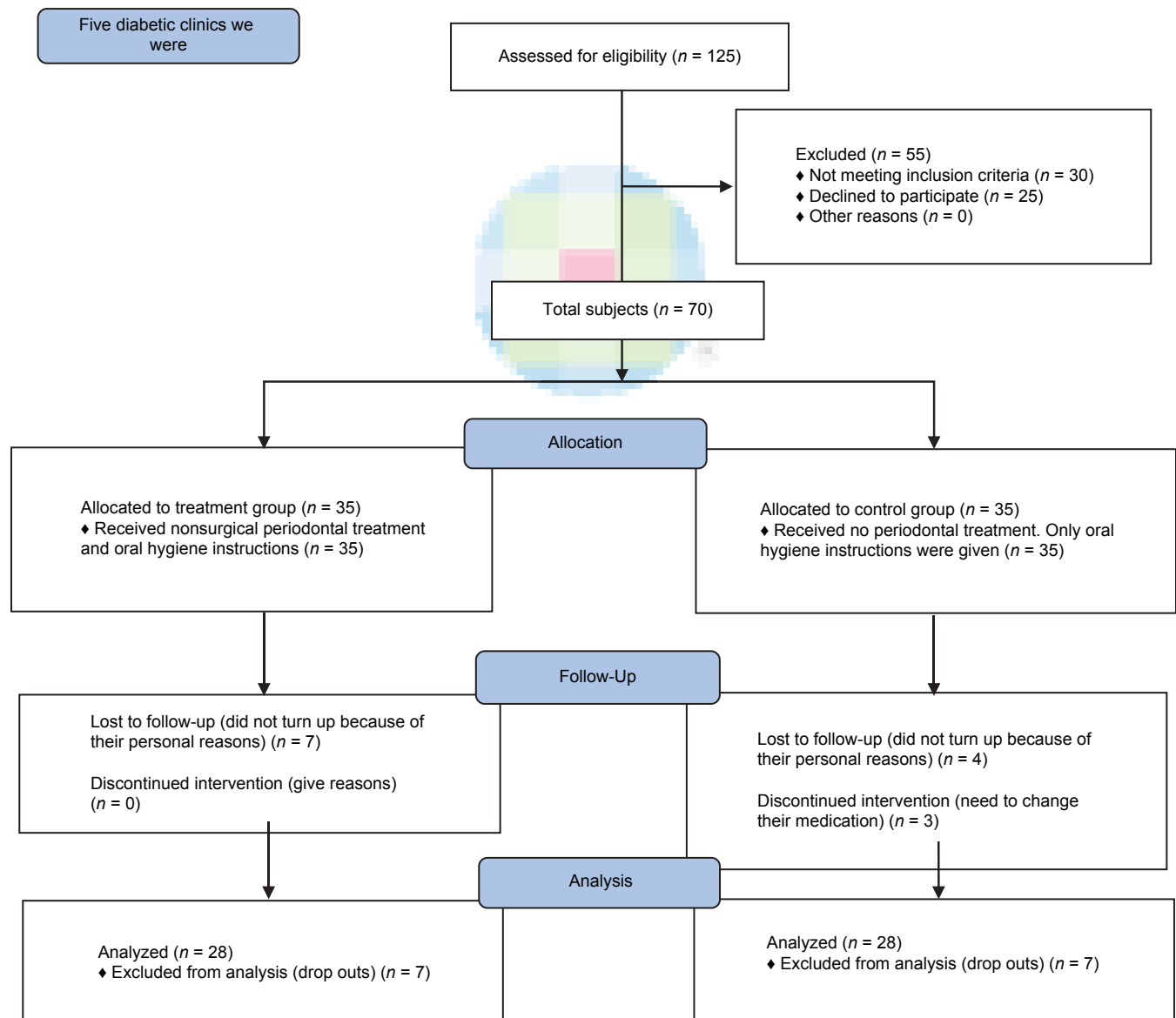


Figure 1: CONSORT 2010 flow diagram

group. Hence, no epithelial attachment was observed, which could lead to the worsening of the condition.

The normal range of HbA1c for the subjects without diabetes is 4.5-6.0%. In the present study, the mean HbA1c values at baseline were 8.50 ± 1.62 and 8.09 ± 0.7 for the treatment group, and control group, respectively. 3 months after the intervention, the mean HbA1c value scores were 8.47 ± 0.89 and 8.27 ± 0.63 for the treatment group and control group, respectively.

A 0.35% reduction ($P = 0.914$, not significant) was observed in treatment group. This observation was less when compared to studies done by Promsudthi *et al.* 2005 (2.11% reduction), Kiran *et al.* 2005 (4.92% reduction), Rodrigues *et al.* 2003 (2.27% reduction), O'Connell *et al.* 2008 (8.41% reduction) in mean percentage of HbA1c values among the diabetic patients in the treatment group.^[3,7,13,16] This is because the subjects in those studies were given antibiotics as an adjunctive in intervention. Furthermore, Stewart *et al.* 2001 have reported a 7.40% reduction following the periodontal treatment. This is may be due to their diabetic medication was changed during the study period.

A 7.14% reduction in the mean FBS values ($P < 0.038$, significant) was observed in the treatment group and 6.1% increase ($P < 0.063$, suggestive significant) in the control group after 3 months. This observation was more when compared to studies done by Promsudthi *et al.* 2005 (0.11% increase), Kiran *et al.* 2005 (0.87% increase) in mean FBS values for the control group.^[3,7] This could be due to the fact that no treatment strategy employed for this group.

Three months after the intervention, 19.9% reduction ($P < 0.001$, significant) in mean PPBS value was observed for the treatment group, and 2.25% increase ($P < 0.042$, significant) in the control group respectively. This observation was more when compared to study done by Kiran *et al.* 2005 (13.9% reduction) among the diabetic patients in the treatment group. The observed improvement could be related to the fact that because of periodontal treatment.

CONCLUSION

The findings from the present study confirm that the nonsurgical periodontal treatment resulted in terms of decreased PDs, decreased gingival inflammation, and decreased glycemic levels for the treatment group. There were increased PDs, more severe gingival inflammation, and increased glycemic levels in the absence of scaling and root planing for the control group in type 2 diabetic patients.

Recommendations

There is a need for highlighting the importance of oral health as an integral part of the general health especially among type 2 diabetic patients. Health education of the diabetic patients, regarding the importance of oral health and its impact on general health and its influence on the periodontal health and its relation to the glycemic control is advised. It is recommended that oral health checkups be considered as a part of diabetic care to prevent the undesired effects of periodontal diseases. It is also recommended that periodontal treatment should be included in DM preventive measures.

Future research directions

Whether the effect of nonsurgical treatment on glycemic levels in type 2 diabetics with periodontitis to be better-clarified through,

- Direct measurement of specific periodontal pathogens in the oral environment in diabetic patients and the measurement of the resulting inflammatory mediator levels would be helpful in either proving or disproving the above possibility
- Use of more specific clinical parameters such as gingival crevicular fluid, microbial estimation of periodontal pocket microflora.

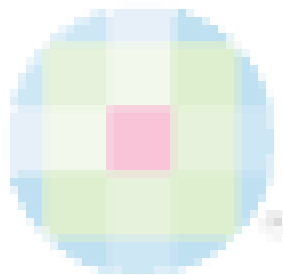
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