

# Effect of Antibiotics and Carbohydrate Diet Control Instructions in Improving Glycated Hemoglobin among Type II Diabetic Patients with Periodontitis

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## ABSTRACT

**Aim:** This study was aimed to assess the effect of the scaling and root planing (SRP) with or without doxycycline and received carbohydrate diet control instructions in improving glycated hemoglobin (HbA1c) among type II diabetes mellitus (DM) patients diagnosed with periodontitis.

**Materials and methods:** Nonrandomized clinical study design was conducted among 150 patients who were referred to the specialist dental centers in Abha city, between April 2019 and March 2021. The patients were allocated into two groups. Those receiving SRP with doxycycline were classified as group A, whereas patients who received SRP alone were classified as group B. The HbA1c levels were assessed at the baseline, and 3, 6, 12, and 24 months. Statistical package for the social sciences SPSS version 26 was used.  $p < 0.05$  was considered statistically significant.

**Results:** There is a statistically significant difference in HbA1c level between the two groups during follow-up after 3, 6, 12, and 24 months ( $p < 0.001$ ,  $p < 0.001$ ,  $p < 0.001$ , and  $p < 0.001$ , respectively). Moreover, the improvement in HbA1c level was significantly observed after 24 months of follow-up in group A compared to group B ( $p < 0.001$ ) and most of this improvement was after the first 3 months of the follow-up.

**Conclusion:** The SRP associated with doxycycline is more effective in improving HbA1c level among type II DM patients diagnosed with periodontitis than SRP alone. Most of the improvement is seen after 3 months of the follow-up.

**Clinical significance:** Valuable information is provided for dental professionals about the importance of prescription of antibiotics with the periodontal treatment in improving the HbA1c level in type II DM patients.

**Keywords:** Antibiotics, Diabetes, Glycated hemoglobin, Periodontitis.

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## INTRODUCTION

Periodontal diseases are common infections that can affect the tooth-supporting structures and eventually lead to tooth loss, if left untreated.<sup>1,2</sup> Periodontitis is affected by systemic disorders.<sup>3</sup> Diabetes mellitus (DM) is one of the causal factors of periodontitis.<sup>1,3</sup> Globally, DM and periodontitis are highly prevalent among the population.<sup>4</sup> Almost 10–15% of adult healthy patients have periodontitis. However, it is reported that type II DM patients were 2.8 times more affected by periodontitis and alveolar bone loss when compared to 1.2 times among non-DM patients.

DM is one of the metabolic diseases characterized by hyperglycemia due to defects in insulin secretion, action, or both.<sup>4</sup> It is classified into two main types. Type I DM is caused by destruction of the pancreatic  $\beta$  cells where insulin is produced. Defect in insulin molecules or from defective cell receptors for insulin (impaired insulin function) causes type II DM.<sup>4</sup> In the Kingdom of Saudi Arabia (KSA), the prevalence of DM reached 14.4% in 2016 and is estimated to increase to 27.1% by 2035. However, an estimated 40.3% of those aged 30 years and above were unaware of their disease status.<sup>6</sup>

Periodontitis is one of the complications of chronic hyperglycemic conditions, and it is more prevalent and severe in patients with DM.<sup>4</sup> Poor glycated hemoglobin (HbA1c) in DM patients can cause a decline in polymorph nucleate leukocyte activity. It can also impair the microvascular endothelium which as a result can cause periodontal disease. DM patients with severe periodontitis are six times more likely to have poor HbA1c than patients with healthy periodontium. However, improved HbA1c has been suggested to reduce the severity of periodontal disease.<sup>5</sup>

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Many studies have revealed that the effective periodontal treatment improves HbA1c level among type II DM patients diagnosed with periodontitis. As well as it might inhibit the development of arteriosclerosis.<sup>2</sup>

Recently, several studies have shown the effects of periodontal treatment on HbA1c. Some studies were reported that the HbA1c levels in type II DM patients who received periodontal treatment with antibiotics were reduced significantly.<sup>3,4,7–16</sup> However, other studies by Raman et al.,<sup>1</sup> Skaleric et al.,<sup>17</sup> and Simpson et al.<sup>18</sup> found no improvement in HbA1c after periodontal treatment with antibiotics. All studies have shown a discrepancy in the effectiveness of antibiotics in improving HbA1c. There was no similar study conducted in Abha city, KSA. Therefore, this study was aimed to assess the effect of the scaling and root planing (SRP) with or

without doxycycline prescription and received carbohydrate diet control instructions in improving HbA1c level among type II DM patients diagnosed with periodontitis.

## METHODOLOGY

### Ethics Approval and Consent to Participate

This study was approved by the research and ethics committee at the authority of medical sector in Abha city. It was carried out in accordance with the Declaration of Helsinki. An official letter to conduct this study was sent to the health authorities and the specialist dental centers in Abha city. Informed consent was taken from all participants. Confidentiality of data was assured and ensured.

### Study Design and Population

Nonrandomized clinical study design was conducted among the type II DM patients diagnosed with periodontitis attending to the specialist dental centers in Abha city, KSA. It was used to assess the effect of doxycycline and carbohydrate diet control instructions in improving HbA1c among type II DM patients diagnosed with periodontitis.

### Inclusion and Exclusion Criteria

This study included all type II DM patients diagnosed with periodontitis who were referred to the specialist dental centers in Abha city, during the period between April 2019 and March 2021. Patients aged above 27 years and those who have completed all follow-up visits (at 3, 6, 12, and 24 months) were included in this study.

However, patients aged 27 years or less, who had type I DM, who are pregnant and lactating women, who had complications and systemic disease other than DM, who received antibiotics in the past 3 months, and who did not complete the follow-up period were excluded.

### Sample Size Calculation

A sample size of 144 patients was estimated by G\* power software, version 3.1.9.4. based on an alpha of 0.05, power of 80%, assuming effect size 0.5 needed to detect the difference between the two groups and allocation ratio group B/group A of 0.5. To compensate for dropouts during the study period, the sample size was increased by 10% so that 159 patients were recruited and were classified into two groups: group A (100 patients) and group B (50 patients).

### Intervention

The study started with a baseline survey among type II DM patients diagnosed with periodontitis. The patients were allocated into two groups according to the type of periodontal treatment. Patients who received SRP with antibiotics prescription (doxycycline 100 mg OD for 2 weeks) and received carbohydrate diet control instructions were classified as group A. Patients who received SRP without antibiotics prescription and received carbohydrate diet control instructions were classified as group B.

At the baseline point (the first visit), all patients received periodontal treatment according to their allocated groups. The collected data consisted of the following variables: age, sex, smoking status, and type of periodontal treatment (SRP with or without antibiotics prescription and receiving carbohydrate diet control instructions). In addition to that, it involved variables

related to the date and HbA1c level at the first visit and follow-up visits at 3, 6, 12, and 24 months.

### Data Processing and Analyses

SPSS version 26 was used for data entry and analysis. Kolmogorov–Smirnov test was used to assess the data distribution. It indicates that the ages in two groups are not normal distribution ( $p < 0.05$ ). The HbA1c in group A is not normal distribution ( $p < 0.05$ ), whereas in group B it is a normal distribution ( $p > 0.05$ ). However, the percentage, median, and interquartile range (IQR) as quartile 1 and quartile 3 were used to describe the data and compare between the two groups. And, the mean and SD were used as an additional measure. The median and mean differences in HbA1c levels between different visits for two groups were calculated. The Mann–Whitney  $U$  and Chi-squared tests were used to test the significant difference between the two groups  $p < 0.05$  was considered statistically significant.

## RESULTS

A total of 150 type II DM patients diagnosed with periodontitis completed the study period. Group A consisted of 100 patients who received SRP with doxycycline prescription and received carbohydrate diet control instructions. The second group consisted of 50 patients who received SRP without antibiotics prescription and received carbohydrate diet control instructions (group B).

### Characteristics of Participants

Table 1 shows the characteristics of subjects among groups A and B. The median (IQR) age of patients among groups A and B were 54 (44 and 64) years and 55 (45 and 63) years, respectively ( $p = 0.791$ ). The percentages of females were 64% and 58% among groups A and B, respectively ( $p = 0.475$ ). The percentage of smokers among group A was 20% as compared to 34% among group B ( $p = 0.061$ ). Moreover, the median (IQR) of the baseline HbA1c level was 7.7 (6.6 and 9.0) among group A as compared to 7.8 (7.0 and 9.2) among group B. There is no statistically significant difference in baseline HbA1c level between groups A and B ( $p = 0.232$ ).

**Table 1:** Characteristics of the type II diabetic patients diagnosed with periodontitis

Characteristics	Group A (n = 100)	Group B (n = 50)	p value
Age-group (years)			
Median (IQR)	54 (44 and 64)	55 (45 and 63)	0.791 <sup>a</sup>
Mean age ( $\pm$ SD)	53.6 (13.9)	54.2 (11.6)	
Sex: no. (%)			
Male	36 (36)	21 (42)	0.475 <sup>b</sup>
Female	64 (64)	29 (58)	
Smoking status: no. (%)			
Smoker	20 (20)	17 (34)	0.061 <sup>b</sup>
Nonsmoker	80 (80)	33 (66)	
Baseline HbA1c level:			
Median (IQR)	7.7 (6.6 and 9.0)	7.8 (7.0 and 9.2)	0.232 <sup>a</sup>
Mean ( $\pm$ SD)	8.0 (1.8)	8.1 (1.4)	

<sup>a</sup>Mann–Whitney  $U$  test; <sup>b</sup>Chi-squared test

### Comparison of Glycated Hemoglobin Level between Two Groups

Table 2 shows the comparison of the glycated hemoglobin levels during the baseline and follow-up periods between the two groups. The median (IQR) of baseline HbA1c level was 7.5 (6.6 and 10.0) in group A compared with 7.8 (7.1 and 9.2) in group B. Therefore, there is no statistically significant difference in the baseline HbA1c level between the two groups ( $p = 0.232$ ). However, in the second visit (after 3 months), the median (IQR) of HbA1c level was 6.4 (6.0 and 7.2) in group A as compared to 7.7 (6.9 and 8.9) in group B. In the third visit (after 6 months), the median (IQR) of HbA1c level was 6.3 (6.0 and 7.2) in group A as compared to 7.9 (6.7 and 8.9) in group B. Furthermore, in the fourth visit (after 12 months), the median (IQR) of HbA1c level was 6.2 (5.9 and 7.2) in group A as compared to 7.8 (6.8 and 8.8) in group B. In the last visit (after 24 months), the median (IQR) of HbA1c level was 6.1 (5.7 and 7.1) in group A as compared to 7.9 (6.7 and 8.7) in group B. In summary, there is a statistically significant difference in HbA1c levels between the two groups during follow-up at 3, 6, 12, and 24 months ( $p < 0.001$ ,  $p < 0.001$ ,  $p < 0.001$ , and  $p < 0.001$ , respectively).

### Comparing the Change or Improvement in Glycated Hemoglobin Level at Different Periods of Follow-up between Two Groups

Table 3 shows the comparison of the change in HbA1c level at different periods of follow-up between the two groups. The median difference (IQR) in HbA1c level during the period between the baseline and 24 months in group A was higher 1.2 (0.6 and 2.3) as compared to 0.3 (0.1 and 0.7) in group B. Therefore, there is a statistically significant difference in improving HbA1c level during the period between the baseline and 24 months between the two groups ( $p < 0.001$ ). Similarly, the median difference (IQR) in HbA1c level during the period between the baseline and 3 months in group A was higher 0.7 (0.5 and 2.3) as compared to 0.2 (0.1 and 0.3) in group B. Therefore, there is a statistically significant difference in HbA1c level during the period between the baseline and 3 months between the two groups ( $p < 0.001$ ).

On the contrary, the median difference (IQR) in HbA1c level during the period between 3 and 6 months was 0.1 (0.0 and 0.2)

**Table 2:** Comparison of the glycated hemoglobin levels during the baseline and follow-up periods between the two groups

	Group A (n = 100)	Group B (n = 50)	p value <sup>a</sup>
<b>Baseline</b>			
Median (IQR)	7.5 (6.6 and 10.0)	7.8 (7.1 and 9.2)	0.232
Mean ( $\pm$ SD)	8.0 (1.8)	8.1 (1.4)	
<b>3 months</b>			
Median (IQR)	6.4 (6.0 and 7.2)	7.7 (6.9 and 8.9)	0.000
Mean ( $\pm$ SD)	6.7 (1.2)	7.9 (1.4)	
<b>6 months</b>			
Median (IQR)	6.3 (6.0 and 7.2)	7.9 (6.7 and 8.9)	0.000
Mean ( $\pm$ SD)	6.6 (1.2)	7.8 (1.3)	
<b>12 months</b>			
Median (IQR)	6.2 (5.9 and 7.2)	7.8 (6.8 and 8.8)	0.000
Mean ( $\pm$ SD)	6.5 (1.2)	7.8 (1.3)	
<b>24 months</b>			
Median (IQR)	6.1 (5.7 and 7.1)	7.9 (6.7 and 8.7)	0.000
Mean ( $\pm$ SD)	6.4 (1.2)	7.7 (1.3)	

<sup>a</sup>Mann-Whitney U test

**Table 3:** Comparison of the change in glycated hemoglobin levels at different periods of follow-up between the two groups

Period of follow-up	Group A (n = 100)	Group B (n = 50)	p value <sup>a</sup>
<b>Change between baseline and 24 months</b>			
Median difference (IQR)	1.2 (0.6 and 2.3)	0.3 (0.1 and 0.7)	0.000
Mean difference ( $\pm$ SD)	1.6 (1.2)	0.4 (0.9)	
<b>Change between baseline and 3 months</b>			
Median difference (IQR)	0.7 (0.5 and 2.3)	0.2 (0.1 and 0.3)	0.000
Mean difference ( $\pm$ SD)	1.3 (1.2)	0.2 (0.2)	
<b>Change between 3 and 6 months</b>			
Median difference (IQR)	0.1 (0.0 and 0.2)	0.1 (0.0 and 0.1)	0.402
Mean difference ( $\pm$ SD)	0.1 (0.3)	0.1 (0.8)	
<b>Change between 6 and 12 months</b>			
Median difference (IQR)	0.1 (0.0 and 0.2)	0.0 (0.0 and 0.1)	0.043
Mean difference ( $\pm$ SD)	0.1 (0.5)	0.04 (0.2)	
<b>Change between 12 and 24 months</b>			
Median difference (IQR)	0.0 (0.0 and 0.2)	0.0 (0.0 and 0.1)	0.081
Mean difference ( $\pm$ SD)	0.1 (0.2)	0.04 (0.1)	

<sup>a</sup>Mann-Whitney U test

in group A and 0.1 (0.0 and 0.1) in group B. Therefore, there is no statistically significant difference in HbA1c level during the period between 3 and 6 months between the two groups ( $p = 0.402$ ), whereas there is a slight statistically significant difference in HbA1c level between the two groups during the period from 6 to 12 months ( $p = 0.043$ ). Moreover, there is no statistically significant difference in HbA1c level between the two groups during the period from 12 to 24 months ( $p = 0.081$ ).

## DISCUSSION

The study was aimed to assess the improvement in HbA1c levels after periodontal treatment of type II DM patients diagnosed with periodontitis. The subjects in group A underwent SRP with doxycycline prescription and received carbohydrate diet control instructions, whereas the subjects in group B underwent SRP without doxycycline prescription and received carbohydrate diet control instructions. It showed that a change or improvement in HbA1c level was higher among group A than group B, particularly after the first 3 months of follow-up.

The results of this study indicate that the ages of participants in both groups were comparable. Besides, there is no significant difference in sex and smoking status between the groups. Similarly, the baseline HbA1c level among type II DM patients diagnosed with periodontitis in both groups was comparable. Findings of our study found that the baseline HbA1c level was no significant difference between groups A and B ( $p = 0.232$ ). This means the HbA1c level of type II DM patients diagnosed with periodontitis before periodontal treatment was comparable in the two groups. After follow-up for 3, 6, 12, and 24 months of periodontal treatment, the HbA1c level was significantly reduced in group A compared to group B ( $p < 0.001$ ,  $p < 0.001$ , and  $p < 0.001$ , respectively). Regarding the overall

change or improvement in HbA1c level after 24 months of follow-up, the results revealed that the HbA1c level has a significant difference between the two groups ( $p < 0.001$ ). This means that after 24 months of follow-up, the overall HbA1c level was reduced by 16% among group A as compared to 3.8% among group B, whereas after 3 months of follow-up, the change in HbA1c level was significantly different between the two groups ( $p < 0.001$ ). The HbA1c level was reduced by 9.3% among group A as compared to 2.6% among group B, whereas the change in HbA1c level during the period between 3 and 6 months of follow-up has no significant difference between the two groups ( $p < 0.402$ ). After that, the difference was again observed slightly during the period between 6 and 12 months of follow-up between the two groups ( $p < 0.043$ ), but it disappeared during the period between 12 and 24 months ( $p < 0.081$ ). However, most of the improvement in the overall HbA1c level (58%) within group A was more when observed after 3 months of periodontal treatment as compared to 6, 12, and 24 months of follow-up. This study suggests that the improvement in HbA1c level is attributed to doxycycline prescription and carbohydrate diet control instructions associated with periodontal treatment for type II DM patients diagnosed with periodontitis. Katagiri et al.<sup>8</sup> suggested that periodontal treatment with antibiotics improves HbA1c through the reduction of C-reactive protein, which may relate to amelioration of insulin resistance, in type II DM patients with periodontal disease. The results of our study agree with studies conducted by Aranzazu-Moya et al.,<sup>7</sup> Tsobgny-Tsague et al.,<sup>9</sup> and Bharti et al.<sup>10</sup> indicated that the periodontal treatment combined with systemic or topical antibiotics improves HbA1c in type II DM patients. Moreover, findings of three studies using doxycycline support our results; Das et al.<sup>11</sup> reported that the adjunct of doxycycline to conventional periodontal therapy provides an additional benefit in reducing glycemic level. Al-Zahrani et al.<sup>13</sup> revealed that the mean HbA1c level after treatment was significantly reduced in groups receiving SRP plus doxycycline. O'Connell et al.<sup>4</sup> showed that a significant reduction in HbA1c levels was obtained, which represented a mean 10.7% improvement compared to baseline values. The SRP plus Doxy group showed a significant reduction of 1.5%, which corresponded to a 13% improvement, whereas the SRP group showed a reduction of 0.9%, which corresponded to only a 7% improvement.

Concerning the follow-up for 3 months, our results are consistent with studies conducted by Rodrigues et al.<sup>15</sup> and Grossi et al.<sup>16</sup> They reported that the periodontal treatment reduced the HbA1c values after the 3-month observation period in both groups; however, the reduction in HbA1c values for the group B (received SRP without antibiotics) was statistically significant, but not for the group A (received SRP without antibiotics) ( $p < 0.05$ ). A study by Macedo et al.<sup>12</sup> showed that the differences of HbA1c between baseline and 3 months were greater for the group that received SRP plus antimicrobial photodynamic therapy (11.4%) than the group that received SRP (10%) ( $0.87 \pm 0.9$  and  $0.4 \pm 0.84$  respectively;  $p < 0.05$ ). Singh et al.<sup>14</sup> indicated that HbA1c values are more significantly decreased over the period of 3 months in group B (received treatment with scaling and root planing followed by systemic doxycycline) than group A (received treatment with SRP only). Qureshi et al.<sup>19</sup> conducted a three-arm randomized controlled trial in which intervention for test group A (received SRP with metronidazole and oral hygiene instructions) and test group B (received SRP and oral hygiene instructions), but control group received oral hygiene instructions only. It revealed that significant reductions were observed in HbA1c in both test groups in comparison with control group ( $p < 0.05$ ).

In contrast, findings of our study disagree with three previous studies. A study by Raman et al.<sup>1</sup> indicated similar improvements in HbA1c levels, but this improvement in mean levels of both groups did not reach statistical significance. A study by Skaleric et al.<sup>17</sup> revealed that the Hb1Ac level was reduced in all patients; however, the difference between the two groups was not significant. The systemic review of published studies conducted by Simpson et al.<sup>18</sup> showed that there was no consistent evidence that the addition of antimicrobials to SRP was of any benefit to delivering SRP alone. The disagreement between the results of previous studies and ours might be due to the discrepancy in methodology, such as randomization and design.

The main limitation of this study is the patients in the two groups were not randomly selected and allocated. Additionally, this study did not measure the inflammation markers; thus, the relation between the improvements in HbA1c levels following periodontal treatment and inflammatory markers was not evaluated.

## CONCLUSION

The periodontal treatment associated with doxycycline prescription and carbohydrate diet control instructions is more effective in improving HbA1c level among type II DM patients diagnosed with periodontitis than periodontal treatment with scaling and planning alone. Most of the improvement in HbA1c level was seen after 3 months of follow-up. A randomized clinical study is recommended to confirm that the improvement in HbA1c level was attributed to doxycycline prescription associated with SRP.

## CLINICAL SIGNIFICANCE

The study provides valuable information for dental professionals about the importance of prescription of antibiotics with the periodontal treatment in improving the HbA1c level in type II DM patients.

## AVAILABILITY OF DATA AND MATERIALS

The data of the study are available from the corresponding author on reasonable request.

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