

A prospective double blind clinical comparative study of extraction socket healing in patients with type 2 diabetes on oral hypoglycemic drugs

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Abstract

Aim: The present study aims to assess the factors involved in delayed tooth extraction socket healing in healthy and Type 2 diabetes on oral hypoglycemic agents.

Materials & Methods: Patients requiring dental extraction upon referral were included in the study prospectively, grouped accordingly into Type 2 diabetes (Group 1) and Healthy (Group 2) based on medical history. Random Blood Glucose Levels (BGL) was noted for all the patients, dental extractions were performed under local anesthesia. Factors causing delay in wound healing were tabulated, evaluated statistically and risk factors were noted.

Results: There were 30 participants with Type 2 diabetes on oral hypoglycemic medication (random blood glucose between 136-178 mg/dl) and 30 non-diabetics (random blood glucose between 66-138 mg/dl), diabetics group were older in age as compared to non-diabetics. Statistical significance was not seen in diabetics and smokers for delayed wound healing

Conclusion: This study highlighted that there was similar healing between Type 2 diabetics on hypoglycemics and healthy group.

Keywords: Diabetes, Delayed healing, tooth extraction.

Introduction

Diabetes is one of the most common metabolic disorders affecting around 422 million people worldwide. Globally a rise is seen from 4.7% to 8.5% people being affected.⁽¹⁾ Estimates as per International diabetes Federation (IDF) states that there are around 40.9 million diabetic subjects in India which further may raise to 69.9 million by 2025.⁽²⁾ Advanced laboratory tests are required to distinguish between Type 1 diabetes which requires insulin injection for survival and Type 2 diabetes where the body cannot use the insulin produced. It was noted that majority of population being affected by Type 2 diabetes.⁽¹⁾ In dentistry tooth extraction socket healing is a complex process which involves repair and regeneration of tissue and traditionally person with diabetes is considered to have a increased healing problem, thus is recommended to determine the stability of known diabetics by means Blood Glucose Level (BGL), by taking patient history, referral from physician or by directly conducting the tests prior to commencement of surgery.^(1,3,4) Factors such as age, obesity, malnutrition with associated macrovascular and microvascular changes due to diabetes are known to contribute towards delayed wound healing.⁽⁵⁾ The initial hindrance towards healing in diabetes is increased glucose levels, which causes cell wall to be rigid and thickened impairing blood flow to the wound surface and impeding red blood cell permeability which leads to tissue stress and hypoxia.⁽⁶⁻⁸⁾ In dento-alveolar surgery, diabetics could be expected to suffer similar complication to those observed in other surgical procedures.⁽⁹⁾

Study aimed to compare and determine a difference in healing between subjects with Type 2 diabetics and

healthy individuals undergoing extraction based on the difference in random BGL.

Materials and Methods

This prospective study was performed in the Department of Dentistry, Karwar Institute of Medical Sciences, Karwar. The protocol for the study was approved by the ethics committee of the institution and informed consent was obtained from the participating patients. Study period was for 6 months from February 2017 to July 2017.

Patient selection

Sixty patients of the both gender with age group ranging from 18 – 75 years who visited the Dentistry Department, for simple dental extraction either due to extensive caries, periodontal problems or any other purpose and who were in good health except for Type 2 diabetes condition in the test group and able to follow the post-operative instruction were enrolled in the study

Inclusion criteria

1. Patients referred for simple extraction with detailed medical history with age 18 years and above.
2. Patients with no history of severe infection, pain or other problems 1 week before the extraction.
3. Patient with Type 2 diabetes on oral hypoglycemic medication willing to give consent to participate in the study.

Exclusion criteria

1. Patients with history of hypersensitivity, irradiation of oro-facial area and other condition like chemotherapy anticoagulant and antiplatelet therapy, physical and mental disability, malignant and benign pathology.

2. Pregnant patients.
3. Patients with peptic ulcers.
4. Patients not willing for follow up and patients not reporting after 1 week.

Patients were divided into Group1 (Known Type 2 non-insulin dependent diabetics mellitus) and Group 2 (Control group of healthy individuals without known conditions to impair wound healing) consisting of 30 patients in each group .Closed simple intra alveolar extractions were performed with forceps and elevators, same surgeon performed the surgery in both group and was blinded. Patients were asked to follow up review at one week post extraction. Recording forms were given to patients and were explained how to enter the details for any pain and other discomfort .Those patients who reported with marginally high BGL were referred for Medical reference .Filled patients questionnaire forms were collected at the time of suture removal or at one week follow up review.

Preoperative recording of data

Type of Tooth, duration of the treatment (Time from the injection of local anesthesia till the placement of the suture), amount of the local anesthesia used.Post-operative pain was assessed subjectively and accordingly marked by the patient on 10point visual analogue scale which was collected at the time of one week review or at the time of removal of suture (0= No pain, 10=severe pain). All extractions were performed using a standardized forceps and elevator technique under 2% Xylocaine which was used as an anesthetic agent comprising lignocaine hydrochloride with 1:200,000 epinephrine.

Medications

Identical medications were used in the study in both groups Tablet Diclofenac sodium 50mg and Capsule Amoxicillin 500 mg three times daily respectively for five days as a standard protocol.

Post-operative follow up (Signs of delayed healing were observed)

Primary Outcome Measure were noted

1. Edema
2. Erythema
3. Alveolar bone exposure
4. Halitosis
5. Trismus
6. Fever
7. Infection
8. Other conditions like unpleasant taste,malaise and itching were noted.

Secondary Outcome measures noted

1. Dental alveolus filled with blood clot and fibrin at day 3 after dental extraction.
2. On the post-operative day 7 the alveolus is filled with granulation tissue or not.
3. On post-operative day 21 wound epithelialization has taken place or not.
4. Delayed wound healing factors like dry socket, bony sequester or excess granulation tissue were also noted.

Along with observation as closed and open wound each sign of inflammation were given each point.

Based on the both primary and secondary outcome measures, each factor was marked as 1 point and the corresponding healing scores were noted.

Statistical Methods

Data collected was coded and entered into Microsoft Excel 2010. The validated data was imported into statistical software, SPSS 16 (Chicago) and analyzed. Results were expressed using descriptive analysis like mean, standard error of mean, range and standard deviation. The difference between mean healing score between diabetics and non-diabetics was analyzed by using independent sample Student's t test with 95% confidence intervals. The association between delayed healing and variables like smoking and blood glucose was analyzed using Fisher's exact test. Results were said to be statistically significant if the P value was <0.05.

Results

The mean age of diabetic's individuals (Group 1) was 60.67± 7.827 (mean ± SD) and of the non-diabetic (Group 2) was 53.20 ± 11.171 (mean ± SD)Table 1. The mean RBS score for Diabetic group was 157.2 mg/dland in non-diabetic group was 103.3 mg/dlTable 2.The Mean healing scores with diabetic group was 1.73±1.2 (Mean ± SD) and for non-diabetics it was 1.57±1.0 (Mean ± SD)Table 3. Among the 5 patients with delayed wound healing with diabetics 3(60.00%) were smokers as seen in Table 4 and 5.

Table 1: Distribution of study participants according to Age

Diabetes Status	Mean Age (in years)	Std. Deviation	Minimum	Maximum
Diabetic (n=30)	60.67	7.827	47	76
Non Diabetic (n=30)	53.20	11.171	33	76

Table 2: Distribution of study participants according to RBS

Diabetes Status	Mean (in mg/dl)	Range(in mg/dl)		Std. Error	Std. Deviation
		Minimum	Maximum		
Diabetic (n=30)	157.2	136.0	178.0	2.0	10.8
Non Diabetic (n=30)	103.3	66.9	138.0	4.2	22.9

Table 3: Comparison of mean healing score between Diabetics and Non-diabetics among the study participants

	Diabetics (n=30)	Non Diabetics(n=30)	T	P-value	95 % CI
Mean Healing Score	1.73	1.57	0.559	0.578	-.430 to .763

Inference

The difference between mean healing score of Diabetics and Non-diabetics among the study participants is not statistically significant (P=0.578)

Table 4: Relationship between Delayed Healing and Blood Glucose Level

Blood Glucose Level (in mg/dl)	Diabetic with Delayed Healing (n=5)*	Non Diabetics with Delayed Healing (n=3)**	P - Value***
BELOW 120	-	2 (66.67%)	0.2143
ABOVE 120	5 (100.0%)	1 (33.33%)	

* 5 among diabetics had delayed healing

**3 among non-diabetics had delayed healing

*** Fishers exact test, P value < 0.05 is significant

Table 5: Relationship between Delayed Healing and Smoking

Smoking	Diabetic with Delayed Healing (n=5)*	Non Diabetics with Delayed Healing (n=3)**	P - Value
YES	3 (60.0%)	2 (66.67%)	0.999
NO	2 (40.0%)	1 (33.33%)	

* Among 5 diabetics with delayed wound healing 3 were smokers

** Among 3 non diabetics with delayed wound healing 2 were smokers

*** Fishers exact test, P value < 0.05 is significant

Discussion

Dental extraction are procedures carried out in the Dental departments on routine basis and diabetes is one of the major factors traditionally known to delay tooth socket extraction healing. Diabetes is defined as a metabolic disease which is characterized by hyperglycemia either due to defects in insulin secretion, insulin action or combination of both.⁽¹⁰⁾ It has become important to know oral health problems in elderly with geriatric dental needs. In our study it was seen that the mean age of the patients in both diabetic and non-diabetic was 60.67±7.83 and 53.20±11.17 respectively. It has been observed that elderly with a mean age above 45 years are more prone to dental problems requiring tooth extraction and diabetes is one of the most important co-morbidities seen in them and have also noted previously patients with poorly controlled diabetes are prone to increased rate of surgical wound infection and poor wound healing.^(4,11,12,13) Traditionally hyperglycemia is noted leading to a range of complication categorized as macro vascular, micro vascular and neuropathic⁽¹⁴⁾ For wound healing the initial barrier in diabetics is increased blood glucose level which causes thickening of basement membrane of the capillaries leading to cell wall becoming rigid,

altered permeability is seen.^(15,16) It is also stated by authors in diabetics due to increased glucose level, accumulation of toxic sorbitol in the tissues, pericapillary albumin deposition which hampers nutrient and oxygen diffusion with disturbed collagen synthesis and collagen maturation.⁽¹¹⁾ Macrophage dysfunction too is observed in diabetics which causes the inflammatory phase to last longer.⁽¹⁷⁾ All these change could adversely effect and thus delaying wound healing. In our study it was seen that number of diabetics with impaired wound healing were less, showing a P value of 0.2143 which is statistically insignificant these could be due the diabetics individuals are already on hypoglycemic agents and antimicrobials before the procedure thus decreasing chances of delayed wound healing. Our study was also in concordance with other studies where delayed wound healing was seen comparatively less in diabetic individuals.⁽¹⁴⁾ There were 2 patients in whom BGL was between 120-150 mg/dl and out of whom 1(33.33%) showed delayed wound healing as seen in earlier works by other noted that every year 3-10 % of the people with prediabetes may go on to develop diabetes and these patients could belong to this group.⁽¹⁸⁾

Among the 5 diabetics (Group 1) who showed delayed wound healing 3(60%) were smokers and in healthy group, out of 3 showing delayed wound healing 2(66.67%) were smokers. Nicotine influences and delays wound healing. It causes micro-vascular occlusions leading to tissue ischemia due to increased platelets adhesiveness causing micro clots.⁽¹⁹⁾ Nicotine

is also known to decrease proliferation of RBC's, fibroblasts, macrophages and causes vasoconstriction.^(20,21) Wound healing requires enzymes but hydrogen cyanide inhibits enzyme systems which is required for oxidative metabolism and oxygen transport at cellular level.⁽²²⁾ It was seen that harmful substances of smoking have a potential to create unfavorable conditions and cause delay in healing but in this statistical significant difference was not observed between smokers and non-smokers among both the groups with regards to delayed wound healing. It was seen that there was no significant difference in the mean healing score between healthy and group of Type 2 diabetics. Both general health care combined with oral health care systems should work together towards improving overall diabetic status of the affected patients.

Conclusion

This study highlighted that elderly were the most affected group but it also concluded that there was similar healing between Type 2 diabetics on hypoglycemics and healthy group and among smokers.

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