# **ORIGINAL RESEARCH PAPER**

# Surgery

# RISK FACTORS ASSOCIATED TO THE INCIDENCE RATE OF DIABETIC FOOT IN RSUP H. ADAM MALIK MEDAN

**KEY WORDS:** Diabetes Mellitus Type 2, Risk factors, Diabetic foot

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**INTRODUCTION.** Diabetic patients worldwide in 2015 were 415 million adults, increased 4 times from 108 million in the 1980s. Diabetic ulcer is a partial thickness or full thickness damage of the skin that may expand to the subcutaneous tissue, tendon, muscle, bone and joints that occur in patients that suffer DM, this condition emerges caused by the increase of high blood glucose level and infection. There are several factors related to diabetic foot. The risk factors are age, gender, duration of diabetes, hypertension, hyperlipidemia, and level of HbA1c

**METHOD.** This study was an analytic with a cross sectional design. The study was performed in the Polyclinic of Thoracic, Cardiac and Vascular Surgery, Department of Surgery and ward of RSUP H. Adam Malik, Medan in the period of January 2014 – December 2016 taken randomly with average of DM patients with diabetic foot approximately 10 patients per month and fulfilled the inclusion criterias and exclusion criterias.

**RESULTS.** Based on the study results, the mean age of patients were 55.5+ 11.7 years old. Based on the gender, most were male as many as 32 patients (69.6%). The mean level of HbA1c was 6.78 + 1.8 mg/dL with level of HbA1c > 7 mg/dL as many as 26 patients. There were 27 subjects (58.7%) having hypertension. The majority of patients having DM had a history of DM more than 8 years: 27 patients (52.2%). Patients with dyslipidemia were 50%: 23 patients. Based on patients with diabetic foot, there were 25 patients (54.3%) having diabetic foot. From the bivariate analysis there three variables related to diabetic foot. The three variables were hypertension, level of HbA1c and duration of diabetes mellitus.

**CONCLUSION.** Based on the multivariate test, only risk factors of hypertension and level of HbA1c that were mostly related, if there were several risk factors obtained by the patient. The Predictive Value Equation of diabetic foot in this study was: P = 0.26 (hypertension) + 0,40 (Level of HbA1c > 7 mg/dl).

#### INTRODUCTION

Diabetics in the world in 2015 were 415 million adults, a 4-fold increase from 108 million in the 1980s with Indonesia ranked seventh in the world for the highest prevalence of diabetics in the world. Most DM treatments are always associated with diabetic ulcers. Mortality and amputation rates are still high, at 32.5% and 23.5% respectively. DM compared with non-DM sufferers have a tendency to be twice as easy to experience cerebral thrombosis, 25 times to occur blind, twice to have coronary heart disease, 17 times to chronic renal failure, and 50 times to suffer from diabetic foot ulcer (Hanifah N, 2017). Diabetic ulcers are partial thickness or full thickness in the skin which can extend to the tissue under the skin, tendons, muscles, bones and joints that occur in someone suffering from DM, this condition arises as a result of an increase in gular levels high blood pressure and infection. (Tambun, 2015) There are several factors related to diabetic foot. These risk factors include age, sex, length of diabetes, hypertension, hyperlipidemia and HbA1c levels. There is currently no research that assesses the overall relationship between risk factors for diabetic foot in H. Adam Malik Hospital so that this research needs to be done.

#### METHOD

This research is an analytic study with cross sectional research design. The study was conducted in the Polyclinic of the Thoracic, Cardiac and Vascular Surgery Department of Surgery and the inpatient room of H. Adam Malik General Hospital Medan. Data collection began since the proposal of this research was approved by the ethics committee. The study sample was DM patients with a diagnosis of diabetic foot and diabetic footless at the Department of Surgical Surgery of the Thoracic, Cardiac and Vascular Surgery Department and the inpatient room of H. Adam Malik General Hospital Medan for the period January 2014 - December 2016 taken randomly with the average DM patient with diabetic foot approximately 10 people per month and meet the inclusion and exclusion criteria. The sample size is calculated using the formula:

$$n = \left\{\frac{Z\alpha + Z\beta}{0.5 \ln\left[\frac{1+\gamma}{1-\gamma}\right]}^2 + 3 = \left\{\frac{1.96 + 0.842}{0.5 \ln\left[\frac{1+0.079}{1-0.079}\right]}\right\}^2 + 3$$
= 43,2 + 3 = 46,3  
So, n = 46 people

## INCLUSION AND EXCLUSION CRITERIA

The inclusion criteria in this study were: Patients with Type 2 DM, Patients with more than 40 years of age, Type 2 diabetes mellitus patients in the Department of Surgery's Thoracic, Cardiac and Vascular Surgery Polyclinic with complete medical records including ethnicity, education, age, sex, length of diabetes, hypertension, hyperlipidemia, and HbA1c levels.

Exclusion criteria in this study were: Patients who are not willing to be a research sample, Patients who do not have a complete medical record, having a history of previous peripheral vascular disorders such as PAD, Buerger's disease.

## **DATA ANALYSIS**

Data that has been collected, processed, and presented descriptively in the form of tables or diagrams. Explanation of tables and diagrams will be presented in narrative form. The data was processed using SPSS v.20.0 in bivariate test and the associated risk factors will be carried out multivariate tests. Ethical Considerations Because researchers use humans as the subject of research, then as humans must be protected by observing the principles in ethical considerations, namely: the respondent has the right to decide whether he is willing to be a subject or not without any sanctions. Respondents also have the right to request that the data reported must be kept confidential, for that there is anonymity and confidentiality.

#### **RESULT**

## **Characteristics of Research Subjects**

The study involved DM patients with diabetic foot diagnosis in the Polyclinic of Cardiac and Vascular Thoracic Surgery Department of Surgery and Inpatient Room of H. Adam Malik General Hospital Medan for the period January 2014 - December 2016 with a total of 46 people and fulfilling the inclusion and exclusion criteria. in the following table:

**Table 1. Characteristics of Research Subjects** 

Characteristics	N	%		
Age (Mean + SD)	55,50+ 11,73			
Gender				
Male	32	69,6		
Female	14	30,4		
HbA1c (Median)				
HbA1c level (Mean+ SD)	6,78+1,8			
HbA1c level > 7	26	56,5		
HbA1c level < 7	20	43,5		
Hypertension				
Hypertension (+)	27	58,7		
Hypertension (-)	19	41,3		
History of DM				
History of DM > 8 tahun	25	62,2		
History of DM < 8 tahun	21	37,8		
HbA1c level (Median)				
HDL level (Mean+ SD)	35,4 + 9,4			
LDL level (Mean+ SD)	111,63 +38,3			
Trigliserida level (Mean+ SD)	199,04 + 9,4			
Dyslipidemia(+)	23	50		
Dyslipidemia(-)	23	50		
Diabetic Foot				
Diabetic Foot (+)	25	54,3		
Diabetic Foot (-)	21	45,7		

Based on the results of the study the mean age of patients was 55.5+ 11.7 years. Based on the sex of the most research subjects were men with 32 people (69.6%). The mean HbA1c level of 6.78 + 1.8 mg/dL with HbA1c levels> 7 mg/dL was 26 patients. There were 27 subjects (58.7%) having hypertension. Most patients who have DM have had a history of DM more than eight years as many as 27 patients (52.2%). Patients with dyslipidemia were 50% with 23 patients. Based on patients with diabetic foot, 25 patients (54.3%) had diabetic foot.

## **Bivariate analysis**

The characteristics of the research subjects assessed in this study included six independent variables (age, sex, HbA1c levels, hypertension, history of DM, and dyslipidemia) with one dependent variable, namely diabetic foot.

- 1. Relationship Between Age and Diabetic Foot. In this analysis bivariate analysis was carried out using the Independent T Test. From the diagram it is found that there is the same average age of patients who experience good with diabetic foot or not experience diabetic foot which is 55.6 years. From the results of the T test obtained is p = 0.218 (p > 0.05) this means there is no significant relationship between age and diabetic foot .
- 2. Relationship Between Gender and Diabetic Foot. In this analysis, bivariate analysis was carried out using Chi-Square, namely patients classified into 2 categories. It was found that 16 patients (50%) had diabetic foot, and 9 patients (64%) had diabetic foot. The results of the analysis obtained were p = 0.371 (p> 0.05), this means there was no significant relationship between the type of diabetic foot and sloth.
- 3. Relationship Between HbA1c Levels and Diabetic Foot. In this analysis, bivariate analysis was performed using Chi-Square, namely patients classified into two categories. From the results of the study there were 17 patients with HbA1c levels> 7 mg / dL experiencing diabetic foot. From the results of bivariate analysis obtained is p = 0.0001 (p <0.05) this means there is a significant relationship between levels of glycosilated hemoglobin (HbA1c) and diabetic foot. In addition, Odd Ratio (OR) was obtained at 3.1 (OR = 1.5-4.6; CI = 95%, p <0.05). This means that patients with glycosilated hemoglobin (HbA1c)> 7 mg / dL has three times the risk of having diabetic foot.
- 4. Relationship between Hypertension and Diabetic Foot. In this analysis, bivariate analysis was carried out using Chi-Square, namely patients classified into 2 categories. From the results of the study, there were 22 patients with hypertension who had diabetic foot. The results of bivariate analysis obtained p value

- = 0.002 (p <0.05), this means that there is a significant relationship between levels of hypertension and diabetic foot. Besides that, it was also found Odd Ratio (OR) of 3.1 (OR = 1.5-4.73; CI = 95\%, p <0.05). This means that patients with hypertension levels had a fourfold risk of experiencing diabetic foot
- 5. The relationship between the duration of diabetes mellitus history and diabetic foot. In this analysis bivariate analysis was carried out using Chi-Square that patients were classified into 2 categories by connecting between the duration of diabetes mellitus and diabetic foot. The results of the analysis obtained are p = 0.017 (p <0.05), this means that there is a significant relationship between the old level of history of diabetes mellitus and diabetic foot. Also obtained was Odd Ratio (OR) of 3.2 (OR = 1.49-4.44; CI = 95%, p <0.05). This means that patients with a history of diabetes> 8 years were three times more likely to experience diabetic foot.
- 6. Relationship Between Dyslipidemia and Diabetic Foot. In this analysis, bivariate analysis was carried out using Chi-Square, namely patients classified into 2 categories. From Figure 4.2 it was found that 14 patients with dyslipidemia had diabetic foot, whereas without dyslipidemia only 11 patients. The results of the analysis obtained were p = 0.554 (p> 0.05) this means there was no significant relationship between dyslipidemia and diabetic foot.
- 7. Relationship Between Tribe and Diabetic Foot. In this analysis, bivariate analysis was carried out using Chi-Square, that is, patients based on tribes were classified into 4 categories. From Figure 4.7 it was found that 11 Batak tribe patients had diabetic foot, and the most three of the Acehnese patients had diabetic foot. The results of the analysis obtained are p = 0.428 (p> 0.05) this means there is no meaningful relationship between ethnicity and diabetic foot.
- 8. Relationship Between Education and Diabetic Foot. In this analysis, bivariate analysis was carried out using Chi-Square, namely patients classified into 2 categories. From Figure 4.2 it was found that 14 patients graduating from elementary school had diabetic foot, and 10 undergraduate patients had diabetic foot. The results of the analysis obtained are p = 0.672 (p> 0.05) this means there is no meaningful relationship between education and diabetic foot.

#### **Multivariate Analysis**

From the bivariate analysis, there were three variables related to diabetic foot. These three variables are hypertension, HbA1c levels and long history of diabetes mellitus. Then the three factors were analyzed multivariately to assess the most associated risk factors and can predict the likelihood of a diabetic foot based on existing risk factors.

Multivariate test results using Logistic Regression Test found that each p value for the three factors is for hypertension p=0.03 (p <0.05) p value of HbA1c p=0.06 (p <0.05) and for a long history of diabetes mellitus p value = 0.248 (p <0.05). It can be concluded based on the multivariate test only risk factors for hypertension and HbA1c levels are most related if there are several risk factors obtained by the patient.

Predictive Value of diabetic foot in this study were: P=0.26 (hypertension) +0.40 (HbA1c level> 7 mg/dl). This is significant if a patient has hypertension and has HbA1c levels> 7 mg/dl so predictive value for diabetic foot events is: P=0.26 (hypertension) +0.40 (HbA1c level> 7 mg/dl) P=0.26 (1) +0.40 (1) P=0.66=66% This means that the possibility of the patient to experience diabetic

foot is 66%.

#### DISCUSSION

The study involved DM patients with diabetic foot diagnosis in the Polyclinic of Cardiac and Vascular Thoracic Surgery Department of Surgery and Inpatient Room of H. Adam Malik General Hospital Medan for the period of January 2014 - December 2016 with a total sample of 46 people and fulfilling the inclusion and exclusion criteria. Based on the results of the study the mean age of patients was 55.5+ 11.7 years. bivariate analysis using Independent T Test found no significant relationship between age and diabetic foot. In

old age physiological function decreases, this is related to the aging process which causes a decrease in insulin secretion or resistance so that the ability of the body's function to control high blood glucose is less optimal. Research in Switzerland cited by Soewondo (2006) states that diabetic ulcers are 6% at age <55 years and 74% at age  $\geq$  60 years. Worldwide, the prevalence of diabetes in adults in the world aged 20-79 years will be 6.4%, affecting 285 million people in 2010 and increasing to 7.7% in 2030 and affecting 439 million people. Between 2010 and 2030 the number of diabetics will increase by 69% in developing countries, and 20% in developed countries. According to Riskesdas 2013, the prevalence of DM based on interviews in Indonesia increased in 2013, which was 2.1% compared to 2007 (1.1%). (Eka Fitria, 2017)

Older age will cause a decrease in body function, one of which is a decrease in pancreatic function and reduced insulin secretion. Reduced glucose tolerance in the elderly is associated with reduced sensitivity of peripheral cells to insulin, which causes an increase in blood sugar levels in the elderly. (Mahfud, 2012) Likewise with research conducted by Ferawati (2014) on 72 respondents there were 58.3% of people aged> 56-65 years suffering from diabetic foot ulcers and the case will increase in line with age due to a decrease in organ function, especially in the pancreas organ disorders. produce the hormone insulin.

Based on the sex of the most research subjects were men with 32 people (69.6%). In line with other studies that found men to be predominant factors associated with the occurrence of ulcers. According to Prastica et al, diabetic ulcer patients studied at Dr. Saiful Anwar Malang is male (53.6%), female (46.4%) (Roza, 2015). However, research conducted by Sukatemin in Yogyakarta in 2015 found the majority of respondents were women (57.8%) (Sukatemin, 2015). Diabetic ulcers occur in patients with diabetes mellitus who have suffered 10 years or more. If uncontrolled blood glucose levels will arise vascular-related complications will develop macroangiopathy and microangiopathy which results in vasculopathy and neuropathy, resulting in a decrease in blood circulation and the presence of tears / wounds on the feet of people with diabetes mellitus which is often not felt due to the occurrence of peripheral neuropathy.

There were 27 subjects (58.7%) having hypertension. The results of bivariate analysis obtained p value = 0.002 (p <0.05), this means that there is a significant relationship between levels of hypertension and diabetic foot. Also obtained was Odd Ratio (OR) of 3.1 (OR = 1.5-4.73; CI = 95%, p <0.05). This means that patients with hypertension levels were four times more likely to experience diabetic legs. . Hypertension (TD> 140/90 mm Hg) in patients with diabetes mellitus because of high blood viscosity will result in decreased blood flow resulting in vascular deficiency, besides hypertension whose blood pressure is more than 130/80 mmHg can damage or result in endothelial lesions . Damage to the endothelium will affect macroangiopathy through platelet adhesion and aggregation processes that result in vascular deficiency so that hypoxia can occur in the tissues which will lead to ulceration.

In patients with diabetes mellitus there is often an increase in plasma triglyceride and cholesterol levels, while HDL (highdensity-lipoprotein) concentration as a plaque cleanser is usually low ( $\leq 45$  mg / dl). Triglyceride levels  $\geq 250$  mg / dl, total cholesterol  $\geq 200$  mg / dl and HDL  $\leq 35$  mg / dl will result in poor circulation to most tissues and cause hypoxia and tissue injury, stimulate inflammatory reactions and atherosclerosis.

The mean HbA1c level of 6.78+1.8~mg / dL with HbA1c level> 7 mg / dL was 26 patients. From the results of bivariate analysis obtained is p=0.0001 (p<0.05) this means there is a significant relationship between levels of glycosilated hemoglobin (HbA1c) and diabetic foot. In addition, Odd Ratio (OR) was obtained at 3.1~(OR=1.5-4.6;~CI=95%,~p<0.05). This means that patients with glycosilated hemoglobin (HbA1c)> 7 mg / dL has three times the risk of having diabetic foot. In another study bivariate there was a relationship between levels of glycosilated hemoglobin (HbA1c) and diabetic foot with p=0.0001 and Odd Ratio at OR = 3.1~(CI=1.5-4.6;~CI=0.0001)

95%, p <0.05). (Fernando, 2017) In people with diabetes, there is a risk of 29 times of diabetic ulcer complications. The incidence of diabetic foot ulcer and diabetic uklus amputation is quite high in developing and developed countries.

Most patients who have DM have had a history of DM more than eight years as many as 27 patients (52.2%). The results of the analysis obtained are p = 0.017 (p < 0.05), this means that there is a significant relationship between the old level of history of diabetes mellitus and diabetic foot. Also obtained was Odd Ratio (OR) of 3.2 (OR = 1.49-4.44; CI = 95%, p < 0.05). This means that patients with a history of diabetes> 8 years were three times more likely to experience diabetic foot, as shown in Figure 4.5 below. The risk of infection in the legs of patients with diabetes mellitus includes more than 10 years of diabetes duration, age over 40 years, smoking history, decreased peripheral pulse, decreased sensation, anatomical deformity or pressure areas (eg bunion, callus, hammer, toes). The prevalence of DM patients with foot ulcers in Indonesia is around 15%. The prevalence of diabetic foot ranges between 1.0% and 4.1% in the United States (US), 4.6% in Kenya, and 20.4% in the Netherlands. The hospital study showed that the prevalence of diabetic foot was between 11.7% and 19.1% among diabetics in Nigeria. The prevalence of diabetic foot inpatients with diabetes in Iran is 20% (Desalu et al., 2011). The prevalence of diabetic ulcer in Indonesia is 15% of people with diabetes. At the RSCM, in 2003 the problem of foot diabetes was still a big problem. Most DM treatments are always associated with diabetic ulcers. Mortality and amputation rates are still high, at 32.5% and 23.5% respectively. The fate of post-amputation DM patients is still very bad, as many as 14.3% will die within a year after amputation and as many as 37% will die 3 years after amputation (Waspadji S, 2007)

DM sufferers have the potential to have 15-25% experience diabetic foot ulcers during their lifetime, and the recurrence rate is 50% to 70% for 5 years. Diabetic ulcer is a complication of DM that occurs repeatedly and seriously with annual incidence rates of 1% to 4% and a risk of 15% to 25% for life (Mitasari, 2014).

Patients with dyslipidemia were 50% with 23 patients. The results of the analysis obtained were  $p=0.554\ (p<0.05)$  this means that there was no significant relationship between dyslipidemia and diabetic foot.

Based on the last ethnicity and education the patient found no relationship between these variables with diabetic feet. This is in accordance with what was stated by (Ahmed, 2014) that there is no relationship between ethnicity and education of diabetic ulcers because diet, exercise, daily habits, and foot care routines in DM sufferers vary widely and do not have a cut-off point. what is clear about the ethnicity and level of one's education. (Ahmed, 2014) Quoted from Manda, 2012 Diabetic ulcers have a higher incidence rate in regions that have high rates of LDL levels (> 150) than regions that have low LDL levels. (Manda, 2012)

Multivariate test results using Logistic Regression Test found that each p value for the three factors is for hypertension p = 0.03 (p <0.05) p value of HbA1c p = 0.06 (p <0.05) and for a long history of diabetes mellitus p value = 0.248 (p <0.05). It can be concluded based on the multivariate test only risk factors for hypertension and HbA1c levels are most related if there are several risk factors obtained by the patient.

### CONCLUSION

There is no significant relationship between diabetic foot and foot (p = 0.218 (p < 0.05, CI = 95%)

There was no significant relationship between diabetic foot paralysis (p = 0.371 (p < 0.05), CI = 95%).

There was a significant relationship between Glycosilated hemoglobin (HbA1c) and diabetic foot (p = 0,0001 OR = 1.5-4.6; CI = 95%, p < 0.05)

There was a significant association between hypertension and diabetic foot (P = 0,002 (OR = 4,2) (OR = 3,1-5,3; CI = 95%, p <0,05).

## **PARIPEX - INDIAN JOURNAL OF RESEARCH**

There is a significant correlation between the length of the diabetes history and the diabetic foot. (P = 0.017 (OR = 2.6) (OR = 2.6))1,4-4,44; CI = 95%, p < 0,05).

There is no significant association between dyslipidemia and diabetic foot. (p = 0.554 (p < 0.05, CI = 95%)

There was no significant association between diabetic foot mass (p = 0,428 (p < 0,05, CI = 95%)

There is no significant relationship between education and diabetic foot (p = 0.672 (p < 0.05, CI = 95%)

Based on multivariate tests, only hypertension risk factors and HbA1c levels are most relevant if there are several risk factors that can be obtained by the patient

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