



## Analysis of Clinical Outcomes Based on Demographic Characteristics of Patients with Type 2 Diabetes Mellitus

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### ARTICLE INFO

Submitted : 02-04-2023

Revised : 21-02-2024

Accepted : 30-05-2024

Published : 30-06-2024

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### ABSTRACT

**Background:** Diabetes is one of the top 10 causes of death worldwide. Many factors increase the risk of mortality and morbidity in patients with diabetes such as age, sex, BMI, educational attainment, and marital status.

**Objectives:** The study aimed to analyze clinical outcomes based on patient demographics.

**Methods:** This method was cross-sectional and was conducted at Antapani Medika Clinic, Bandung. Inclusion criteria for this study were diabetic patients who had complete medical records, and who were receiving oral antidiabetic therapy for at least 6 months. Exclusion criteria for study were patients with diabetes who were on insulin therapy, patients with tuberculosis, and pregnant and lactating women. Data on demographic characteristics were analyzed descriptively. Chi-square and likelihood ratio tests were used to analyze differences in clinical outcomes based on therapy achievement on patient demographics.

**Results:** The results showed that HbA1c target levels were achieved by patients who were 65 years of age or older (68%), had a BMI in non-obese category (80.8%), had diabetes for six years or more (80.8%), were married (62.9%), attended college (68.4%), exercised 3 to 6 times per week (64.9%), did not smoke (61.9%), and had no comorbidities (65.3%). This study concludes that there is an association between BMI and duration of diabetes and achievement HbA1c target ( $p < 0.05$ ).

**Conclusion:** The clinical implications of this study are as a guide for health workers in Indonesia in management of diabetes so that they can provide services to patients according to the medical needs of patients.

**Keywords:** Clinical Outcome; Diabetes; HbA1c; Patient demographic

### INTRODUCTION

Diabetes mellitus (DM) is a serious condition that occurs when blood glucose levels rise above normal levels due to the body's inability to produce enough insulin and is a global health threat.<sup>1,2</sup> Diabetes is one of the top 10 causes of death worldwide.<sup>3</sup> According to the International Diabetes Federation (IDF), the number of patients with DM will reach 643 million in 2030 and 783 million in 2045, and more than 6.7 million people between the ages of 20 and 79 years will suffer from type 2 DM. The World Health Organization (WHO) predicts that the rate of type 2 DM in Indonesia will increase to 21.3 million by 2030, and Indonesia will occupy the second position of country with the highest diabetes rate in Southeast Asia.<sup>4</sup> Data from the Basic Health Survey (RISKESDAS) explained the increase in DM to 8.5% in 2018, and one of the factors causing the increase in DM prevalence is obesity. The increase in central obesity increased from 25.6% to 31% in DM patients, while body weight increased from 11.5% to 13.6% in DM patients.<sup>5</sup>

Diabetes Mellitus (DM) can cause complications such as macrovascular disease (heart, brain, or vascular disease) and microvascular disease (eye and kidney disease), nervous system disease, or neuropathy (motor, sensory, or autonomic neuropathy).<sup>1</sup> In addition, diabetes increases the risk of Coronary Artery Disease (CAD)

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and stroke by a factor of 2-4 times.<sup>6</sup> Therefore, lowering HbA1c levels is one of the main goals of therapy to prevent complications of DM.<sup>1</sup>

Obesity impairs insulin secretion and pancreatic beta-cell function, leading to hyperglycemia. Patients who are obese have a 14% increased risk of DM. Obesity is a risk factor for cardiovascular disease, including hyperlipidemia, hypertension, insulin resistance, endothelial dysfunction, and inflammation.<sup>7</sup> Research shows that diabetes is associated with metabolic risk factors such as increased BMI and lifestyle factors such as poor diet, smoking habit, and physical inactivity. An increase in BMI is associated with a 30.8% increase in mortality in patients with diabetes.<sup>3</sup>

In addition to obesity, another factor that contributes to the high prevalence of DM is ethnicity or culture, such as unhealthy lifestyle habits. These risk factors cause the development of DM to become increasingly worse because of the relationship with increased blood pressure, dyslipidemia, smoking habit, and obesity. The age factor influences the prevalence of DM, where with increasing age, changes occur in the anatomy and physiology of the body, resulting in a decreased life expectancy in DM patients.<sup>7</sup> This study is supported by a study conducted by Munganyinka et al., which explained that women are more likely to be diagnosed with diabetes. In addition, in several countries, the prevalence of diabetes increases with age, especially in patients over the age of 65 years.<sup>8</sup>

Another demographic factor that is responsible for the high prevalence of DM is educational attainment. Educational attainment is related to the ability to make lifestyle choices. Patients with low educational attainment tend to have unhealthy lifestyles, obesity, and increased alcohol consumption, which lead to worsening of DM. As with educational attainment, employment status influences the development of DM. Patients with a status of not having a job may have an increased risk of unhealthy lifestyles, such as lack of exercise, increased alcohol consumption and smoking, and cause worsening of the clinical outcome of DM.<sup>7</sup> In line with this study, the results of the study by Park et al., which examined the relationship between physical activity and the risk of atrial fibrillation in diabetes patients, explained that the group of diabetes patients who regularly did physical activity (exercise) had a low risk of Atrial Fibrillation (AF) (HR 0.91, 95%CI 0.89 – 0.94).<sup>9</sup>

Control of Glycemic Variability (GV) is one of the factors that have been proven to affect the psychological state of patients and quality of life of patients. So increasing GV will improve the quality of life of diabetes patients, which will ultimately affect clinical outcomes.<sup>10</sup> Uncontrolled clinical outcomes have an economic impact as indicated by hospital costs, especially for patients over 65 years of age, by 26% from 2012 to 2017.<sup>11</sup> Antapani Medika Clinic in Bandung was selected for this study because it is one of the teaching clinics in Bandung. Antapani Medika Clinic Bandung has a vision statement which is to become the leading and best family health service center of choice in West Java Province, and a mission statement which is to improve the level of public health by providing quality services at affordable costs and having professional human resources who continuously develop their competencies. Pharmaceutical services are an inseparable part of realizing this vision and mission, and outcome evaluation for diabetes patients had never been conducted at Antapani Medika Clinic in Bandung. In addition, this study provides a demographic overview in the form of age, sex, body mass index, duration of diabetes, marital status, educational attainment, exercise frequency, smoking status, and comorbidities, which can indirectly make a difference in the clinical outcome targets to be achieved. This study is expected to contribute to science in general by providing an overview of patient demographics that influence clinical outcomes in patients with diabetes. It suggests that patient demographics should be considered in the delivery of therapy to improve outcomes. Based on the above explanation, this study aimed to analyze clinical outcomes based on demographics in type 2 diabetes patients.

## METHODS

### Study design and ethical approval

This study is a cross-sectional observational study with a total of 69 participants. This study was conducted at the outpatient department of Medika Antapani Clinic in Bandung from April to May 2019. Ethical approval to conduct this study was obtained from the Ethics Committee of CUCMS (Cyberjaya University College of Medical Sciences), with reference number CUCMS/CRERC/AL-ER(06/2019).

### Population and samples

The sample size was calculated using the Lameshow formula with a precision level of 0.05 (5%)<sup>12</sup>, where  $n$  is the minimum sample size required,  $Z$  is the standard value of 1.96 at the 95% confidence level,  $p$  is the population estimate ( $418,000 \approx 0.04$ ),  $q$  is  $1-p$  (0.96), and  $e$  is the sampling error (standard value 5% or 0.05). The

number of diabetes patients in Indonesia was 10,300,000 and the number of diabetes patients in West Java was 418,000 patients, so  $p = 418,000/10,300,000 = 0.04$  and  $n = \frac{1.96^2 \times 0.04 \times 0.96}{0.05^2} = 60$ . The minimum sample size in this study was 60 participants, and participants in this study were increased by 15% of the minimum number of participants to account for incomplete medical record data (69 participants). Inclusion criteria for this study were patients diagnosed with diabetes, both male and female, patients with complete medical records, and patients receiving oral antidiabetic therapy for at least 6 months. The exclusion criteria for this study were patients with diabetes who were on insulin therapy, patients with TBC, and women who were pregnant and lactating.

### Study instruments

The data was collected using medical records, and who were receiving oral antidiabetic therapy for at least 6 months at the outpatient department of Medika Antapani Clinic in Bandung.

### Data collection and analysis

Data collection was based on the inclusion and exclusion criteria data. Patient demographics such as age, sex, body mass index (BMI), comorbidities, educational attainment, occupation, smoking habits, marital status, and baseline HbA1c from the patient's medical record were recorded. Data were analyzed using statistical test software. The clinical outcome was categorized as achieved if the HbA1c for 6 months achieved a decrease of <7% and as not achieved if the HbA1c level for 6 months did not decrease and was  $\geq 7\%$ . Data on demographic characteristics were analyzed descriptively. Differences in clinical outcomes based on patient demographics were analyzed using the chi-squared and likelihood ratio tests.

## RESULTS AND DISCUSSION

### Patient Characteristics

Based on the data in Table I, most patients with diabetes in this study were female (71%) and less than 65 years of age (63.8%). Based on a study by Ciarambino et al., it is clear that hormones have a major impact on metabolism and inflammatory responses in women. Women have poorer metabolic control and therefore have a higher risk of developing diabetes.<sup>13</sup>

In line with this study, a study by Celik et al., also explained that diabetes risk factors are increasing in young women around the world because of unhealthy lifestyles, resulting in increased body weight and obesity compared to men.<sup>14</sup> The Korean Diabetes Association stated that the prevalence of diabetes in adults aged 30 years or older doubled from 2.23 million in 2006 to 4.94 million in 2018. The study explained that in the case of diabetes, blood glucose control is more difficult to achieve in the younger age group because of environmental factors such as smoking habits, alcohol preferences, lack of physical activity, obesity, sleep disorders, and poor dietary habits.<sup>15</sup> According to Palungan et al., the high incidence of diabetes in adolescents and young adults is due to puberty, insulin resistance, and deterioration of beta cell function.<sup>16,17</sup> Similar to this study, they explained that in adolescents and young adults, increased consumption of calorie-dense foods, and sugary drinks and decreased physical activity lead to an increased risk of diabetes.<sup>18</sup> The study by Kim et al., also explained that in 2014, 4.8 million people aged 30 years or older in Korea had diabetes.<sup>19</sup>

In this study, the highest duration of diabetes was less than 6 years (62.3%), and most patients were obese (62.3%). Obesity increases the risk of developing diabetes because obesity is an important factor in insulin resistance. In addition, duration and obesity are also associated with the risk of developing cardiovascular complications in diabetes.<sup>20,21</sup> This is consistent with studies explaining that the duration of diabetes is associated with progressive impairment of insulin secretion over time due to failure of beta-cell function.<sup>22</sup>

The predominant educational attainment among the participants in this study was high school (47.8%), with the predominant marital status was married (89.9%). Educational attainment is associated with improved biomedical and psychosocial outcomes in patients with diabetes and obesity. Patients with a high educational attainment can make decisions, self-manage disease symptoms, and in the future may help prevent complications and increase patient compliance.<sup>23</sup> Meanwhile, marital status is associated with a significant increase in body weight, thereby increasing the risk of diabetes.<sup>24</sup>

The frequency of exercise in this study was dominated by 3 to 6 times per week (53.6%), with most participants not having a smoking habit (91.3%). Physical activity has been associated with metabolic syndrome.<sup>25</sup> In contrast to this study, a study by Veridiana et al., showed that the prevalence of diabetes was highest in those

**Table I. Data on Demographic Characteristics of Patients with Type 2 DM**

<b>Characteristics</b>	<b>Number of Patients (n=69) (%)</b>
<b>Age</b>	
< 65 years old	44 (63.8)
≥ 65 years old	25 (36.2)
<b>Sex</b>	
Woman	49 (71)
Man	20 (29)
<b>Body Mass Index (BMI)</b>	
Obesity	43 (62.3)
Non-obesity	26 (37.7)
<b>Duration of Diabetes</b>	
< 6 Years	43 (62.3)
≥ 6 Years	26 (37.7)
<b>Marital Status</b>	
Married	62 (89.9)
Unmarried	7 (10.1)
<b>Educational Attainment</b>	
Elementary and middle school	17 (24.6)
High school	33 (47.8)
College	19 (27.6)
<b>Frequency of exercise</b>	
Once every 1–2 weeks	32 (46.4)
3–6 times per week	37 (53.6)
<b>Smoking Status</b>	
Smoker	6 (8.7)
Non-smoker	63 (91.3)
<b>Comorbidities</b>	
With comorbidities	20 (29)
Without comorbidities	49 (71)

with light physical activity (3.1%) and low in those with heavy physical activity (0.9%), indicating a relationship between physical activity and the incidence of diabetes.<sup>26</sup> Meanwhile, smoking is associated with the influence of nicotine, which affects the body's metabolism, insulin sensitivity, and pancreatic beta-cell function.<sup>27</sup> A meta-analysis of research explained that environments with cigarette smoke cause fatal and serious diseases and significantly increase the risk of diabetes.<sup>19,28,29</sup> The majority of patients in this study had no comorbidities (71%). This contrasts with the study conducted by Jelinek et al., which explained that the prevalence of diabetes increases in patients with comorbidities such as dyslipidemia and hypertension. In addition, comorbidities of diabetes are associated with risk factors for kidney disease, hypertension, and dyslipidemia.<sup>30</sup>

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Table II shows the demographic characteristics of patients and clinical outcomes on HbA1c levels. The results obtained statistically show that there was a significant difference between demographic characteristics (body mass index and duration of diabetes) and clinical outcomes ( $p < 0.05$ ). This explained that there was a relationship between BMI and duration of diabetes on achieving the HbA1c target. Similar to this study, the study by Harahap et al., explained that there was a significant relationship between body mass index and the outcome of blood glucose levels ( $p = 0.000$ ). It is explained that a BMI in the "obese" category causes changes in the body's metabolism and an increase in blood glucose levels due to high body fat, so that the formation of blood glucose continues continuously and causes adipose tissue to release fat molecules into the blood, which will affect the cell's response to insulin.<sup>31</sup> Weight loss improves outcomes in patients with diabetes. Patients with a BMI of <24, 24-28, and ≥28 kg/m<sup>2</sup> can achieve controlled clinical outcomes of HbA1c (HbA1c < 7%) of 35.7%, 39.1%, and 33.7%.<sup>32</sup> An increase in BMI of 1 kg/m<sup>2</sup> can increase the risk of uncontrolled blood glucose by 11%.<sup>33</sup> This indicates that the management of overweight and obesity is important in achieving HbA1c targets.<sup>34</sup> Similar to

**Table II. Differences in clinical outcomes by patient demographic characteristics**

Variable	HbA1c Level (n=69)		P-Value
	Achieved (%)	Not Achieved (%)	
<b>Age</b>			
< 65 years old	27(61,4)	17(38.6)	0,581 <sup>a</sup>
≥ 65 years old	17(68)	8(32)	
<b>Sex</b>			
Female	28(57,1)	21(42,9)	0,073 <sup>a</sup>
Male	16(80)	4(20)	
<b>Body Mass Index (BMI)</b>	23(53,5)	20(46.5)	0,045 <sup>*a</sup>
Obesity			
Non-obesity	21(80,8)	5(19.2)	
<b>Duration of Diabetes</b>			
< 6 Years	23(53,5)	20(46.5)	0,022 <sup>*a</sup>
≥ 6 Years	21(80,8)	5(19.2)	
<b>Marital Status</b>			
Married	39(62,9)	23(37.1)	0,656 <sup>a</sup>
Unmarried	5(71,4)	2(28.6)	
<b>Educational Attainment</b>			
Elementary and middle school	9(52,9)	8(47.1)	0,635 <sup>b</sup>
High school	20(60,6)	13(39.4)	
College	13(68,4)	6(31,6)	
<b>Frequency of exercise</b>			
Once every 1–2 weeks	20(62,5)	12(37,5)	0,839 <sup>a</sup>
3–6 times a week	24(64,9)	13(35,1)	
<b>Smoking Status</b>			
Smoker	5(83,3)	1(16,7)	0,297 <sup>a</sup>
Non-smoker	39(61,9)	24(38,1)	
<b>Comorbidities</b>			
With comorbidities	12(60)	8(40)	0,677 <sup>a</sup>
Without comorbidities	32(65,3)	17(34,7)	

this study, other studies explained that the duration of diabetes affects blood glucose control, as indicated by patients with diabetes duration of ≥5 years having an average HbA1c level of between 6.5% and 7.9% and a lower risk of death compared to those with a shorter duration of diabetes (<5 years). This study explained that the longer the duration of diabetes with good blood glucose control, the lower the risk of death.<sup>35</sup>

Table II shows that the proportion of participants under 65 years of age who achieved HbA1c target was 61.4%, while the proportion of participants 65 years of age or older who achieved HbA1c target was 68%. This explained that patients who are less than or equal to 65 years of age, exercised regularly, and had healthy lifestyle habits such as not smoking were able to achieve optimal therapy. In contrast to this study, the study by Shamshirgaran et al., showed that the groups of those aged 49 years or older, 50 to 59 years, and 60 years or older were not able to achieve target blood glucose (OR = 0.49 95% CI: 0.28–0.86 and OR = 0.44 95% CI: 0.24–0.80).<sup>36</sup> This was due to the influence of income level, disease duration, hypercholesterolemia, high LDL levels, and hypertension.<sup>36</sup> Another study also showed that patients with diabetes aged < 60 years and ≥ 60 years did not achieve blood glucose targets with average HbA1c levels of 8.6% ± 2.1% and 8.0% ± 1.6% with OR HbA1c > 7.0% because of obesity, dyslipidemia, smoking, long illness, and kidney disease.<sup>37</sup>

The achievement of HbA1c target in women was 57.1% and in men was 80%, as both women and men had the habit of physical activity 3 to 6 times a week. In line with this study, a study explained that there were no differences in the achievement of blood glucose control between men and women and there was a decrease in HbA1c levels in both men and women. This was because both men and women can self-manage healthy lifestyle habits and improve quality of life to control blood glucose levels.<sup>38,39</sup>

Achievement of HbA1c target was 62.9% in participants with "married" marital status. According to one study, marital status is associated with better adherence among patients who have a partner with diabetes.<sup>40</sup>

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The results of the study of Kposowa et al., explained that married men have social support from their partners and they have a better quality of life so that clinical outcomes are achieved.<sup>41</sup> Achievement of HbA1c target was 60.6% among participants with a high school education and 68.4% among those with a college education. Educational attainment influences the improvement of glycemic control in patients with diabetes. The study results explain that the level of education can increase patients' knowledge about the disease, so patients pay more attention to their habits and blood glucose control can reach targets.<sup>42</sup> Among participants who exercised 3 to 6 times per week, 64.9% achieved their HbA1c target. Physical activity has been a recommendation for diabetes management. Physical activity has benefits that improve glycemic control and glycemic variables and reduce insulin resistance. Low levels of physical activity may increase the risk of cardiovascular disease in patients with diabetes.<sup>43</sup> Physical activity 3 times a week for 60 minutes for 2 months significantly reduces blood glucose and HbA1c levels.<sup>44</sup>

The patients who participated in this study were mostly non-smokers. The non-smoking rate was 61.9%. Consistent with this study, the results of the study by Sia et al., explained that there was a significant difference in reducing HbA1c levels in smoking and non-smoking patients by 0.30%. In addition, patients who smoked had higher HbA1c levels than non-smokers (6.65% vs 6.44%,  $p < 0.001$ ).<sup>45</sup> The patients in this study were dominated by those without comorbidities, with an HbA1c target achievement of 65.3%. The factor that caused the absence of comorbidities to influence clinical outcomes in this study was that monotherapy is effective in reducing HbA1c levels in patients. In addition, patients also had the habit of not smoking and regularly engaging in physical activity to achieve therapy targets. In line with this study, the results of another study explained that 78% of diabetes patients with chronic kidney disease (CKD) (OR: 1.78, 95% CI: 1.55-2.05) had uncontrolled blood glucose levels that were higher than patients without CKD.<sup>46</sup>

### CONCLUSION

There was an association between BMI and duration of diabetes and achievement of HbA1c target ( $p < 0.05$ ).

### ACKNOWLEDGEMENT

The author would like to thank the leadership and staff of the Medika Antapani Clinic in Bandung who have permitted researchers to carry out this research.

### STATEMENT OF ETHICS

Ethical approval to conduct this study was obtained from the Ethics Committee of CUCMS (Cyberjaya University College of Medical Sciences), with reference number CUCMS/CRERC/AL-ER(06/2019).

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