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Original Research Article

Efficacy of metformin monotherapy in newly diagnosed type 2 diabetes mellitus patients treated at Prince Mohammed Bin Abdulaziz hospital, Riyadh, Saudi Arabia

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ABSTRACT

Background: Metformin monotherapy is the primary therapeutic approach in most cases of newly diagnosed type 2 diabetes mellitus (T2DM) as it is safe, efficient, and is known to lower risks like vascular complications in patients. Previous studies have shown that glycemic control provided by metformin monotherapy is not consistent and needs to be monitored in association with other factors. Due to the complex nature of the disease and other factors like genetic predisposition, ethnicity, and geographic distribution, it is crucial to investigate its effect on the Saudi population. This study aimed to evaluate the glycemic response of metformin monotherapy in individuals with newly diagnosed T2DM who had not previously taken any other medications.
Methods: A retrospective study model was followed to determine metformin monotherapy in newly diagnosed type 2 diabetes patients. The efficacy of the metformin monotherapy was evaluated in the patients who were drug naive and had undergone treatment for six months.
Results: HbA1c levels for our study population (n=136) before and after metformin monotherapy for a period of six months was collected from patient records. The study cohort included both male (n=71) and female (n=67) patients. There was a significant difference in the HbA1c levels of all diabetes patients before (Mean=9.1, SD=2.84) and after (Mean=7.13, SD=1.51) medication; 2-tailed significance $p<0.001$.
Conclusions: Metformin monotherapy was effective in reducing the HbA1c levels across both genders and all age groups in the present study. These results suggest that metformin monotherapy could be the first line of therapy for newly diagnosed T2DM individuals.

Keywords: Type 2 diabetes, Metformin monotherapy, HbA1c, First-line therapy

INTRODUCTION

Diabetes mellitus (DM) is a disease that is manifested as a set of metabolic disorders having hyperglycemia as a common denominator. Elevated blood glucose levels may be caused by inadequate insulin secretion and/or defects in insulin action.[1] It is one of the main health problems growing rapidly in the world and is caused by various

physiological and lifestyle issues. There are different types of diabetes depending on the cause; the most common types of diabetes are type 1 diabetes, type 2 diabetes, and gestational diabetes.[2]

There are approximately more than 380 million people worldwide who are currently suffering from DM, due to the rapid rate of disease growth the statistical projection of its prevalence is expected to cross the 590 million mark by the year 2035.[3] Saudi Arabia is among the countries which have the highest occurrence of diabetes in the world; in a recent report, world health organization (WHO) has marked Saudi Arabia as the second highest in the Middle East region and seventh in the world. Due to the Rapid economic development urbanization and changes in lifestyle patterns in the region increased rate of diabetes has been reported in recent years. It has been previously reported according to the ministry of health that in the year 2015, 4660 diabetes patients visited the family healthcare centre in Saudi Arabia.[4] The number of diagnosed cases of diabetes was reportedly 0.9 million in the year 1992, but this figure rose to 2.5 million in the year 2010; this represents a spike of 2.7 times in the incidence rate in less than two decades.[4] The recent reports provide an even higher number of the estimated population with diabetes in the kingdom at around 7 million and almost 3 million people with pre-diabetic conditions.[5] The huge population suffering from lifestyle diseases like diabetes places a significant burden on healthcare services and the community as a whole.

The prevalence of T2DM is significantly increasing in the Saudi population over the past years. The increasing risk of T2DM might be linked to a varied range of geographical and socioeconomic factors, however, the prevalence is higher in urban populations in comparison to rural areas. Increasing trends of lifestyle changes and factors linked to obesity, which is one of the significant risk factors for T2DM, are also in high prevalence in Saudi Arabia. Another aspect of T2DM is the development of certain cancers as well as various disorders in micro and macrovascular systems which links it directly to high morbidity rates.[6]

Metformin monotherapy is among the first line of medical treatment advised in most cases of newly diagnosed T2DM. Metformin is a non-insulin secretion modifying agent; its action is based on reducing the production of hepatic glucose, increasing the muscle sensitivity to insulin, improvement of glucose uptake, and by delaying glucose absorption in the intestines.[7]

It activates the AMP-activated protein kinase which results in reduced acetyl CoA carboxylase ACC activity affecting the glucose metabolism in the liver.[8] Metformin monotherapy has reportedly achieved a significant reduction of glycated hemoglobin (HbA1c) levels with a predicted low risk of cardiovascular diseases. Apart from diagnosed patients, metformin is also used in pre-diabetic patients to prevent their progression to T2DM. Some patients on metformin usually present with common Side Effects like abdominal discomfort which might include decreased appetite nausea vomiting and diarrhea.[9]

METHODS

A retrospective study model was followed to assess metformin monotherapy in newly diagnosed type 2 diabetes patients. Efficacy of metformin monotherapy was evaluated in patients who were drug naive and had undergone treatment for a period of 6 months.

Study subjects and study setting

This retrospective study collected data from 136 subjects who were newly diagnosed with diabetes; and was prescribed metformin monotherapy as their treatment regimen. HbA1c levels for these patients were recorded before and after administration of metformin therapy during the first three months of the treatment. This data along with their demographics was collected from the hospital database for this study.

Prince Mohammed Bin Abdulaziz hospital in Riyadh City is crucial in handling various health-related issues including Diabetes. Usually, the diagnosis is done under the supervision of a specialist hospital department along with recurrent follow-ups and drug dispensation.

Duration and inclusion criteria

This planned study was conducted over a period of six months, from October-2022 to April-2023. All patients who were newly diagnosed with T2DM in past given year and had been prescribed only metformin for their treatment routine considered for study. Only patients with baseline HbA1c values before commencement of metformin regimen and who have been tested again after a period of 6 months were deemed eligible for this study. As HbA1c levels are used as primary endpoint indicator of metformin efficacy, any patient with non-coherent/ missing values will be excluded from this study, also it will be made sure not to include subjects who have taken any other medications which might affect carbohydrate metabolism and blood glucose levels.

Demographics

For this study, we only recruited patients who are adults with newly diagnosed DM. Patients who are ≥18 years of age were classified as adults.

Metformin exposure

Commonly used average daily metformin dosage in newly diagnosed diabetes subjects will be established clearly from high to low range values for proper assessment (Sanchez-Rangel et al). The daily dosage will be further associated with metformin refills claimed by the patients to measure their medication exposure.

HbA1c levels

Baseline HbA1c levels before medication was tabulated against subsequent A1C levels tested after six months to quantify drug efficacy in terms of primary endpoint.

Statistical analysis

The study's key findings were changes in HbA1c levels over the six-month timeframe that was defined. All included patients by the criteria definition have at least 2 HbA1c levels separated by a minimum of six months while being treated with a metformin monotherapy regimen. These values were then compared, reading taken before treatment will be considered as a baseline and their correlation with the readings obtained after the medical intervention will be analyzed using standard statistical analysis. All the analysis was done using standard statistical tests or software (like SPSS) under the supervision of a competent biostatistician.

RESULTS

The following results present descriptive data analysis for our patient group along with statistical analysis for comparing the change in HbA1c levels of these patients.

Table 1: Descriptive analysis of age distribution among diabetes patients.

Age (In years)		Statistic	Std. error
Mean		61.26	1.196
95% CI for mean	Lower bound	58.89	
	Upper bound	63.62	
5% trimmed mean		60.92	
Median		60.00	
Variance		194.444	
Std. deviation		13.944	
Minimum		31	
Maximum		95	
Range		64	
Interquartile range		18	

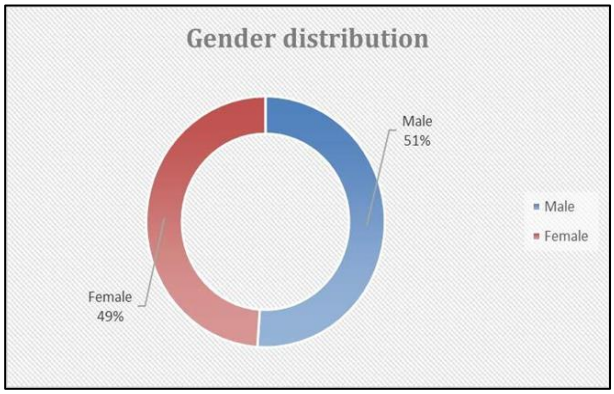

Figure 1: Frequency of age groups among diabetes patients.

Diabetes patients included in study had an almost equal distribution of gender-49% female, 51% male patients.

HbA1c levels in newly diagnosed T2DM patients at beginning of metformin therapy recorded and change in HbA1c after 6 months of treatment was observed for this study. HbA1c levels in diabetes patients before and after metformin intervention is presented below.

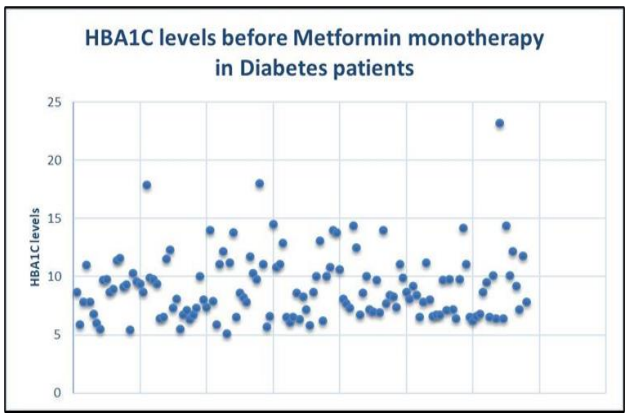

Figure 2: HbA1c levels in all diabetes patients before metformin therapy.

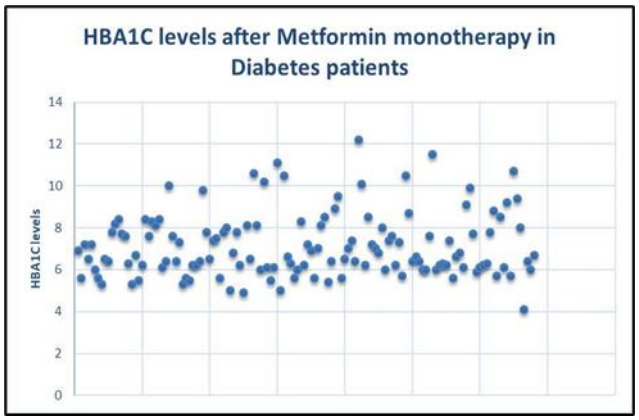

Figure 3: HbA1c levels in all diabetes patients after metformin therapy.

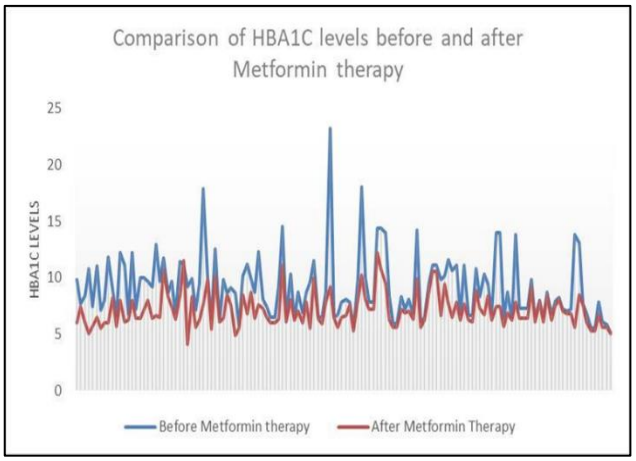

Figure 4: Change in HbA1c levels.

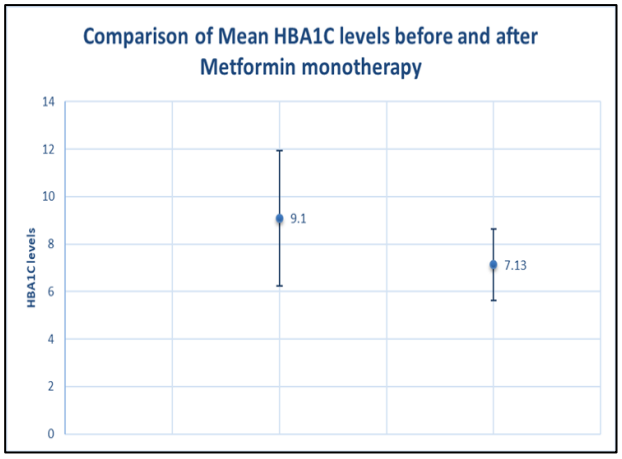

Figure 5: Mean HbA1c levels before and after 6 months of treatment.

There was a general trend of negative change in HbA1c levels for our study population (n=136). The mean HbA1c levels at the beginning of the treatment in our study cohort was 9.1, after 6 months of treatment the mean HbA1c levels recorded were 7.13.

An average negative change in HbA1c levels of 1.97 was observed in all patients, which accounts for an 18% average reduction post-medication in our cohort. A paired-sample t-test was conducted to evaluate the HbA1c levels in diabetes patients before and after metformin medication. There was a significant difference in the HbA1c levels before (Mean=9.1., SD=2.84) and after (Mean=7.13, SD=1.51) medication; 2-tailed significance p<0.001. These results suggest that Metformin monotherapy does have a clear impact on glycemic control in recently diagnosed drug naïve diabetes patients. Specifically, our results indicate that metformin can significantly reduce HbA1c levels in diabetic patients who are not taking any other medication.

For statistical analysis and comparison, the dataset was further divided into subgroups of gender and age groups as mentioned here. Change in HbA1c levels in different groups of diabetes patients designated for analysis before and after metformin intervention is presented below.

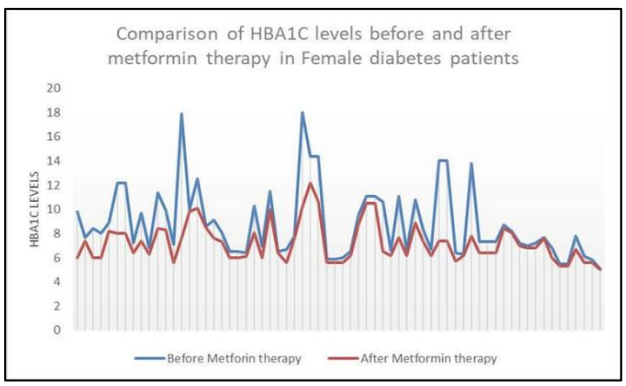

Figure 6: Change in HbA1c levels of female patients.

In male patients, mean HbA1c level before medication was 9.36 while post-Metformin therapy mean HbA1c dropped to 7.04. An average change of 2.32 was observed in male patients (n=71, median age 59), which accounts for 22% average reduction post-medication in our cohort. A paired-samples t test was conducted to compare HbA1c levels in male diabetes patients before and after metformin medication. There was a significant difference in HbA1c levels before (Mean=9.36., SD=2.75) and after (Mean=7.04, SD=1.45) medication; 2-tailed significance p<0.001. These results suggest that metformin monotherapy significantly reduces HbA1c levels in diabetic patients who are not taking any other medication.

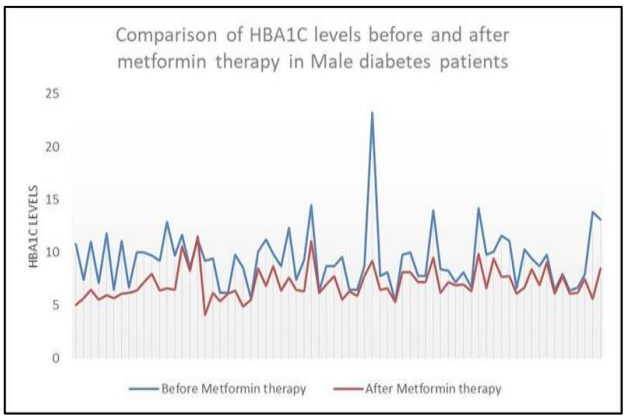

Figure 7: Change in HbA1c levels of male patients.

Change in HbA1c levels of male patients was higher than female patients as depicted in Figure 7. An independent-samples t test was conducted to compare this change in HbA1c levels of female and male diabetes patients. However, there was no significant difference in change in HbA1c levels of both Female (Mean=7.23, SD=1.57) and Male (Mean=7.04, SD=1.45) patients post metformin intervention; 2-tailed significance p=0.458. These results indicate that the efficacy of Metformin in our study cohort is independent of gender, as the drug efficiently controlled glycemic levels in both male and female patients reflected by their respective HbA1c levels.

As the onset of diabetes has been strongly associated with aging and most of the new cases diagnosed every year are reported to be between 45-64 years of age.[10] We distributed our dataset above and below the age of 50 years for our study to see any variation in the effect of metformin on HbA1c levels.

The mean HbA1c level before medication was 9.5 in patient group younger than 50 years of age, after Metformin therapy the mean HbA1c levels reduced to 6.9. An average change of 2.6 was observed in male patients (n=31), which accounts for a 26% average reduction post-metformin therapy in our cohort after 6 months. A paired-sample t test was conducted to compare HbA1c levels in diabetes patients below 50 years of age before and after metformin medication. There was a significant difference in the HbA1c levels before

(Mean=9.48., SD=1.85) and after (Mean=6.91, SD=1.53) medication; 2-tailed significance p<0.001. These results suggest that metformin monotherapy significantly reduces HbA1c levels in diabetic patients younger than 50, similar to other groups.

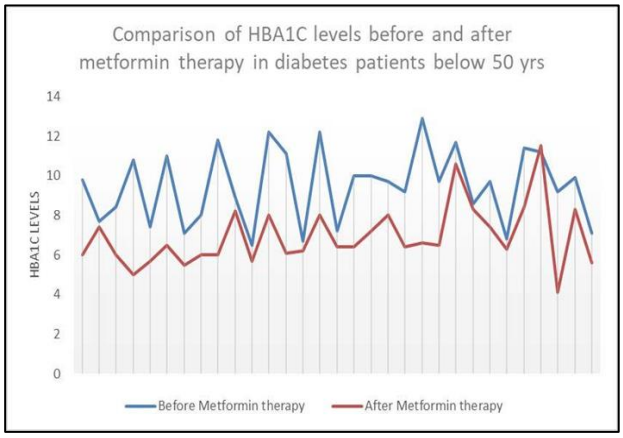

Figure 8: Change in HbA1c levels of patients below 50 years of age.

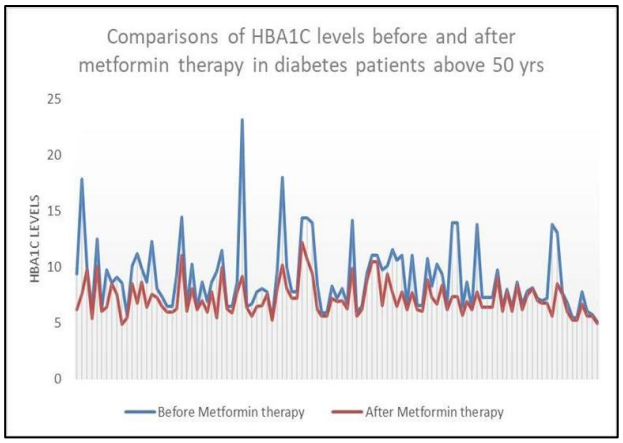

Figure 9: Change in HbA1c levels of patients above 50 years of age.

The mean HbA1c level before medication was 8.99 in the patient group older than 50 years of age, after metformin therapy the mean HbA1c levels reduced to 7.2. An average change of 1.79 was observed in patients older than 50 years (n=94), which accounts for a 16% average reduction post-medication in our cohort. A paired-sample t test was conducted to compare HbA1c levels in diabetes patients above 50 years of age before and after metformin medication. There was a significant difference in the HbA1c levels before (Mean=8.99, SD=3.07) and after (Mean=7.2, SD=1.50) medication; 2-tailed significance p<0.001. These results suggest that metformin monotherapy significantly reduces HbA1c levels in diabetic patients older than 50, similar to other groups.

Change in HbA1c levels of patients below 50 years of age was higher than patients above 50 years as depicted in Figure 10. An independent-samples t test was conducted to evaluate this change in HbA1c levels of diabetes patients below and above 50 years of age after metformin therapy. However, there was no significant difference in change in HbA1c levels of both patients below 50 years of age (Mean=7.20, SD=1.50) and patients older than 50 years (Mean=6.91, SD=1.53) post-metformin intervention; 2-tailed significance p=0.353. These results indicate that the efficacy of metformin in our study cohort is independent of age, as the drug efficiently controlled glycemic levels in both patients of all age groups reflected by their respective HbA1c levels.

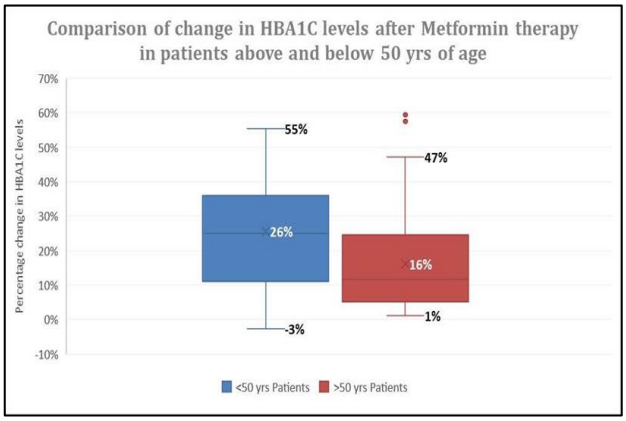

Figure 10: Box plot showing difference in percentage reduction between patients below and above 50 years of age after metformin therapy.

DISCUSSION

DM is one of the most prolific diseases, with social, economic, and health repercussions. It is a metabolic condition of increasing incidence, characterized by a dysfunction in glucose homeostasis, with chronic hyperglycemia due to absolute or relative immunodeficiency. It is progressive in nature and is associated with a high risk of causing vascular damage. Early diagnosis of DM favors the start of treatment to prevent complications. In developing countries, this condition is diagnosed in less than 50% of those who suffer from it, and in about 25% of people in whom it has been recently confirmed, there is some microvascular complication, which began 4 to 7 years earlier. Specifically, type II or non-insulin dependent DM is caused by 3 fundamental defects: a dysfunction in the beta cells of the pancreatic islets in insulin secretion, peripheral resistance to insulin, and overproduction of hepatic glucose; all of which leads to hyperglycemia that is also perpetuated by lipotoxicity.

Metformin improves glycemic control, even when used as monotherapy, reduces the value of glycated hemoglobin (Hb A1c) by 1-2%, does not cause hyperinsulinemia, has a favorable effect on lipids since it reduces LDL cholesterol levels by approximately 10 mg/dL and triglycerides; it does not modify body weight, although it has been seen that in some obese patients, it is

ideal due to the anorexia it causes with secondary weight loss, which is why it is the drug of choice as initial therapy in non-insulin-dependent and type II diabetics. Metformin can be used as monotherapy or with other oral antidiabetics or insulin. As monotherapy, metformin lowers fasting blood sugar by about 20% and lowers HbA1c by 1-2%, which is similar to the effectiveness of sulfonylureas.

Metformin is the most preferential therapy drug used in newly diagnosed drug-naïve diabetes patients. Metformin monotherapy also does not show any major adverse effects like weight gain Hypoglycemia as well as any cardiovascular effect. It is also a very cost-effective drug and has been in clinical practice much longer than glucagon-like peptide 1 (GLP-1) receptor agonists and sodium-glucose core ransporter 2 (SGLT-2) inhibitors. In addition, the cardiorenal benefits which are positively associated with GLP-1 receptor agonists have not been established in newly diagnosed drug-naive patients. There have been multiple meta-analyses of various trials and observational studies, which have evaluated the effect of metformin monotherapy administered orally as well as by injection in terms of intermediate outcomes including reducing the HbA1c levels. Meta-analysis of 134 trials, which evaluated monotherapy treatment for diabetes in drug-naive patients, reported an effective reduction in HbA1c levels up to 1.5% after metformin treatment, as well as the greatest reduction in HbA1c when metformin was used as add-on therapy with insulin and GLP-1 receptor agonists. However, in drug naïve patients change in HbA1c levels after metformin monotherapy was slightly lower at 0.97 %.[11]

Even though most medications used for monotherapy in diabetes had relatively similar efficiency in reducing HbA1c levels, metformin reduces these levels more than DPP4 inhibitors. In a diabetes outcome progression trial, monotherapy of various drugs was randomly assigned to 4360 newly diagnosed diabetes patients. Drugs included in this study thiazolidinedione, rosiglitazone, metformin, and glyburide, 36% of patients who were given metformin reported having HbA1c values less than 7.[12]

A systematic literature review that analyzed clinical trial data published over the duration of 60 years highlighted the efficiency of metformin treatment on glycemic control, the results for metformin monotherapy showed that on average of 35 trials, HbA1c levels were lowered by 1.12%.[13] Zeitler et al also reported in a similar study that metformin monotherapy after a short period of medication was able to lower the HbA1c levels significantly in diabetes patients.[14]

In the present study, the HbA1c levels were lowered by 1.97% in all diabetes patients just after 6 months of metformin monotherapy. Other studies have also indicated a similar trend of reduction in HbA1c levels, Mu et al in their cohort of drug naïve patients reported a 1.6% mean negative change from baseline in HbA1c.1[4]

Maruthur et al conducted a meta-analysis comparing various monotherapies and combination regimens including metformin, moderate to high efficacy of metformin monotherapy was observed across multiple studies with a 1-2% reduction in HbA1c levels.[15] In a recently published multicenter retrospective study efficacy of high-dosage metformin therapy was observed, where glycemic control achieved in 91.2% of patients with a mean negative change in HABA1C of 1.08%.[16]

The evident efficacy of metformin in T2DM management makes it the most commonly used first line of treatment. In Saudi Arabian hospitals, metformin is usually prescribed for both newly diagnosed and long-term diabetes patients.[17] A recent retrospective study done in the Kingdom of Saudi Arabia by Al-Rubeaan et al reported that among 519 Saudi type 2 diabetics 89.2% were prescribed metformin as the first line of treatment which shows that the majority of physicians still consider metformin as the best option in diabetes management.[18] Various meta-analyses and systemic reviews have described metformin's role in glycemic control shown by reduced HbA1c levels by an average of 1 to 2% in most cases.[19] Similar to our findings previous studies conducted in Saudi Arabia have also reported metformin monotherapy as an efficient line of treatment especially in newly diagnosed patients. Due to its efficacy and availability across both government and private healthcare centers, metformin is still most recommended drug for T2DM management in Saudi Arabia.

Limitations

This study represents the patient population restricted to the central region of Saudi Arabia; therefore, does not reflect the geographical variations and socioeconomic variables. The study has a small sample size, which follows up only for a duration of 6 months, long- term evaluation and follow-up of these subjects undergoing diabetes treatment are required for a better clinically significant conclusion. No exclusion: Inclusion criteria for population study are defined clearly, that in certain instances could lead to misleading results.

CONCLUSION

Metformin can be started as first-line therapy at the time of diagnosis of type 2 diabetes, in parallel with recommendations for lifestyle modifications. In the absence of contraindications, metformin represents the first therapeutic choice in the treatment of type 2 diabetes, due to its high efficiency (decrease in HbA1c), its low risk of hypoglycemia, its neutral effect on weight, its potential benefit on the reduction of cardiovascular risks, and its low cost.

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