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DRUG UTILIZATION REVIEW OF METFORMIN USED IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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ABSTRACT

Back ground: Drug Utilization Review (DUR) is a planned and continuing process of reviewing drug prescribing, dispensing, and use to ensure optimal therapeutic outcomes. It is a quality improvement method that tries to encourage medication adherence while reducing adverse events, wasteful healthcare costs, and drug-related complications.

Aim: The main of study is to determine drug utilization review on patients receiving metformin drug used in the treatment of type 2 DM.

Method: It is retrospective study conducted for a period of 6 months in Gandhi Hospital, Secunderabad, Telangana, India. Total number of 140 patients who meets the study criteria is included in the study. The required data has been collected from case sheets, and medical records by using a suitable patient profile form, and obtained data will be evaluated statistically.

Results: In this study, type 2 DM is more prevalent in males than females. Type 2 DM is more effectively cured when additional anti-diabetic drugs used along with metformin one compared to metformin alone used in the treatment. Management of type 2 DM with the medication metformin along with the combination and a diabetic drug with the timely and suitable approach with proper pharmaceutical care may lower the incidence. Significant difference was found in the GRBS and HbA1c levels in the patients who have been receiving metformin in combination with other anti-diabetic drugs (insulin or sulphonylureas) when compared to metformin alone used.

Conclusion: It was found that type 2 DM is more prevalent in patients with hypertension 69% followed by CVS disease 20% as comorbid condition.

Key words: Drug utilization review, diabetes mellitus, cardiovascular diseases, metformin, combinational therapy

INTRODUCTION

Drug Utilisation Review examines the prescription, distribution, and consumption of drugs in an effort to increase adherence to treatment, lower adverse events, and save medical expenses. It entails a thorough examination of test findings, patient histories, prescription orders, and medication histories to look for any problems such drug interactions. DUR can be electronic (using computerised systems), retrospective (post-patient medication), prospective (pre-administration), concurrent (dispensing in real-time), and instructional (centred on awareness). Each kind focusses on particular elements to improve the overall efficacy of drug use **[4, 5]**.

The global prevalence of diabetes is a growing concern, with an estimated 537 million cases in 2021, making up 6.7% of the global population according to the International Diabetes Federation. Regional disparities exist, with the Western Pacific, South and Central America, and South-East Asia showing higher concentrations. While the majority of cases occur in the 40-59 age group, type 2 diabetes is increasingly affecting younger demographics. Type 2, comprising 90% of cases globally, is linked to factors like obesity, inactivity, poor diets, ageing, and family history, with disproportionate impacts on certain ethnic groups. Gestational diabetes, affecting 1 in 7 babies globally, elevates the risk of type 2 diabetes in women. The economic toll of diabetes, encompassing medical expenses and lost productivity, is projected to be in the trillions of dollars globally. To address this public health concern, efficient prevention and management strategies are imperative **[6-10]**.

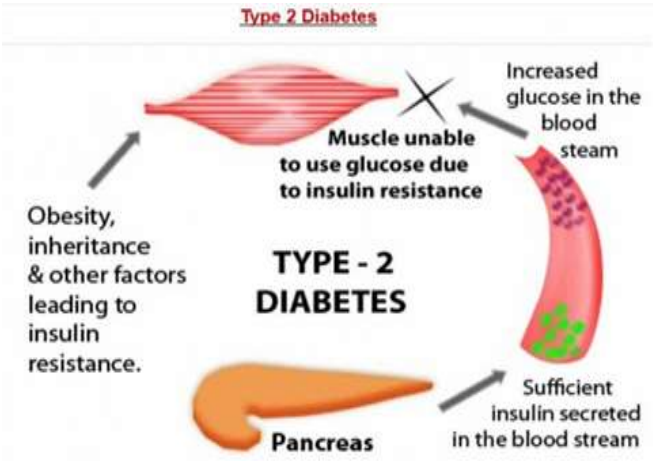

Figure 1: Type 2 DM

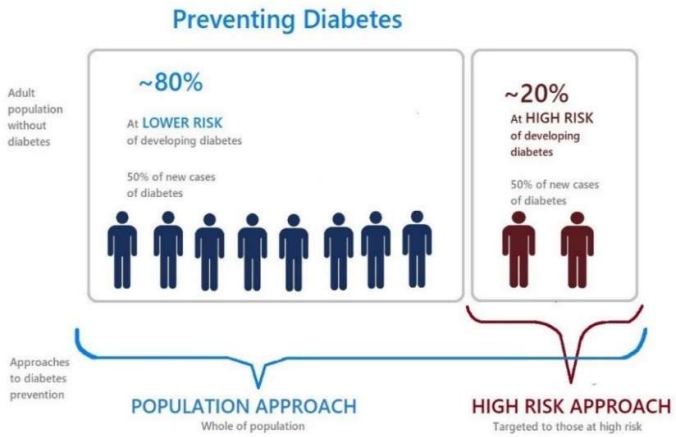

Figure 2: Prevention of DM

Aim:

The main aim of the study is to determine drug utilization review in patients receiving metformin drug used in the treatment type 2 DM.

Objectives:

- To assess the efficiency of metformin therapy in enhancing glycaemic control in people with type 2 DM.
- To determine how frequently people with type 2 DM take metformin (prevalence rate).
- To examine how doctors, tend to recommend metformin to individuals with type 2 DM.
- To look into the metformin safety profile for those with type 2 DM.
- To determine the response in patients with type 2 DM were given either metformin alone as monotherapy or metformin in combination with other medications to gauge their responses.
- To ascertain the effect of diabetes mellitus on long-term outcomes in type 2 DM patients, such as cardiovascular events, cerebral vascular events.

METHODOLOGY

The retrospective study for 6 months is planned and a patient who meets these study criteria are included in this study. The required data will collect from case sheets, or through medical records by using a suitable patient profile form, and obtained data will be evaluated statistically [11-14].

Study design: It is a retrospective study with a duration of 6 months.

Study site: The study will be conducted in a super specialty government tertiary care facility named Gandhi Hospital, Secunderabad, Telangana, India.

Study period: The study will be conducted for 6 months from September 2022 to February 2023.

Study population: An expected number of patients to be included in this study is between 100-150 sample size.

Study criteria:

Inclusion criteria:

- Inpatients and outpatients of all age groups with type 2 DM,
- Both males and females,
- Diabetes with other co-morbidities (hypertension, cardiovascular diseases, thyroid).

Exclusion criteria:

- Pregnant woman,
- Type 1 diabetes, and
- Non-diabetic patients.

Source of data: The data will be collected from various sources such as patient case sheets, treatment charts, nurse notes, and doctor prescription chart [15,16].

RESULTS

The retrospective studies on patient's received metformin drug in combination with other anti- diabetic drug (combinational therapy) in type 2 DM was done and results are based on the information (data) which has collected from Gandhi Hospital, Secunderabad, Telangana, India.

- ✓ Software used: SPSS version 24
- ✓ Sample size: 140
- ✓ The confidence interval is 95%, hence P value <0.05 is considered significant.

Table 1: Age distribution

Age interval (years)	N	Percentage
16-30	03	02
31-45	35	25
46-60	65	46
61-75	32	23
76-90	05	04

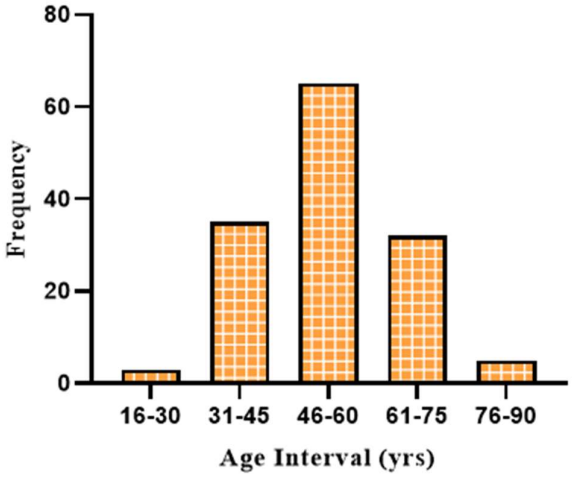

Figure 3: Age distribution

The above **Table 1** are calculated based on the age distribution of the diabetes cases and the probability of getting diabetes at their age according to the age from a minimum of age 16 to a maximum age.

Table 2: Gender distribution of the patients

Gender	N	Percentage
Male	73	52
Female	67	48

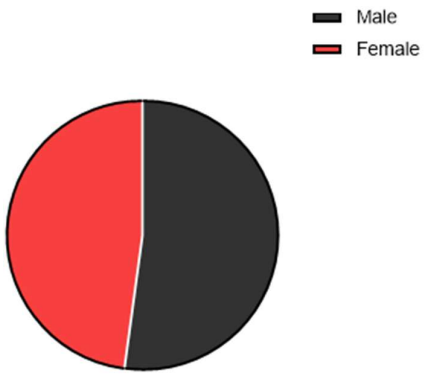

Figure 4: Gender distribution

This **Table 2** is calculated based on the gender distribution of the patients with diabetes cases and the probability of getting according to their gender in which the distribution in males shown higher than females.

Table 3: Distribution based on social history

Social history	N	Percentage
Smoker	21	15
Gutka/Tobacco chewer	06	04
Alcoholic	41	29

The category mainly based upon distribution of social history where parameters such as alcohol, smoking and tobacco chewers are considered.

Table 4: Comorbidities

Comorbidity	N	Percentage
Hypertension	96	69
CAD	7	5
CVA	5	4
Epilepsy	3	2
Hypothyroidism	6	4
Dyslipidemia	5	4
Others	11	8

This category based upon the co-existing conditions along with type 2 DM various other diseases are also diagnosed with patients during the treatment, from which HTN hold common and higher rank that is of 69%.

Table 5: Past medication history

Drug	N	Percentage
Metformin	87	62
Glimepiride	04	03
Voglibose	04	03
Telmisartan	27	19

Amlodipine	**12**	**09**
Hydrochlorothiazide/chlorothiazide	**02**	**01**
Enalapril	**01**	**01**
Lisinopril	**03**	**02**
Atorvastatin	**05**	**04**
Nicardipine	**03**	**02**
Rifaximin	**01**	**01**
Ursodeoxycholic acid	**01**	**01**
Diazepam	**01**	**01**
Aspirin	**2**	**1**
Atenolol	**02**	**01**
Clopidogrel	**01**	**01**
Thyronorm	**03**	**02**
Insulin	**05**	**04**
Losartan	**02**	**01**
Bisoprolol	**01**	**01**
Ramipril	**01**	**01**
Gliptins	**04**	**03**

Table 6: Current diagnosis

Diagnosis	N	Percentage
Acute gastritis	**4**	**3**
ADHF	**10**	**7**
CAD	**17**	**12**
Anemia	**7**	**5**
AKI	**15**	**11**
CKD	**4**	**3**
AFI	**6**	**4**
Asthma/COPD	**4**	**3**
CVA/Stroke	**21**	**15**
DCLD	**3**	**2**
Seizures	**7**	**5**
Cellulitis	**4**	**3**
Uncontrolled DM	**28**	**20**
Hypoglycemia	**10**	**7**

The category based on current diagnosis here along with diabetes and other comorbidities these are the other various medical conditions of the patients which are diagnosed as final diagnosis based upon the symptoms and laboratory investigations.

Table 7: Class of anti-diabetic drugs

Class	N	Percentage
Biguanides	**140**	**100**
Sulfonylureas	**67**	**48**
Glitazones	**01**	**01**
Alpha-glucosidase inhibitors	**02**	**01**
Meglitinides	**02**	**01**
Gliptins	**02**	**01**
SGLT-2 inhibitors	**10**	**07**
Insulin	**64**	**46**

This category of anti-diabetic drugs has mainly demonstrated that, above mentioned class of drugs has been widely used based upon age, gender, glucose levels (mild, moderate and severe) in overall treatment of DM for which the highest accountability holds for biguanides and insulin therapy.

Table 8: Anti-diabetic drugs

Drug	N	Percentage
Metformin	140	100
Glimepiride	66	47
Glipizide	01	01
Pioglitazone	01	01
Voglibose	02	01
Repaglinide	02	01
Vildagliptin	02	01
Dapagliflozin	10	07
Inj. Human Mixtard	17	12
Inj. Human Actrapid	33	24
Inj. Human Albumin	02	01
Inj. Human Regular Insulin	07	05
Inj. Thiamine	01	01
Inj. NPH	4	3

These are the different class of anti-diabetic drugs used in different patients with different treatment regimen in which metformin belongs to biguanides has been used commonly in all the patients.

Table 9: Type of therapy

Therapy	N	Percentage
Mono	31	22
Dual	74	53
Triple	31	22
Quadruple	04	03

The given therapy has been classified into mono, dual, triple and quadruple therapy in which dual therapy has higher percentage of 53%.

Table 10: Drugs used in different therapies

Therapy	N	Percentage
Mono		
Metformin	31	22
Dual		
Metformin + Glimepiride	34	24
Metformin + Inj. Human Actrapid	16	11
Metformin + Inj. Human Mixtard	09	06
Metformin + Inj. Human Regular insulin	03	02
Metformin + Inj. Human Albumin	02	01
Metformin + Dapagliflozin	05	04
Metformin + Inj. NPH	01	01
Metformin + Inj. Thiamine	01	01
Metformin + Repaglinide	01	01
Metformin + Vildagliptin	01	01
Metformin + Glipizide	01	01
Triple		
Metformin + Glimepiride + Inj. Human Actrapid	15	10
Metformin + Glimepiride + Inj. Human Regular insulin	02	01
Metformin + Glimepiride + Inj. Human Mixtard	07	05
Metformin + Glimepiride + Inj. NPH	01	01
Metformin + Glimepiride + Pioglitazone	01	01
Metformin + Glimepiride + Vildagliptin	01	01
Metformin + Glimepiride + Voglibose	01	01
Metformin + Repaglinide + Inj. NPH	01	01
Metformin + Dapagliflozin + Inj. Human Regular insulin	02	01
Quadruple		
Metformin + Glimepiride + Dapagliflozin + Inj. Human Mixtard	1	1
Metformin + Glimepiride + Dapagliflozin + Inj. Human Actrapid	1	1
Metformin + Glimepiride + Voglibose + Inj. Human Actrapid	1	1
Metformin + Glimepiride + Dapagliflozin + Inj. NPH	1	1

The distribution table is based on the category four different therapies in which dual therapy holds the highest percentage of 34% (metformin + glimepiride) followed by monotherapy of 31% (metformin), triple therapy of 15% (metformin + glimepiride + Human Actrapid).

Table 11: Dose of metformin

Dose	N	Percentage
250 mg	01	01
500 mg	135	96
750 mg	01	01
1000 mg	03	02

The maximum number of patients has received standard dose of metformin that is 500 mg.

Table 12: GRBS level

Therapy	Minimum	Maximum	Mean ± SD	P value
Mono	99	319	206 ± 105.3	0.8042
Dual	96	325	165.6 ± 98.98	
Triple	100	322	172.4 ± 99.45	
Quadruple	110	230	179.2 ± 96.23	

Statically significant difference was not found in the base line in GRBS levels of four different therapies.

Table 13: HbA1c level

Therapy	Minimum	Maximum	Mean ± SD	P value
Mono	8	11.5	9.81 ± 1.12	0.0246
Dual	7.4	10	8.55 ± 1.03	
Triple	6.9	11	7.88 ± 1.56	
Quadruple	6.7	11.8	7.27 ± 2.16	

Statically significant difference was found in the HbA1c level before and after the treatment. P value was calculated by dependent T-test. This category is based upon the comparison of glycated haemoglobin levels (HbA1c) between all the four therapies before and after the treatment with minimum to maximum are taken by that mean standard deviations and probability value (P value) are calculated.

Table 14: Association of age with no. of anti-diabetic agents used

Age interval (years)	No. of anti-diabetic agents				P value
	1	2	3	4	
16-30	0	03	0	0	0.2517
31-45	10	17	08	0	
46-60	17	34	12	02	
61-75	04	15	11	02	
76-90	0	05	0	0	

Significant difference was not found. P value was calculated.

This category is based upon number of anti-diabetic drugs used in all the four therapies has been association with the age factor.

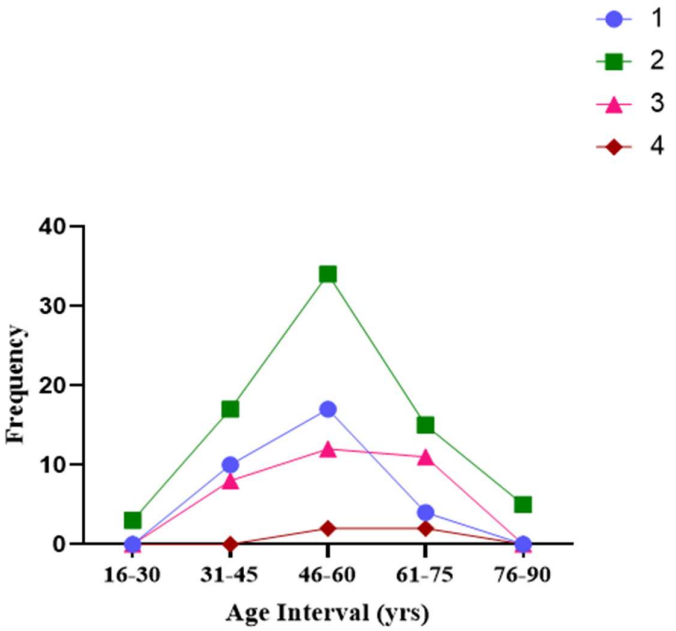

Figure 5: Association of age with no. of anti-diabetic agents used

Table 15: Association of gender with no. of anti-diabetic agents used

Gender	No. of anti-diabetic agents				P value
	1	2	3	4	
Male	16	36	18	03	
Female	15	38	13	01	0.6507

Significant difference was not found. P value has been calculated.

This category is based upon the association of gender with number of anti-diabetic agents used.

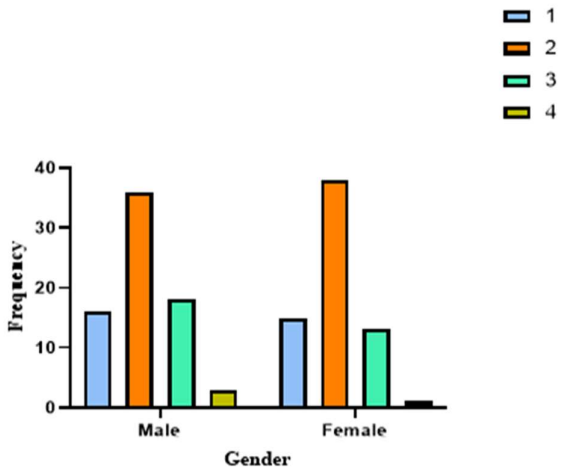

Figure 6: Association of gender with no. of anti-diabetic agents used

DISCUSSION

The initial trial population consisted of 150 patients with type 2 diabetes; 140 of them finished the study. Men and women made up roughly half of the population. Men are more likely than women to get diabetes, according to research. When the data are produced with the SPSS Version 24 software, a P value of 0.05 is considered significant because the confidence interval is 95%. The majority of research participants who reported events were between the ages of 46 and 60 (46%), followed by those between the ages of 31 and 45 (25%). This was the case because, when females were computed individually, the majority of individuals who were impacted belonged to the same age group. According to the participants' social history, 29% of them drank alcohol, 15% smoked, and 4% chewed tobacco.

There is evidence that smoking and alcohol consumption both increase the risk of diabetes. According to the International Federation of Diabetes' most recent research, 463 million people worldwide are estimated to have diabetes in 2019. The number of individuals with diabetes is continuously increasing; 425 million were estimated to have the disease in earlier estimations from 2017. By 2030, the number is expected to almost double. Based on research, 85–90% of cases of diabetes are type 2. Rising overall rates of diabetes prevalence are mostly caused by increases in type 2 risk factors, including longer lifespans and drinking or smoking rates. Advanced age, drinking or smoking, reduced glucose tolerance, insulin resistance, racial or ethnic origin, diabetes during pregnancy, family history, sedentary lifestyle, and polycystic kidney disease are risk factors for type 2 diabetes.

Individuals with DM are going to be divided into several classes based on random blood glucose levels. Lower, mild, and moderate amounts make up the classes (during which the blood sugar levels rise). Despite the fact that DM is a worldwide condition, type 2 diabetes in highly industrialised countries is more common. Regional areas with a low and moderate income like Asia and Africa, where the frequency is rising the fastest, the majority of patients are likely to live there by 2030. The Who reports that with an estimated 1.5 million fatalities in 2012, hyperglycaemia was the tenth most common cause of death. However, 2.2 million more fatalities were caused by excessive blood pressure worldwide. sugar levels and its increased risk of complications (such as heart disease, stroke, and kidney failure). May frequently cause quick mortality and frequently replaces diabetes as the primary a death's cause is listed on a death certificate.

In the following group, which is based on social history, alcohol use, chewing

tobacco use, and smoking are each represented with rates of 29%, 4%, and 15%, correspondingly. According to theresearch, individuals who frequently consume alcohol and smoke cigarettes, as well as those who take unstable medications and maintain an unbalanced diet, are most at risk of acquiring diabetes.

When comorbidities are categorized, according to the studies, high blood pressure may be an indicator of risk for or a side effect of DM. Approximately 69% of diabetic individuals appear to have hypertension, which is followed by coronary artery disease and dyslipidemia with 5% and 4% of instances each. In order to prevent cardiovascular disease, it is advised that people with highblood pressure and diabetes monitor, control, and maintain excellent health. Based on the present diagnosis, it is seen that the following conditions are linked to diabetes and are included in the table: The data suggest that uncontrolled diabetes, heart disease and stroke with ischemic attack account for a larger percentage of disease occurrence, at 20%, 15%, and 12% respectively.

The anti-diabetic medications are the next distribution category. Biguanides were used by 100% of the patients, followed by insulin administration and sulfonylureas, which were often used in conjunction with biguanides (30 patients, 34 patients). For better blood glucose control (glycemic control) in diabetic patients. The most common anti-diabetic drugs used in the treatment are metformin (500mg) 100%, glimepiride 49% and most common insulin used is Human Actrapid and Human Mixtard with 11% and 6% which has shown more effective result.

The following distribution is based on the treatment. The supplied therapy is grouped into four categories: monotherapy, dual therapy, triple therapy, and quadruple therapy with dual therapy being utilized more frequently (53%) than the other therapies. The results of the analysis of GRBS levels between all four therapies are now available. For monotherapy, the minimum is 99mg/dl and the maximum is 319mg/dl, with a mean standard deviation of 206±105.3; for dual therapy, the minimum is 96mg/dl and the maximum is 325mg/dl,with a mean standard deviation of 165.6±98.98; and for triple therapy, the minimum is 100mg/dl and the maximum is 322mg/dl, with a mean standard deviation of 172.4±99.45. Minimum of 110mg/dl to maximum of 230mg/dl values and mean standard deviation The probability values 0.8042 of computed using T-test are 179.2±96.23. In all four regimens, no statistical change in GRBS levels was identified.

In the final assessment of HbA1c levels in all four regimens, the results for mono therapy range from 8mg/dl to

11.5mg/dl, with a mean standard deviation of 9.81±1.12 for Dual therapy. Triple therapy requires a minimum of 7.4mg/dl and a maximum of 10 levels, with a mean standard deviation of 8.55±1.03. Minimum of 6.9 mg/dl to maximum of 11 mg/dl levels and mean standarddeviation of 7.88±1.56 for quadruple minimum of 6.7 mg/dl to maximum of 11.8 mg/dl levels and mean deviation of 7.27±2.16 calculated using T-test statistical difference in HbA1c levels was found in all four therapies. According to the ADA guidelines, metformin + insulin is recommended as a combination therapy in patients with a HbA1c of >13. In our study, insulin was administered as a combination therapywith metformin in 21% of the cases. SUs (glimepiride + metformin) (24%) as dual therapy, (metformin + glimepride + insulin) (10%) as triple therapy. thiazolidinedione's (1%), alpha-glucosidase inhibitors (1%), DPP-4 inhibitors (2%), meglitinides (1%), and gliflozin (7%) were the OHAs used with metformin.

Based on the link between the number of anti-diabetic drugs divided into four treatments and age, this distribution category is based; a probability value of 0.2517 indicates a statistically significant difference, as not indicated. Based on the correlation between gender and the quantity of anti-diabetic medications allocated to males and females throughout four treatments, this distribution category has a probability value of 0.6507, which indicates a statistically significant difference as not established. Throughout the 140 subjects' therapy, no patient deaths have been documented.

CONCLUSION

The current investigation examined retrospective observational studies on DUR for patients receiving combination medication for type 2 diabetes and individuals receiving metformin as monotherapy. Men are more likely than women to have type 2 diabetes. The study discovered that a significant issue was that many patients were not taking their prescribed prescriptions on a regular basis, which resulted in uncontrolled blood glucose levels. After identifying and classifying all of the comorbidities found in the research group, we found that the most frequent comorbidity was hypertension, which affected 96 people (69%) and 20% of those patients had CVS. It is more common for DM and hypertension to coexist than for them to do so alone. Diabetes-related hypertension significantly raises the chance and rate of developing heart attacks, peripheral vascular disease, strokes, glaucoma, and nephritis.

In most situations, a single OHA is insufficient to achieve target glycemic control and overcome insulin resistance in people with type 2 DM. Metformin is no exception, as it is usually recommended in

combination rather than as a monotherapy. Similarly, in our study, all of the patients (100%) were on metformin and only a small percentage (22%) were on monotherapy. By combining another OHA (glimepiride) with metformin, a total of 34 individuals (24%) were given a dualtherapy regimen, were for 15% patients, triple therapy drug regimen was designed in which metformin + glimepiride + insulin was administered. We've seen that metformin is regularly prescribed along with other anti-diabetic medications innuts hell. Metformin monotherapy is not widely used. In the context of our investigation, a 500mg daily dose of metformin was typically recommended. In the context of our investigation, glimepiride and metformin were the most frequently prescribed dual-drug combination, while SUs was the most frequently prescribed pharmacological class when metformin was also used. Insulin was most typically administered as an anti-diabetic drug in adjuvant therapy with metformin. None of the anti-diabetic medications used in this study have been associated with any potential drug interactions. This study highlights the need for ongoing monitoring of diabetes with hypertensive patients since they may be at risk for future CVS or CVA problems.

Limitations

In our study, glycemic control achieved by metformin as many of the cases, metformin is prescribed with other OHAs in combination thus glycemic control achieved solely by metformin was not possible to be attributed. As these is just a retrospective observational study the adverse drug reactions of pattern of metformin in mono and combinational therapy was not identified.

Abbreviations

DUR-drug utilization review; DM-diabetes mellitus; SUR-sulfonyl urea receptors; CVD-cardiovascular disease; HTN-hypertension; GRBS-general random blood sugar; HbA1c-glycohemoglobin; OHAs-orally administered antihyperglycemic agents; CAD-coronary artery disease; CVA-cerebrovascular accident; ADA-adenosine deaminase; CVS-chorionic villus sampling; DCLD-decompensated chronic liver disease; COPD-chronic obstructive pulmonary disease; ADHF-acute decompensated heart failure; AKI-acute kidney injury; AFI-amniotic fluid index; CKD-chronic kidney disease; SGLT-sodium-glucose cotransporter; NPH-normal pressure hydrocephalus; CI-convergence insufficiency; SPSS-statistical Package for Social Sciences.

Conflicts of interest

None declared

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Nil

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