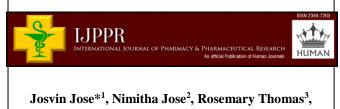
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# Knowledge Assessment of Diabetes in Patients and Cost Analysis Study of Antidiabetic Drugs in Type 2 Diabetes Mellitus



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# ABSTRACT

Diabetes mellitus is a group of metabolic disorders characterized by hyperglycemia. It is associated with abnormalities in carbohydrate, fat and protein metabolism, thus result in chronic complications including microvascular, macrovascular and neuropathic disorder. India is one among the top three countries where diabetes is prevalent according to the study carried out in 2015. Since diabetes is a chronic condition that occurs extremely due to the combination of sedentary lifestyle and imbalanced diet. The medications are to be taken for lifetime. So there is a need for the prescribers to prescribe the medication, which would be cost effective to the patients. Through this study, we aim to analyse cost variations of antidiabetic drug available in Indian market and we also assess the knowledge of patients about diabetes mellitus. Aim: The aim of this study is to assess the knowledge of patients about diabetes and to perform a cost analysis study of antidiabetic drugs in type 2 diabetes mellitus. Materials & Method: A Prospective, Cross sectional study was carried out in a 450 bedded tertiary care hospital. The study subjects include 80 patients admitted in the general medicine, cardiology, surgery, orthopedics, gynecology and neurology departments. Ambulatory patients, patients in emergency ward, pediatric and psychiatry departments were excluded from the study. Result: Prescription of 80 patients were studied and found that 63.75% were males and 36.25% were females. Most of the patients are from age group of 66-75 years (31.75%). The mostly prescribed drug is metformin and in combination, metformin + glimepride is given most. In cost analysis of drug it was found that instead of prescribing combination of drug, mono-drug regimen is more cost effective. And most patients were unaware about the diabetic condition and its treatment. Conclusion: Our study emphasizes on the cost analysis of anti-diabetic drugs and knowledge assessment of patients with type 2 DM. The cost analysis reveals that metformin and glimepride were highly prescribed drugs. When analysis the cost of single drug and combinations, we conclude that single drug regimen is more cost benefit. In assessing patients knowledge about diabetes, most of the elderly had poor knowledge compared to middle age group patients. This can be improved through giving proper counseling to patients.

#### **INTRODUCTION**

Diabetes Mellitus is a group of metabolic disorders characterized by hyperglycemia. It is associated with abnormalities in carbohydrate, fat, and protein metabolism and results in chronic complications including microvascular, macrovascular, and neuropathic disorders.<sup>[58]</sup> WHO project that DM will be the 8<sup>th</sup> leading cause of death around 2030. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels. Several pathogenic processes are involved in the development of diabetes. These range from autoimmune destruction of the  $\beta$ -cells of the pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action. In type 1 diabetes, the cause is an absolute deficiency of insulin secretion. In type 2 diabetes, the cause is a combination of resistance to insulin action and an inadequate compensatory insulin secretory response. Type 2 diabetes accounts for ~90–95% of all diabetic cases.

The prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. According to statistics from the International Diabetes Federation (IDF), India has more diabetics than any other nation of the world. Current estimates per the number of diabetics in the country at about 62 million – an increase of over 10 million from 2011when estimate suggested that about 50.8 million people in the country where suffering from the disease. By the year 2030 over100 million people in India are likely to suffer from diabetes.<sup>[8]</sup>

#### MANAGEMENT

- Non-pharmacological treatment
- Diet Medical nutrition therapy is recommended for all person with DM
- Physical activity It include aerobic exercise
- Weight reduction if obese
- Pharmacological treatment
- Biguanides (Metformin)

- > Sulphonylureas ( Glimepiride, Glipzide, Glibenclamide)
- Thiazolidinediones (Pioglitazone)
- Alpha-glucosidase inhibitors (Voglibose, Acarbose)
- > DPP-4 inhibitors (Vidagliptin, Sitagliptin)
- Meglitinide analogues (Repaglinide, Nateglinide)
- ➢ Glucagon-like peptide −1/ GLP − 1 (Liraglutide, Exenatide)
- > Amylin analogue ( Pramlintide)
- Dopamine- D2 receptor agonist (Bromocriptine)
- Sodium-glucose cotransport -2 (SGLT-2) inhibitor (Dapagliflozin)

# **INSULIN THERAPY**

CLASSIFICATION OF INSULIN

Rapid acting

- Lispro
- > Aspart
- ➢ Glulisine

Intermediate acting

- > NPH(Isophane)
- ➢ Lente

Slow acting

- > Ultralente
- Protamine zinc



# ➢ Glargine and Detemir<sup>[62]</sup>

# NEED FOR COUNSELING IN DIABETES

The principal task of the health care team is to give each patient knowledge, self- confidence and support. Patients with diabetes and their families provide 95% of their care themselves, and, as a consequence, educational efforts to improve self- management are central components of any effective treatment plan.

Studies have confirmed that the complications of diabetes can be reduced by proper control of blood glucose. The proper control is dependent on the patient's adherence to medications, lifestyle modifications, frequent monitoring of blood glucose, etc and can be influenced by proper education and counseling of the patient. Pharmacists, being one of the indispensable members of the health care team, have an immense responsibility for counseling these patients.

# ROLE OF PHARMACISTS IN DIABETES MANAGEMENT

Because of the rapid expansion of available therapeutic agents to treat diabetes, the pharmacist's role in caring for diabetic patients has expanded. The pharmacist can educate the patients about the proper use of medication, screening for drug interactions, explain monitoring devices, and make recommendations for ancillary products and services.

Since diabetes is a chronic complication affecting diabetic patient at various levels, the counseling should focus on the nature of the disease, lifestyle modifications, medications, and acute and chronic complications.

# MATERIALS AND METHODS

A prospective cross sectional study was conducted in the general medicine, cardiology, surgery, orthopedics, obstetrics and neurology department of a 450 bedded tertiary hospital (st.james hospital chalakudy, Kerala, India) for a period of 6 months in 2019. The sample population of 80 was selected based on inclusion exclusion criteria. The study was conducted by collecting data from the medical records of inpatients receiving anti-diabetic drugs in various departments.

The protocol of study submitted to Institutional Human Ethics Committee (IHEC). The protocol was approved by committee with an approval number of SJPCEC/P25/PP/2016/028 and hospital approval number SJCP/DIR/A.13/2018-2019.

A computerized literature and manual search was conducted to identify relevant studies, for knowledge assessment of diabetes and cost analysis. Literatures which found to support the study was collected and properly reviewed. A data entry form was specially designed to collect the relevant information, and a properly validated DKQ was utilized. The mostly used drug alone and in combination was identified and the cost effective analysis was done. The study was done to investigate and compare the cost of various brands of same generic drug. Patient compliance with the drug plays a key role. Increase in drug cost is associated with the decline in medication adherence, which in turn lead to poor patient outcome. Cost between different brands of same generic drug was compared and the least cost was selected. This was also done for combinations of drugs and the most cost benefit one was selected.

#### Inclusion criteria

Diabetic patients from general medicine, cardiology, surgery, orthopedics, obstetrics and neurology departments.

Patients above the age of 35 years. HUMAN

#### Exclusion criteria

- > Ambulatory patients, patients present in emergency, pediatric and psychiatry departments.
- Patients below the age of 35 years.
- > Patients who were not prescribed with antidiabetic drugs.
- > Patients who were not willing to take part for the study.

#### **RESULT AND DISCUSSION**

Diabetes is a chronic condition where compliance with drugs plays a key role. Adherence of the drugs can be ensured by decreasing the cost of the drugs prescribed. The study entitled "knowledge assessment of diabetes in patients and cost analysis of anti-diabetic drug in type 2 diabetes mellitus" was a prospective cross sectional study carried out for a period of 6

months in all the departments of a 450 bedded tertiary care hospital. A total of 80 patients who met the inclusion criteria were enrolled in the study.

# AGE

In the study (Table 1, fig 1) shows out of 80 patients majority belonged to 66 -75 years( 31.25%) followed by 56-65 years (23.75) and 23.75% was above 75 years. The lowest age group was found to be 35-45 years (2.5%).

# GENDER

36.25% male and 63.75% being female. From this study, the majority was found to be female.(Table 2 & fig 2 )

# LENGTH OF STAY

Out of 80 patients, average length of stay of most were found to be between 1-5 days (66.25%) and only 7.5% stayed above 11 days.

# COMORBIDITES

Most of the patients with diabetes had comorbid conditions like hypertension, dyslipidemia and other. Out of this 80 patients 59 had hypertension, 26 had dyslipidemia, 13 had coronary artery disease and 30 were diagnosed with other disease. (Table 3 & fig 3)

# COMMONLY PRESCRIBED ORAL ANTI-DIABETIC DRUGS

In this study, it was found that metformin was prescribed for 36 patients, followed by glimepiride for 19 patients, 8 were prescribed with teneligliptin, 4 patients prescribed with gliclazide. Voglibose was prescribed only for 3 patients and 2 patients with glipizide. (Table 4 & fig 4)

# DISTRIBUTION BASED ON COMMONLY PRESCRIBED COMBINATIONS OF ANTI-DIABETIC DRUGS

Out of 80 patients, most (17) were prescribed with a combination of glimepiride & metformin. A combination of sitagliptin & metformin was prescribed only for 3 patients. And only 2 patients each were prescribed with pioglitazone + metformin, vildagliptin + metformin, glipizide + metformin and gliclazide + metformin. (Table 5 & fig 5)

#### DISTRIBUTION BASED ON COMMONLY PRESCRIBED INSULINS

Through our study we found that insulin isophane and human insulin combination were prescribed mostly to all patients (20) followed by 19 patients with regular human insulin and only 2 patients were prescribed with human premix. Insulin glargine was only given to 1 patient.(Table 6 & fig 6)

#### DISTRIBUTION BASED ON INSULIN AND ORAL ANTI-DIABETIC DRUGS

This study shows that about 69 patients were prescribed with oral anti-diabetic agent. And combination of anti-diabetic drug was given for 26 patients. And 42 patients were prescribed with insulin.(Table 7 & fig 7)

# DISTRIBUTION BASED ON MOSTLY PRESCRIBED ANTI-DIABETIC MEDICATIONS

Analysis of the study shows that metformin (36) was mostly prescribed drug. In combination therapy, metformin + glimepiride (17) was frequently administered. And in case of insulin about 20 patients were administered with a combination of isophane + human insulin.(Table 8 & fig 8)

HUMAN

#### **COST ANALYSIS**

According to the study, we found that there is an extensive variation in the cost of antidiabetic drugs. In the analysis of the comparative cost of therapies, it showed that the monotherapy is less costlier than that of the combination therapy.

Study showed that there is a wide variation in the prices of different brands of anti-diabetic drugs. Highest number of trades usable are respectively Metformin-500mg (n=6brands) Teneligliptin-20mg (n=5brands); followed by Glimepride-1mg (n=3brands); Glimepride-2mg (n=2brands) and Voglibose-0.2mg, 0.3mg, Pioglitazone-15mg, Glipizide-2.5mg, 5mg (n=1brand)(Table 9-13 & fig 9-13)

In combination with Metformin-500mg, highest number of brands are observed in Glimepride-2m.g & 1mg (n=2brands); Sitagliptin-50mg (n=2brands); vildagliptin-50mg & Pioglitazone-15mg (n=1brand); Gliclazide-80mg (n=1brands) and Metformin-1000mg+Glimepride-2mg (n=2brand) (Table 14-16 & fig 14-16).

From the above data we assume that, if a mono drug regimen is given to the patient for a month then, in Metformin **Glyciphage** is the least costly (47.17 Rs) prescribed drug compared to other brands. In glimepride 1 mg **Glimestar** (79.2Rs), 2mg **Amaryl** (179.7 Rs) was least prescribed brand. In case of Tenligliptin 20 mg **Tenepride** (288 Rs) was cost beneficial drug. When comparing the cost of mono-drug regimen and combination of metformin & glimepride, the combination therapy was found to be costlier.

#### **QUESTIONNAIRE RESULT**

In our study, by using a validated DKQ we found that most of the patients (80%) within the age group 46-55yrs have adequate knowledge about diabetes, followed by 68.42% from the age group 56-65. Between the age of 66-75 only 40% have knowledge about their condition. In geriatric patients (above 75), only 31.56% were aware about diabetes mellitus. (Table 18)

When statistically analyzed there was no significance between age and the knowledge about diabetes.

Mater

#### DISTRIBUTION OF PATIENTS BASED ON AGE GROUP

N=80

AGE GROUP(YEARS)	FREQUENCY	PERCENTAGE (%)
35-45	2	2.5
46-55	15	18.75
56-65	19	23.75
66-75	25	31.25
Above 75	19	23.75

# Table No. 1: Distribution Based On Age

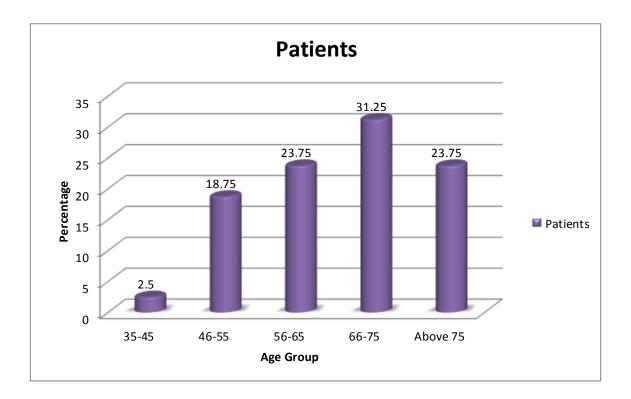


Figure No. 1: Percentage Distribution Based on Age

# **DISTRIBUTION BASED ON GENDER**

N=80

# Table No. 2: Distribution Based On Gender

SEX	FREQUENCY	PERCENTAGE (%)
MALE	29	36.25
FEMALE	51	63.75

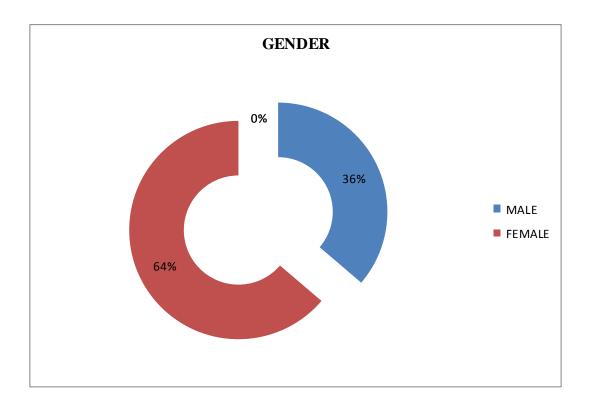


Figure No. 2: Percentage Distribution Based on Gender

HUMAN

# DISTRIBUTION BASED ON CO-MORBIDITY

N=80

#### Table No. 3: Distribution Based On Co-Morbidity

Past medical history	Number of patients	Percentage (%)
With co-morbid conditions	70	87.5
Without co-morbid conditions	10	12.5

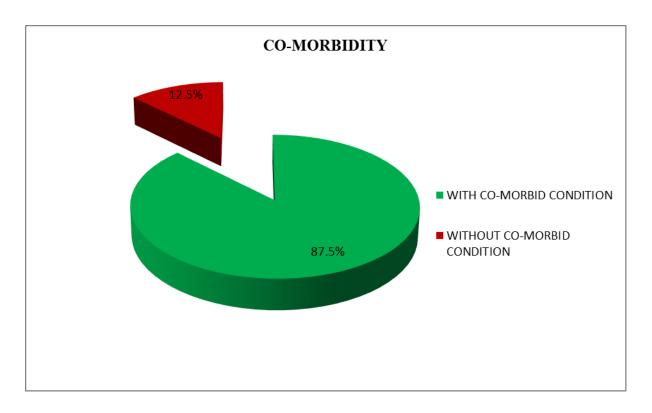
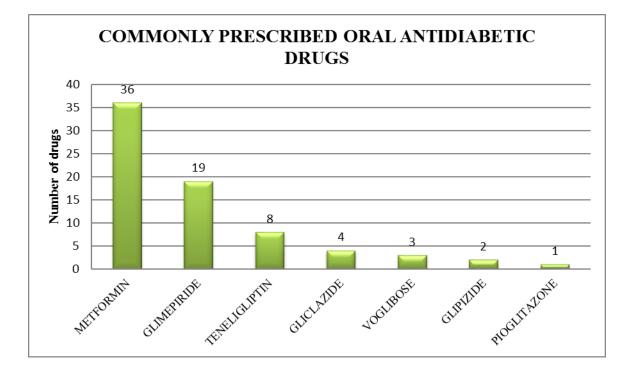


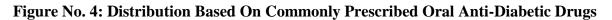
Figure No. 3: Percentage Distribution Based on Co-Morbidity

# DISTRIBUTION BASED ON COMMONLY PRESCRIBED ORAL ANTI-DIABETIC DRUGS

Table No. 4: Distribution Based On Commonly Prescribed Oral Anti-Diabetic Drugs

ORAL ANTI-DIABETIC DRUGS	NUMBER
METFORMIN	36
GLIMEPIRIDE	19
TENELIGLIPTIN	8
GLICLAZIDE	4
VOGLIBOSE	3
GLIPIZIDE	2
PIOGLITAZONE	1





DISTRIBUTION BASED ON COMMONLY PRESCRIBED COMBINATIONS OF ANTI-DIABETIC DRUGS

 Table No. 5: Distribution Based On Commonly Prescribed Combinations of Anti-Diabetic Drugs

DRUGS	NUMBER
GLIMEPIRIDE + METFORMIN	17
SITAGLIPTIN + METFORMIN	3
PIOGLITAZONE + METFORMIN	2
VIDAGLIPTIN + METFORMIN	2
GLIPIZIDE + METFORMIN	2
GLICLAZIDE + METFORMIN	2

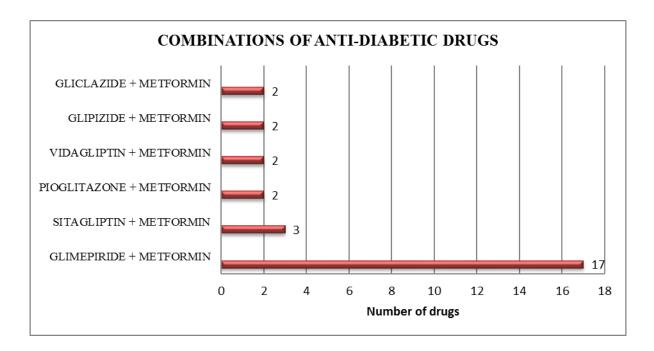
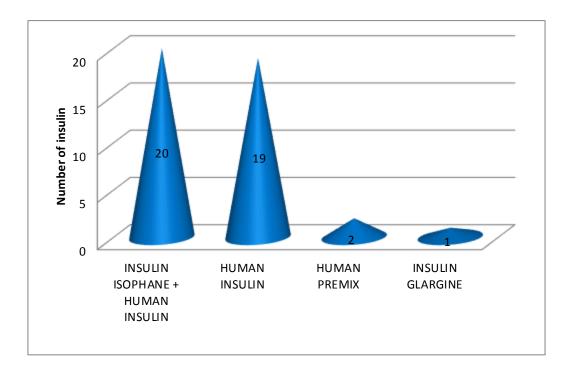


Figure No. 5: Distribution Based On Commonly Prescribed Combinations of Anti-Diabetic Drugs

# DISTRIBUTION BASED ON COMMONLY PRESCRIBED INSULIN

Table No. 6: Distribution Based On Commonly Prescribed Insulin

INSULIN HUMAN	NUMBER
INSULIN ISOPHANE + HUMAN INSULIN	20
HUMAN INSULIN	19
HUMAN PREMIX	2
INSULIN GLARGINE	1



# Figure No. 6: Distribution Based On Commonly Prescribed Insulin

# DISTRIBUTION BASED ON INSULIN AND ORAL ANTI-DIABETIC DRUGS

(N=137)

# Table No. 7: Distribution Based On Insulin and Oral Anti-Diabetic Drugs

DRUGS	NUMBER OF PATIENTS
ORAL ANTI-DIABETIC AGENT	69
INSULIN	42
COMBINATION	26

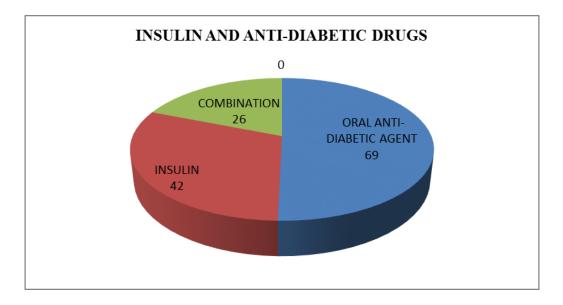


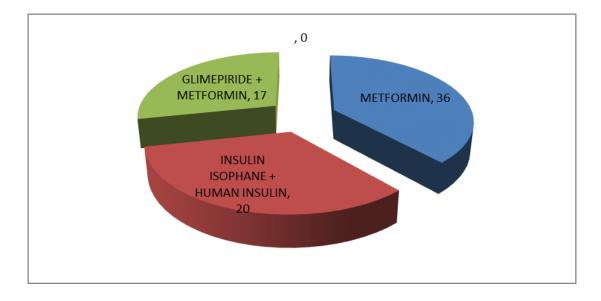
Figure No. 7: Distribution Based On Insulin and Oral Anti-Diabetic Drugs

# Distribution based on mostly prescribed anti-diabetic medications

(N=73)

# Table No. 8: Distribution Based On Mostly Prescribed Anti-Diabetic Medications

N. Vietza / //			
DRUGS	NUMBER OF PATIENTS		
METFORMIN HUN	1AN 36		
INSULIN ISOPHANE + HUMAN INSULIN	20		
GLIMEPIRIDE + METFORMIN	17		



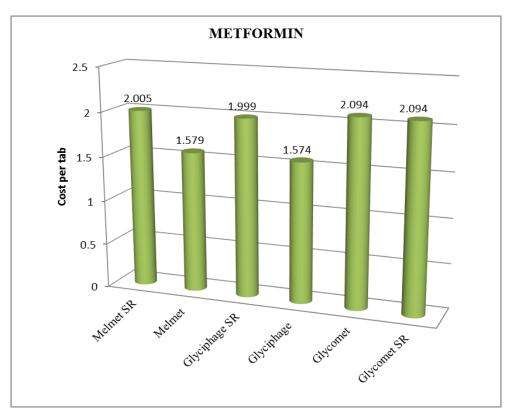


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# COST COMPARISON OF DIFFERENT BRANDS OF METFORMIN

DOSE	Melmet SR	Melmet	Glyciphage SR	Glyciphage	Glycomet	Glycomet SR
500 MG	2.005	1.579	1.999	1.574	1.579	2.094





# Figure No. 9: Cost Comparison of Different Brands of Metformin(Cost/Tab)

# COST COMPARISON OF DIFFERENT BRANDS OF GLIMEPIRIDE

Table No. 10: Cost Comparison of Different Brands of Glimepiride (cost/tab)

DOSE	Amaryl	Glimitab	Glimestar	Glimy
1MG	3.75	_	2.53	3.75
2MG	5.99	5.55	_	_

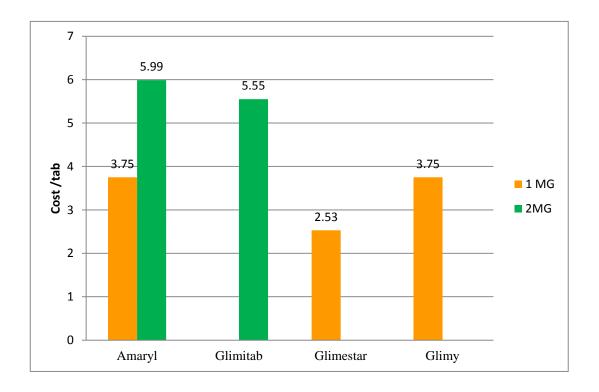


Figure No. 10: Cost Comparison of Different Brands of Glimepiride (cost/tab)

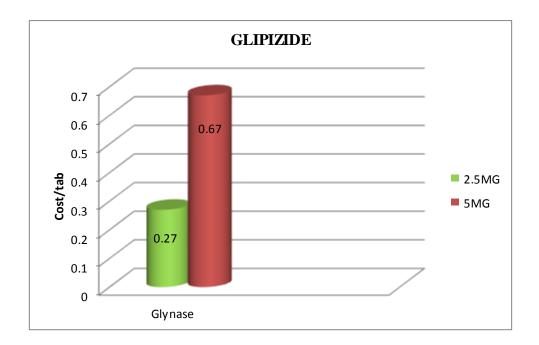
# COST COMPARISON OF DIFFERENT BRANDS OF GLIPIZIDE

 Table No. 11: Cost Comparison of Different Brands of Glipizide (Cost/Tab)

	MAN
DOSE	Glynase
2.5MG	0.27
5MG	0.67



72

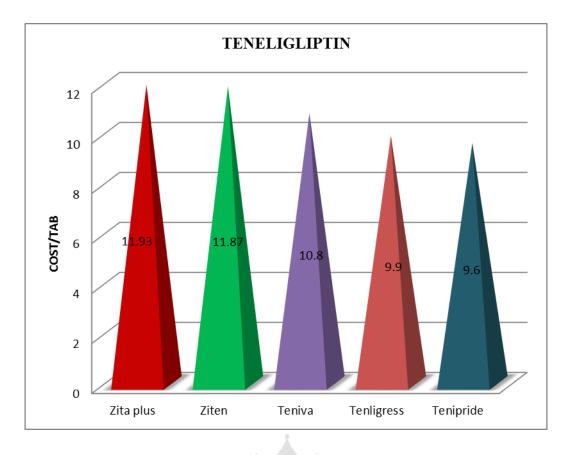




# COST COMPARISON OF DIFFERENT BRANDS OF TENELIGLIPTIN

Table No. 12: Cost Comparison of Different Brands of Teneligliptin (Cost/Tab)
Nutri //

DOSE	Zita plus	Ziten	Teniva	Tenligress	Tenipride				
20MG	11.93	11.87	A 10.8	9.9	9.6				



# Figure No. 12: Cost Comparison of Different Brands of Teneligliptin (Cost/Tab)

# COST COMPARISON OF DIFFERENT BRANDS OF VOGLIBOSE

DOSE	Vobose	Voglite
0.2MG	_	3.3
0.3MG	10.4	_

73

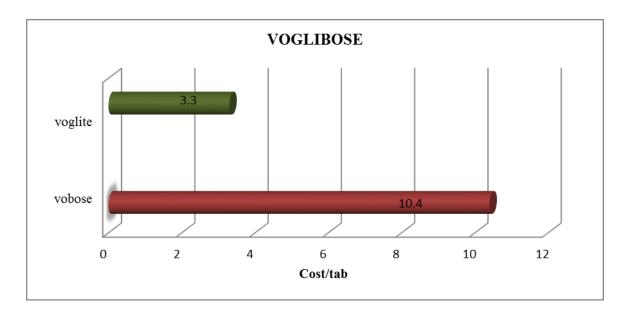


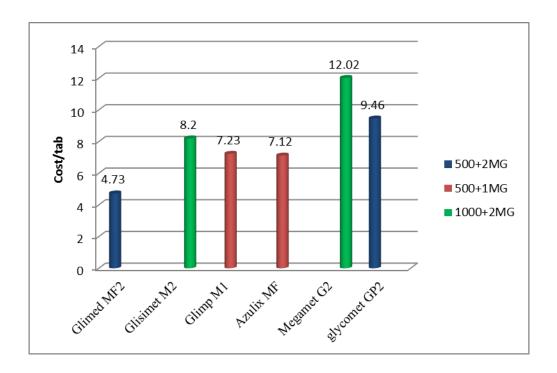
Figure No. 13: Cost Comparison of Different Brands of Voglibose

COST COMPARISON OF DIFFERENT BRANDS OF METFORMIN + GLIMEPIRIDE

 Table No. 13: Cost Comparison of Different Brands of Metformin + Glimepiride

 (Cost/Tab)

DOSE	Glimed MF2	Glisimet M2	Glimp M1	Azulix MF	Megamet G2	Glycomet GP2
500 +	4.73		пима	IN		9.46
2MG	4.75	—	—	—	—	2.40
500+			7.23	7.12		
1MG	—	—	1.25	1.12	—	—
1000 +		8.20			12.02	
2MG	—	8.20	_	—	12.02	—



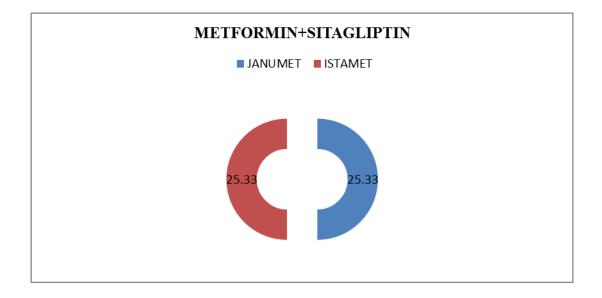


# COST COMPARISON OF DIFFERENT BRANDS OF METFORMIN+SITAGLIPTIN

 Table No. 14: Cost Comparison of Different Brands of Metformin+Sitagliptin

 (Cost/Tab)

DOSE	JANUMET	ISTAMET
500+50MG	25.33	25.33



# Figure No. 15: Cost Comparison of Different Brands of Metformin+Sitagliptin

Citation: Josvin Jose et al. Ijppr.Human, 2020; Vol. 18 (3): 713-739.

COSTCOMPARISONOFDIFFERENTBRANDSOFMETFORMIN+VILDAGLIPTIN

Table No. 15: Cost Comparison of Different Brands of Metformin + Vildagliptin(Cost/Tab)

DOSE	JALRA M	GALVUS MET		
500 + 50 MG	27.63	27.77		

# **METFORMIN+VILDAGLIPTIN**

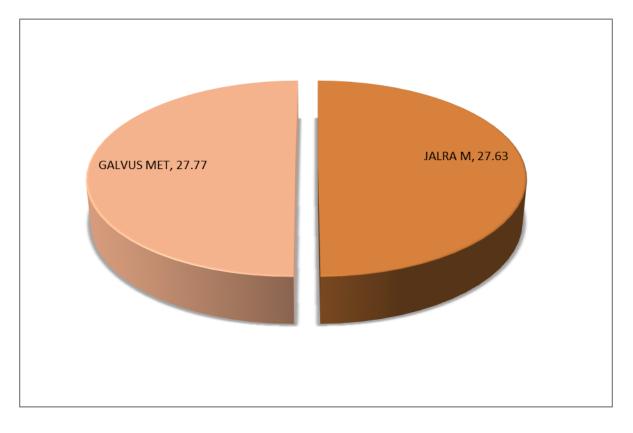


Figure No. 16: Cost Comparison of Different Brands of Metformin + Vildagliptin

TABLE No.	16:	MINIMUM	AND	MAXIMUM	COST	AMONG	MONO-DRUG
REGIMEN							

Sl. No.	Generic name	Strengt h [mg]	Least cost brand	Price (per tab)	Highest cost brand	Price (per tab)	Numbe r of brands	Averag e price	Percentage variation [%]
1	Metformin	500	Glyciphage	1.57	Glycomet SR	2.09	6	1.83	33.12
2	Glimepride	1	Glimestar	2.64	Amaryl	3.77	3	3.21	42.80
		2	Amaryl	5.99	Glimitab	6.76	2	6.37	12.85
3	Teneligliptin	20	Tenepride	9.60	Zita plus	11.93	5	10.77	24.27

# Single brand

Sl. No.	Generic Name	Strength [mg]	Brand	Price	Number of brands
4	Glipizide	2.5	Glynase	0.27	1
		5	Glynase	0.67	1
5	Vildagliptin	50	Galvus	26.52	1
6	Gliclazide	40	Glizid	3.75	1
		80	Glizid	6.05	1
7	Pioglitazone	15	Pioz	5.25	1
8	Voglibose	0.2	Voglibose	3.3	1
		0.3	Vobose	10.43	1

# TABLE No. 17: MINIMUM AND MAXIMUM COST AMONG COMBINATION DRUG

	DRUG			НИМ	1AN				
Sl. No.	Drug 1	Strength [mg]	Brand	Least Price	Brand	Highest Price	Number of brands	Mean	Percentage variation[%]
1	Metformin+ Glimepiride	500+ 1mg	Azulix MF	7.12	Glimp M1	7.23	5	7.17	1.54
2	Metformin+ Vildagliptin	500+ 50mg	Jalra M	27.63	Galvus met	27.77	2	27.70	0.50

# Single brand

Sl. No.	Drug	Strength (mg)	Brand	Price	No.of brands
3	Metformin+gliclazide	500+40	Glycinorm M 40	5.84	1
4	Metformin+glipizide	500+5	Glynase MF	1.53	1
5	Metformin + pioglitazone	500+15	Pioz MF	9.67	1
6	Metformin+sitagliptin	500+50	Janumet, Istamet	25.3	2

Citation: Josvin Jose et al. Ijppr.Human, 2020; Vol. 18 (3): 713-739.

Variables	Subgroups	General	questions	p-value	Significance	
variables	Subgroups	Adequate	Inadequate	p-value	Significance	
	35-45	1	1			
	55-45	(50)	(50)			
	46-55	12	3		NS	
	40-33	(80)	(20)			
Age group	56-65	13	6	0.220		
Age group		(68.42)	(31.58)	0.220		
	66-75	66.75 10		15		
		(40)	(60)			
	Above 75	6	13			
	A001075	(31.57)	(68.43)			

# **TABLE No. 18: QUESTIONNAIRE RESULT**

#### CONCLUSION

Diabetes mellitus is a group of metabolic disorders associated with abnormalities in carbohydrate, protein, and fat metabolism which results in hyperglycemia. Its risk factor can be related to obesity, history of GDM, hypertension, dyslipidemia, PCOD and history of cardiovascular disease. DM is frequently cause by physical inactivity and diet, which is often accompanied by excessive thirst and hunger, weight loss, blurred vision and skin infections.

From the above data, we found that in mono-drug regimen Metformin followed by Glimepride were frequently prescribed. When comparing the cost of mono-drug regimen and combination of Metformin &Glimepride, the combination therapy was found to be costlier. By assessing the patient's knowledge about diabetes using a DKQ we found that most of the patients were unaware of diabetes. So we done the patient counseling to improve the patient's knowledge.

The major advantage of our study is that it helps to decrease the overall health care cost and increase the patient's adherence which results in better patient outcome. The limitation is that no patients having diabetes from gynecology department is reported in our study. Most of our supporting studies shows that combination therapy is cheaper than mono- drug regimen. But our study result reflects that mono-drug regimen is cheaper when compared to combination therapy.

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