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Drug Utilization Evaluation and Cost Effective Analysis of Oral Anti - Hyperglycemic in DM-II

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Abstract: ***Aim:*** *To perform the drug utilization evaluation and cost effective analysis for oral anti hyperglycemic in type 2diabetic millets.* ***Objectives:*** *1) To carry out the prospective observational study of oral anti hyper glycemic agent, 2) To know the cost effective of prescribed drug, 3)To assess the clinical outcome. 4) To provide the patient counseling.* ***Methods:*** *The method uses prospective observational studied carried out in a tertiary care hospital for a period of six months.* ***Results:*** *1) 87% of the patient were prescribed with metformin and 13.33% were prescribed with glimepiride, out of 87% the 23% were given the combination of metformin and insulin and other 10% with combination of metformin and glimepiride. The cost effective analysis shows that metformin is the most cost effective drug. The results show that very few number of patients were aware about the knowledge and medication of diabetics.* ***Conclusion :*** *This study concludes that metformin is the most prescribed drug, Metformin is also most cost effective drug, Metformin is mostly prescribed to the patient who are with long dura*tion *of disease, Other than biguanide the other class of drug used is sulfonylureas and some patent were prescribed with combination with insulin with metformin*

Keywords: Observational study, drug utilization evaluation, metformin, sulfonylureas, patient counseling.

1. Introduction

Drug use is a complex process. Uncertainties in diagnosis, treatment and medication adherence contribute to wide variations in the way drugs are used for any given condition. In any country, a large number of sociocultural factors also contribute to the way drugs are used. In India, these include national drug policy, illiteracy, poverty, use of multiple health care systems, drug advertising and promotion, sale of prescription drugs without prescription etc. Inappropriate drug use may also lead to increased cost of medical care, anti-microbial resistance, adverse effects and patient mortality. One method to evaluate and improve drug use is conducting Drug Evaluation Studies.

1.1 Drug Use Evaluation

Drug use evaluation (DUE) is an ongoing, authorized and systematic quality improvement process, which is designed to:

1) Review drug use and/or prescribing patterns.
2) Provide feedback of results to clinicians and other relevant groups.
3) Develop criteria and standard which describe optimal drug use.
4) Promote appropriate drug use through education and other intervention
5) Improving prescriber awareness and practice towards appropriate prescribing.

DUE can play a key role in helping the healthcare system understand, interpret and improve the prescribing, administration and use of medications. DUE information may assist healthcare systems and hospitals to design educational programs that may improve prescribing and drug use. Some DUE programs may provide physicians with feedback on their performance and prescribing patterns compared to predetermined criteria or treatment protocols. DUE information may also physicians to compare their approach to treating certain diseases with their peers. The 'peer pressure' generated by these comparisons may be useful in motivating physicians to change their prescribing habits in an effort to improve care.

1.2 Diabetes Mellitus

Diabetes mellitus is a clinical syndrome characterized by hyperglycemia and disturbance of carbohydrates, fat and protein metabolism that are associated with absolute or relative deficiency of insulin action or secretion. Lack of insulin affects the metabolism of carbohydrate, protein and fat, and causes a significant disturbance of water and electrolyte homeostasis. Death may result from acute metabolic decompensation.

1.3 Indian Scenario

At present, India is considered as the diabetic capital of the world. There are approximately 3.5 crore diabetics in India, and this figure is expected to increase up to 5.2 crore by 2025. Every fifth patient visiting a consulting physician is a diabetic and every seventh patient visiting a family physician is a diabetic. Keeping in view the alarming increase in the incidence and prevalence of diabetics in India, the World Health Organization (WHO) has declared India as the 'Diabetic Capital' of the world.

1.4 Complications

The complications of diabetes can be classified as:

1) Acute Problems: (Otherwise termed the diabetic medical emergencies)
   a) Diabetic ketoacidosis.
   b) Hypoglycaemia.
2) The Chronic Complications Of Diabetes:

a) Microvascular complications.
b) Macrovascular complications

2. Literature Review

1) D'Alessio, in et al. conducted a study over a period of 2 years. Their study includes over 600 patients having type 2 diabetes mellitus by using suitable questioners. A total of 380 females and 320 males were investigated with serum profile. The patient's knowledge about the disease. Their attitude and practices were the main outcome measures. This study concluded that this type of studies should be conducted on a large scale in India so that it is possible to design awareness program me to promote prevention. This study carried out the scientific review and clinical applications with source from med line searched which concluded that with few exceptions the available anti diabetic agent are equally effective at lowering glucose concentration. Their MOA are different as results they appear to have distinct metabolic effect these are reflected in their adverse effects profiles and their effect on serious risk which may influence drug choice.

2) L.D Roberts D.G et al. assessed knowledge of type 2 diabetes management and control in diabetic patients clinical practice guidelines for the prevention and management of diabetic in Canada in year 2007. A descriptive research design and a sample of 500 patients were used. More than 80% of the patients knew about the diabetes it's signs and symptoms, complications. On knowledge of management of diabetes 74% know how to avoid complications and prevention/control diabetes respectively. The drug metformin in 33% relative in diabetes Oral hypoglycemics agents are currently approved for only treatment and not for the prevention.

3) L. Kuritzky, G.P et al. conducted study on oral anti-hyperglycemic agents in management of type 2 diabetes mellitus in 2008 in France. The study reported that 90% of diabetics had received some education about diabetes mellitus. Most of the patients knew about the other information like risk factors, signs and symptoms and management and monitoring of the disease. Among the informed diabetics various issues like cost and lack of motivation need to addressed to close the gaps between knowledge and drill especially with regards to glucose levels monitoring and regular exercise. Among the all sulfonyl urease metformin has the more advantage. oral anti diabetic compounds have and establish role in the treatment of type 2 diabetes sulfonyl urease and metformin are most used drugs.

4) Kannan S, Arshad et al. performed study on drug utilization of oral anti hyper glycemic drugs in type 2 diabetes mellitus patients. The main objective of the study to find out the knowledge and awareness of diabetic retinopathy among diabetes patients. Diabetic retinopathy usually occurs due to poor management of diabetes mellitus and lack of knowledge on the complications of diabetes mellitus. There is general awareness of diabetic retinopathy amongst the majority of patients 83% there is however little or no knowledge of its risk and prevention. Therefore there is a need to increase awareness and also the provision of access to retinopathy screening services to the patients.

Table 2: Prevalence of diabetes in urban India since 2000

Region	*Year*	*Age*	*DM*	*IGT*	*IFG*
National	2000	>20	12.1%	14%	…..
Ramachandran et al					
Reddy et al	2003	20-69	8.4%	6.3%	6.4%
Northern India	2000	>20	11.6%	8.6%	…….
Ramachandran et al					
Gupta et al	2003	>20	8.6%	…..	5.3%

3. Methodology

A comparative prospective study will be carried out for comparing have type 2 diabetes mellitus to the standard criteria accepted by the **International Diabetes Federation** (IDF). The study was conducted in Department of General Medicine in MALLA REDDY HOSPITAL and NARAYANA HRUDAYALAYA Which is 500 bedded Multispecialty Hospital. This study is proposed to be conducted for six months, from November 2015 to April 2016.

Study Criteria:

Inclusion Criteria:
Patients with TYPE 2 Diabetes Mellitus.
Patients Using Initial Therapy of Diabetes.
Gestational diabetic patients.

Exclusion Criteria:
Patients below age 18 years, Patients who did not give consent, Patients already part of this study who was again readmitted during study period., Patients discharged to long-term care facility. Pregnant women.

4. Results

A prospective observational study with 150 Diabetic patients is undertaken to assess the drug utilization evaluation of Diabetes and patient counseling in a teaching hospital. Prospective Observational study as the use of drug for oral anti-hyperglycemic therapy:

Drug	*No. Of Patients*	*Percentage*
METFORMIN	130	86.66%
GLEMIPRIDE	20	13.33%
METFORMIN+ INSULIN	35	23.33%
METFORMIN+ GLEMIPRIDE	10	6.66%

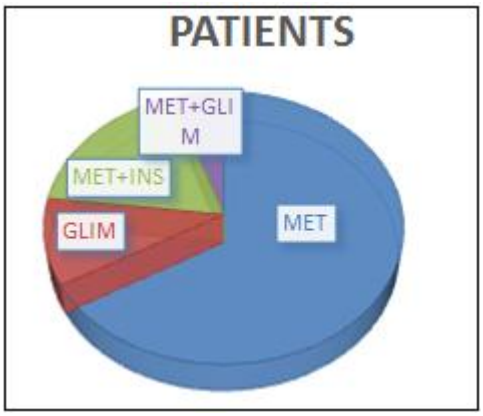


Table 1: Gender distribution of patients

Gender	*Number*	*Percentage*
Male	60	40%
Female	90	60%
Total(n=150)	150	100%

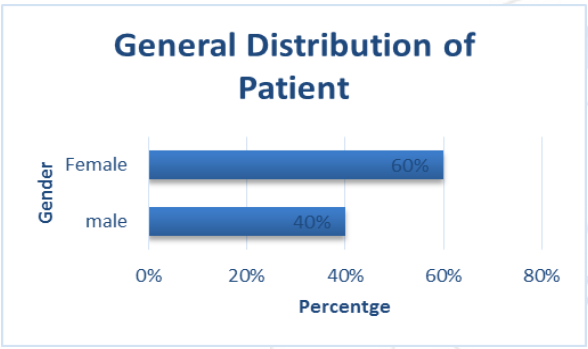


Table 2: General distribution of patients in In-patient and Out-patients

Department	*Number*	*Percentage*
In-patient	130	86.66%
Out-patient	20	13.33%
Total(n=150)	150	100%

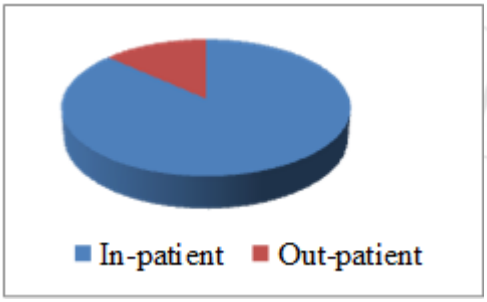


Table 3: Age distribution in patients

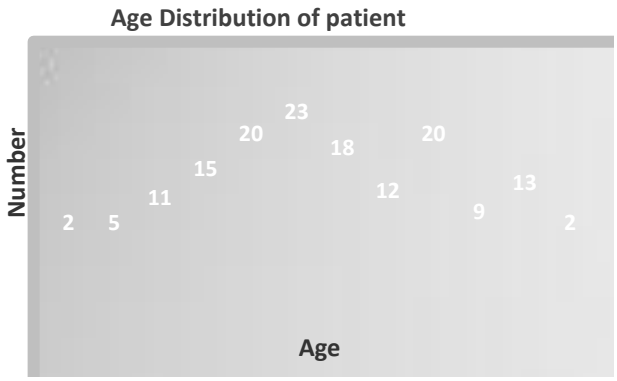


Table 3: Age Distribution among Patients

Age(Years)	*Number*	*Percentage*	*Drug Prescribed*
20-25	2	1.3%	Metformin
26-30	5	3.3%	Metformin
31-35	11	7.3%	Metformin with glimipride
36-40	15	10%	Metformin
41-45	20	13.3%	Metformin
46-50	23	15.3%	Metformin
51-55	18	12%	Metformin with insulin
56-60	12	8%	Metformin
61-65	20	13.3%	Metformin
66-70	9	6%	Metformin
71-75	13	8.6%	Metformin with insulin
76-80	2	1.3%	Metformin with insulin
Total (n= 50)	150	100%	

Table 4: Occupation distribution of patient:

Occupation	*No. Of Patients*	*Percentage*
Employed	10	6.6%
Unemployed	40	26.5%
House-wife	25	16.66%
Retired	75	50.0%
Total(n=150)	150	100%

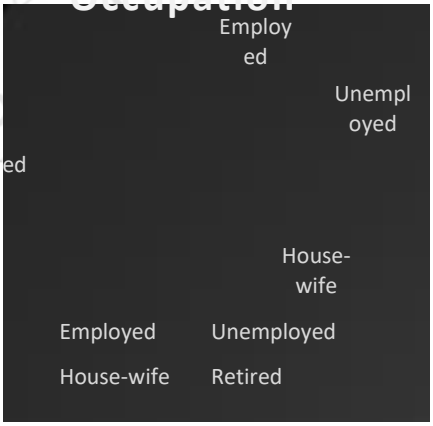


Table 5: Education distribution of patients studied:

Education	*No. of Patients*	*Medication knowledge*	*Percentage*
Illiterate	55	20	13.33%
1-5 Class	15	25	16.66%
6-10 Class	10	20	13.33%
11- Graduation	28	40	26.66%
Post-Graduation	42	45	30%
Total(n=150)	150	150	100

Table 6: Personal habits studied in Diabetic Patients

Habits	Number	Percentage
Tea	15	10.0%
Alcohol	20	13.33%
Smoking/ Tobacco	25	16.66%
Paan(Betel leaf)	40	26.66%
None	50	33.33%
Total(n=150)	150	100%

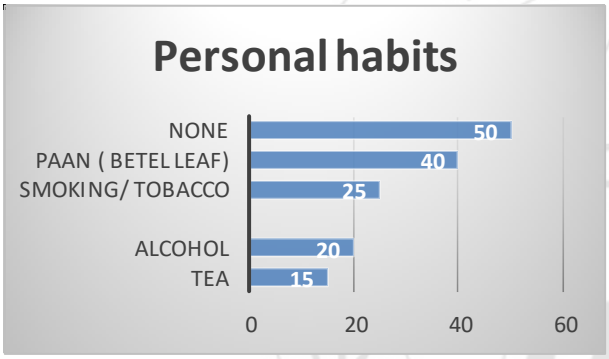


Table 7: Number of patients studied with Co-morbidities

Disease	Number	Percentage	With drug
Hypertension	60	40.0%	
Heart disease	18	12.0%	
Renal impairment	22	14.66%	
Others	12	8.0%	
None	38	25.33%	
Total(n=150)	150	100%	

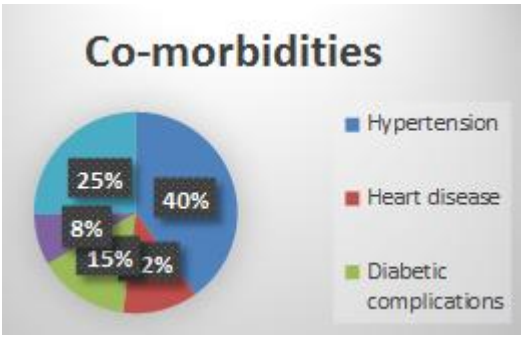


Table 8: Family history of Diabetes studied in Diabetic patients

History	Number	Percentage
Positive Family History	90	60.0%
Negative/No family History	60	40.0%
Total(n=150)	150	100%

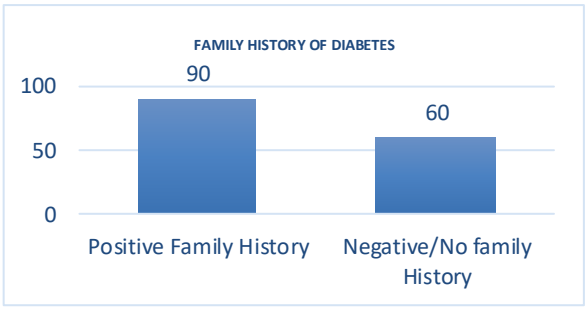
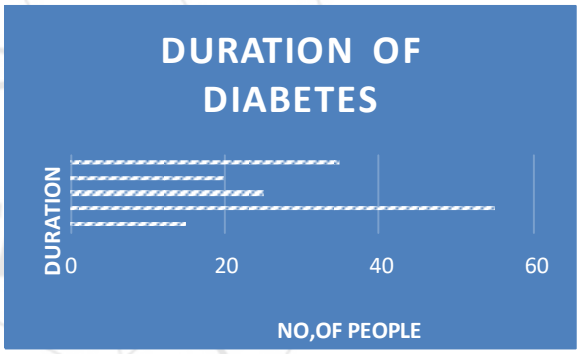


Table 9: Duration of Diabetes (History of Diabetes):

Duration of Disease	No. of people	Percentage	With drugs
1-11 months	15	10.0%	
1-5 years	55	36.66%	
6-10 years	25	16.66%	
11-20 years	20	13.33%	
> 20 years	35	23.33%	
Total	150	100%	



Cost Effectiveness of Oral Anti Hyperglycemic Therapy

Drug	BA	DOA	T 1/2	No. of doses/day and cost per tab
Metformin	50-60%	8-12hrs	4-8.7 hrs.	500mg first the dose is not more than 2000 mg/day, Rs 3
Glimepiride	100%	12-18hrs	5hrs	1-2mg/day not to exceed more 8mg/day Rs 11
Metformin + insulin	Insulin: 40-50IU.	20-24hrs.	2hrs.	500mg OD can inc.500mg every week if req.dose is not more than 2500mg/day Rs140-210
Metformin + glimepiride				Determine the dose with each medicine: met:500mg/day Glim:1 – 2 mg/day

5. Discussion

In the present study, 150patients had diabetes, among 90 patients had a family history of diabetes and 60 patients had no family history, a finding similar to that obtained in study conducted by **Alex *et al.*** Duration of diabetes has a significant role in its management. Patients who have diabetes for <5years could usually be managed with single drug therapy while combination therapy is required in patients having more than this period. In the present study, most of the patients (36.6%) had a diabetic history of <5years, a findings consistent with that of the study of **Alex *et al.*** Co-morbidity has been shown to intensify health care utilization and to increase medical care costs for patients with diabetes. And majority of the patient with co-morbidities are predominant than without co morbid conditions, Hypertension was the most common co-morbid condition, which is similar to the study conducted by **Kannan *et al* and Alex *et al.***

Monotherapy v/s multi therapy: The present study result shows number of drugs prescribed multi therapy less as compared to monotherapy. In our study, it was found that Metformin(86.66%) was the commonly prescribed drug followed by combination of Metformin + Glimepiride 23.33%, similar to the study conducted by **Alex *et al*** and is contradicted to the study reported by **Kannan *et al***

Drug under utilization of anti-diabetics: the study showed that different anti-diabetic drug prescribed alone or in combination which totally 3drugs constitute in utilization which includes metformin, glimepiride, and insulin. Cost of drug therapy is a cause for non adherence. In the present study a total of 150 patients the cost of drugs in **xx**patients was % and it was affordable comparing to the combination of drugs in **xx** patients

6. Conclusion

Prospective Observational study for drug utilization evaluation on oral anti-hyperglycemic was carried out on 150 patients in a tertiary care hospital. Patient counseling was provided to 100 patients regarding the disease and the drug knowledge. The main drugs noted in this study are metformin, glimepiride, metformin with insulin and metformin with glimepiride in combination. It shows that metformin is the most commonly prescribed drug which is prescribed to about 130 patients. The females were higher in number 90 i.e., 60% in the study. Strategically data include 87% of the inpatients. The mean age of the patient in the study is found to be 40-60. Education patter in the subject was observed to be in relation to the medication knowledge. About 90% of the patients were with family history of diabetes. The patients with only metformin were using the drug since long duration. 53% says that alcohol & smoking can worsen the health in diabetic patients. About 60% were aware of the sign and symptoms of diabetes. And 60% patients consider medication more important than diet and exercise. A large group was aware of regular monitoring of blood glucose level and about maintenance of their records. 20% of the patients were not aware of normal value of blood glucose level. Only 30% of the patients were having knowledge about the diet to be followed. 90% of the patients prefer an extra tablet when they have sweets. 33% of patients were aware of the drug names they are using.

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