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Research article

DRUG UTILIZATION PATTERN OF ANTI-DIABETIC DRUGS IN A TERTIARY CARE HOSPITAL OF SOUTH INDIA, TRIVANDRUM

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ABSTRACT

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Drug utilization evaluation is employed to assure quality care by assessing the appropriateness of drug therapy. The purpose of the study is to evaluate the drug use that will help to ensure that medicines are used appropriately and thus improving patient care and outcome. It was a prospective, observational study conducted in a tertiary care multispecialty hospital in Trivandrum. The duration of the study was six months. A total of 110 diabetic patients were evaluated during the study period. Out of these patients, 42 were males and 68 were females. It was recorded that 59.09% of participants had a family history of diabetes. Total 278 anti-diabetic drugs were prescribed. In which 130 drugs were prescribed as monotherapy, 71 drugs as the two-drug combination and 6 drugs as a three-drug combination. Metformin was the only anti-diabetic drug that was commonly prescribed in both monotherapy and in combination therapy. Most of the patients had comorbid condition along with diabetes in which hypertension was most prominent. This study reveals that Metformin continues to be the best choice of the oral hypoglycemic agent with least adverse effects and the pattern of anti-diabetic prescription was largely comply with NICE guidelines.

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INTRODUCTION

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels (Diagnosis and Classification of Diabetes Mellitus, 2018). The management of type 1 Diabetes depends mainly on Insulin whereas type 2 diabetes is mainly managed by Insulin and OHAs (Oral hypoglycemic agents). The Center for Disease Control and Prevention (CDC) has released a report estimating the prevalence and incidence of diabetes and there are 30.3 million people with diabetes, including 23.1 million people who are diagnosed and 7.2 million peoples are undiagnosed (The National Diabetes Statistics, 2017). Drug utilization evaluation is a process employed to assure quality care by assessing the appropriateness of drug therapy via the evaluation of data on drug use in a given healthcare environment and comparing this use against predetermined criteria and standards (Drug Utilization Evaluations, 2018).

The purpose of the study is to evaluate the pattern of drug use that will help to ensure that medicines are used appropriately and thus improving patient care and outcome (Drug and Therapeutics Committees, 2018).

MATERIALS AND METHOD

It was a prospective, observational study. The study was carried out at a tertiary care multispecialty hospital in Trivandrum. The duration of the study was six months. This study was conducted only after obtaining approval from the institutional ethics committee.

Inclusion criteria

- Either gender is included.
- Age more than 30 years
- Patients with type 2 diabetes

Exclusion criteria

- Gestational diabetes mellitus
- Incomplete medical records
- Age less than 30 years
- Mentally challenged patients
- Patients with type 1 diabetes.
- Newly diagnosed patients.

Study population

Sample size of 110 patients was included in the study. All patients with 30 years and above diagnosed with type 2 diabetes attending the outpatient's department of medicine of a tertiary care hospital and on drug therapy were included in the study. The details were collected from their case files and were recorded in the specially designed patient profile form.

Socio-demographic and relevant clinical data of participants was noted. The socio-demographic details included age, sex, gender, educational status, geographical area, social history and family history. clinical and biochemical data included a number of symptoms, fasting and postprandial blood glucose level, duration of diabetes, comorbidities, polypharmacy, drugs prescribed. Glycemic control was determined by latest FBG and PPBG levels.

Statistical analysis

Details were collected by using specially designed Performa were analyzed by using descriptive statistical methods.

RESULTS

Based On Gender

A total of 110 patients were enrolled in the study, 42 (38.18%) were males and 68 (61.81%) were females.

Based on Age

Out of 110 patients included for the study, 2 (1.81%) patients had an age 30-35, 1 (0.90%) patients had an age 35-40, 3 (2.72%) patients had an age 40-45, 10 (9.09%) patients had an age 45-50, 8 (7.27%) patients had an age 50-55, 12 (10.90%) patients had an age 55-60, 24 (21.81%) patients had an age 60-65 , 20 (18.18%) patients had an age 65-70,16 (14.54%) patients had an age 70-75, 11 (10%) patients had an age 75-80, 3 (2.72%) patients had an age 80-85.

Based On Family History

In the present study, 110 patients participated and it was recorded that 59.09% of participants had a family history of diabetes.

Based on Area of Residence

The majority 57 (51.81%) of patients were from the urban area and 53 (48.18%) from a rural area.

Based on Educational Status

The majority of the patients 26 (23.63%) were from the graduate level of education and only 7 (6.36%) were from the postgraduate group and there are patients from all segments of education class.

Based on Comorbidities

Out of 110 patients, diabetes was associated with hypertension (36%), DLP (27.5%), CAD (14.22%), Thyroid (11.11%), Gout (2.6%), Neurological complaints (1.77%), COPD (1.77%), Arthritis (2.22%), Asthma (1.33%), UTI (0.88%), CLD (0.44%).

Based on Fasting Blood Sugar (FBS)

Based on fasting blood sugar 54 patients were in the FBS level of 100-150 mg/dl followed by 28 patients (150-200mg/dl), 12(50-100mg/dl), 9(200-250mg/dl), 5 (250-300mg/dl) respectively.

Based on Duration of Diabetes

The majority of patients 55 (50%) having the diabetic duration of 1-10 years, 33 (30%) patients having 11-20 years, 19 (17.2%) patients have 21-30 years and 3 (2.72%) patients have greater than 30years.

Frequency of Drugs Prescribed

Among these patients, the most commonly prescribed OHA was metformin which was preferred as monotherapy as well as for combined therapy with other agents like gliclazide, glimepiride, glipizide, vildagliptin, sitagliptin, and miglitol. The most commonly prescribed two-drug combinations were metformin and glimepiride and three-drug combinations are metformin, glimepiride and voglibose (1.07%) and metformin, glimepiride and pioglitazone (1.07%).

Among 110 prescriptions, 278 anti-diabetic drugs were used in the encounters in which 130 were

monotherapy (46.76%), 71 (25.53%) drugs were included in the two – drug combination, 6 (2.15%) drugs were a three-drug combination and 71 (25.53%) drugs were insulin.

Table 1. Gender Categorization

S. NO.	SEX	NO. OF PATIENTS	% OF PATIENTS
1.	Male	42	38.18
2.	Female	68	61.81

Table 2. Age Group Categorization

SL. NO.	AGE	NO. OF PATIENTS	% OF PATIENTS
1	30-35years	2	1.81%
2	35-40years	1	0.90%
3	40-45years	3	2.72%
4	45-50 years	10	9.09%
5	50-55 years	8	7.27%
6	55-60 years	12	10.90%
7	60-65 years	24	21.81%
8	65-70years	20	18.18%
9	70-75 years	16	14.54%
10	75-80 years	11	10%
11	80-85 years	3	2.72%

Table 3. Family History

SL NO	FAMILY HISTORY (positive/negative)	NO:OF PATIENTS	PERCENTAGE
1	POSITIVE HISTORY	65	59.09%
2	NEGATIVE HISTORY	45	40.90%

Table 4. Percentage distribution based on area of residence

SL:NO	Urban/Rural	Number of patients	Percentage (%)
1	Urban	57	51.81
2	Rural	53	48.18

Table 5. Percentage distribution based on educational status

SL: No	Level Of Education	No: of patients	Percentage (%)
1	Below Primary	12	10.90%
2	Primary	19	17.27%
3	Secondary	23	20.90%
4	Higher Secondary	23	20.90%
5	Graduate	26	23.63%
6	Post Graduate	07	06.36%

Table 6. Distribution depicting comorbidities

Sl. No.	Disease	No: of patients with comorbidities	Percentage (%)
1	HTN	81	36
2	DLP	62	27.55
3	CAD	32	14.22
4	THYROID	25	11.11
5	GOUT	6	2.66
6	NEURO	4	1.77
7	COPD	4	1.77
8	ARTHRITIS	5	2.22
9	ASTHMA	3	1.33
10	UTI	2	0.88
11	CLD	1	0.44

Table 7. Distribution based on Fasting blood Sugar Values

SL No:	FBS Range	No: of patients	Percentage (%)
1	50-100	12	10.90
2	100-150	54	49.09
3	150-200	28	25.45
4	200-250	9	8.18
5	250-300	5	4.54
6	300-350	1	0.90
7	350-400	1	0.90

Table 8. Distribution based on duration of diabetes

SL No:	Duration of diabetes mellitus(years)	No: of patients	Percentage (%)
1	1-10	55	50
2	11-20	33	30
3	21-30	19	17.2
4	>30	3	2.72
	TOTAL	110	100

Table 9. Frequency of OHA Prescribed

SL NO:	Drugs (OHA)	No: of drugs prescribed	Percentage (%)
	MONOTHERAPY		
1	Glimepiride	18	6.47
2	Metformin	35	12.58
3	Sitagliptin	4	1.43
4	Pioglitazone	3	1.07
5	Miglitol	1	0.35
6	Vildagliptin	4	1.43
7	Teneligliptin	15	5.39
8	Gliclazide	10	3.59
9	Acarbose	3	1.07
10	Repaglinide	1	0.35
11	Voglibose	33	11.87
12	Canagliflozin	1	0.35
13	Saxagliptin	1	0.35
	Dapagliflozin	1	0.35
	TWO-DRUG COMBINATION		
14	Glimepiride+Metformin	44	15.82
15	Metformin+Vildagliptin	4	1.43
16	Glipizide+Metformin	7	2.51
17	Sitagliptin+Metformin	12	4.31
18	Gliclazide+Metformin	3	1.07
19	Metformin+Miglitol	1	0.35
	THREE DRUG COMBINATION		
20	Glimepiride+Metformin+Voglibose	3	1.07
21	Glimepiride+Metformin+Pioglitazone	3	1.07
	TOTAL	**207**	**100**

Table 10. Frequency of Insulin Prescribed

SL NO:	Types Of Insulin	No: of prescription	Percentage (%)
1	Huminsulin	13	4.67
2	Humalog	8	2.87
3	Actrapid	4	1.43
4	Novomix	10	3.59

5	Insuman combo	4	1.43
6	Human Mixtard	26	9.35
7	Lantus	1	0.35
8	Novorapid	3	1.07
9	Normaxin	1	0.35
10	Insulatard	1	0.35
	TOTAL	**71**	**100**

Table 11. Frequency of Anti - diabetic drugs prescribed

SL NO:	Drugs	No: of drugs/prescription	Percentage (%)
1	Monotherapy	130	46.76
2	Two drug combination	71	25.53
3	Three drug combination	6	2.15
4	Insulin	71	25.53
	TOTAL	**278**	**100**

Fig 1. Percentage Gender Distribution
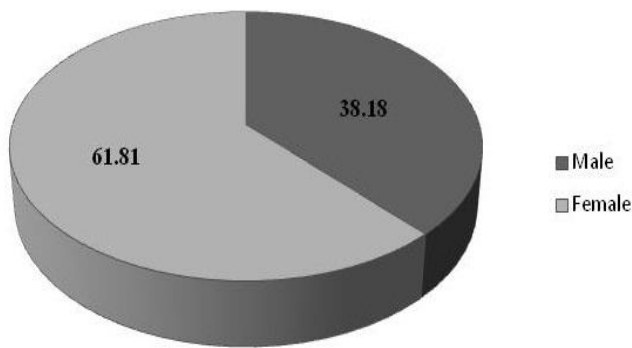
Fig 2. Percentage Distribution of Age
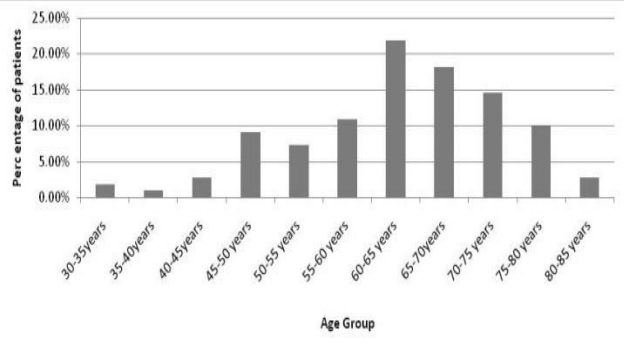
Fig 3. Percentage Distribution based on familial history
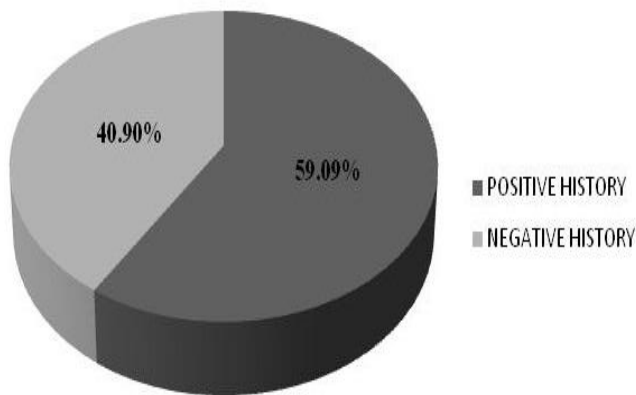
Fig 4. Percentage distribution based on educational status
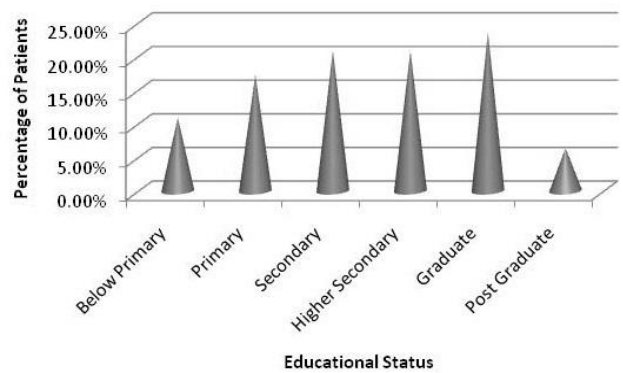
Fig 5. Percentage distribution based on comorbidities
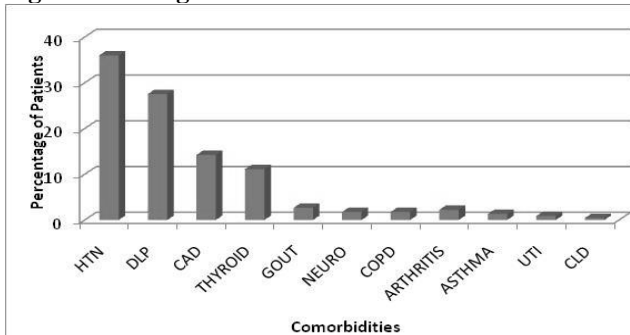
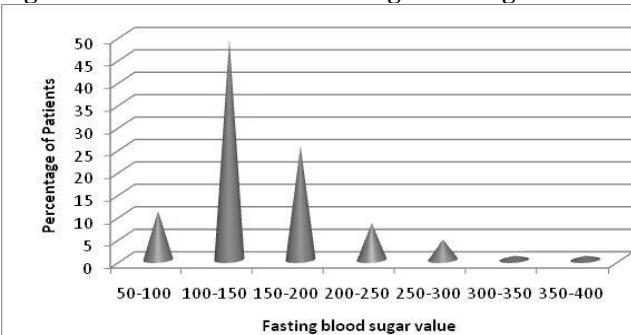**Fig 6. Distribution based on fasting blood sugar values**

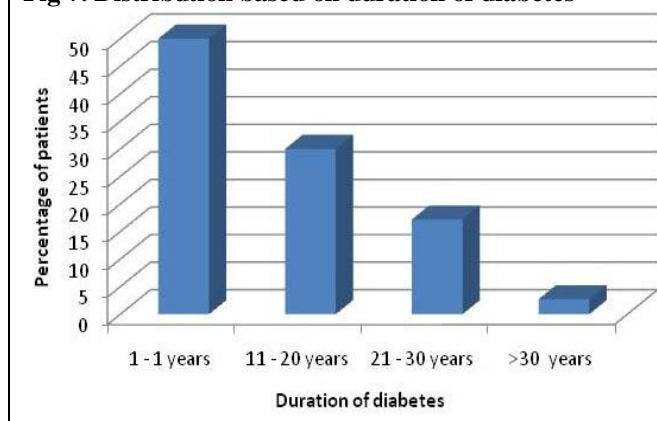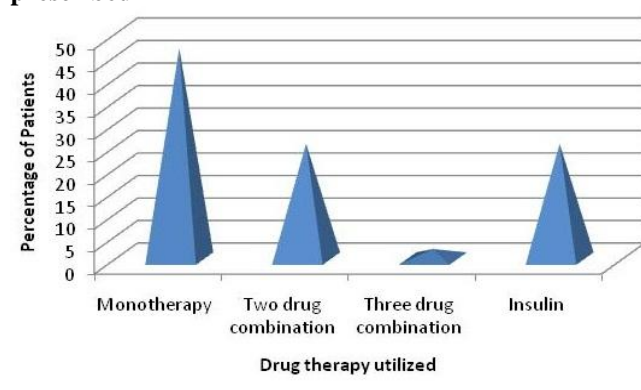**Fig 7. Distribution based on duration of diabetes**

Fig 8. Percentage distribution of Anti - diabetic drugs prescribed

DISCUSSION

A total of 110 diabetic patients were evaluated during the study period. Out of these patients, 42(38.18%) were males and 68(61.81%) were females. Similar results were found in previous studies (Thushara C *et al.,* 2018; Kumar V *et al.,* 2017; Siddhartha N *et al.,* 2016; Satpathy SV *et al.,* 2016) . Majority of patients (24) were in the age group of 60-65 years (21.81%) followed by 20 (18.18%) patients in the age group of 65-70, followed by 16 (14.54%) patients in the age of 70-75, and 12 patients (10.90%) in the age group of 55-60 respectively. The results of the study were in accordance with a study conducted in Karnataka, Dhaka, Mumbai (Pavan G *et al.,* 2016; Karim R *et al.,* 2016; Ashutosh K *et al.,* 2017). Among them 110 hypertension being the commonest comorbidity (36%), followed by DLP (27.5%), CAD (14.22%), Thyroid (11.11%) (Mandal S *et al.,* 2016). Our study reveals that about 54 patients were in the FBS level of 100-150 mg/dl followed by 28 patients (150-200mg/dl) 12 patients had (50-100mg/dl), 9 patients had (200-250mg/dl), 5 patients had (250-300mg/dl) respectively. The study found that majority of patients 55 (50%) having the diabetic duration of 1-10 years, 33 (30%) of patients having 11-20 years, 19 (17.2%) patients have 2130 years and 3 (2.72%) patients have greater than 30years. In the present study, it was recorded that 59.09% of participants had a family history of diabetes, the results contrast with the studies done in U.A.E (Lisha JJ *et al.,* 2012; Ramesh R *et al.,* 2011; Venkateswaramurthy N *et al.,* 2016). The majority 57 (51.81%) patients were from the urban area and 53 (48.18%) from a rural area (Purushothaman A *et al.,* 2015). 23.63% were from the graduate level of education and only 6.36% were from the postgraduate group (Patel B *et al.,* 2013; Ahmed Z *et al.,* 2016; Sultana G *et al.,* 2010). Total 278 anti-diabetic drugs were prescribed. In which 130 drugs were prescribed as monotherapy and 71 drugs as the two-drug combination and 6 drugs as a three-drug combination. The result of the study was in accordance with the study conducted in Tamil nadu. Metformin was the only anti-diabetic drug that was commonly prescribed in both monotherapy and in combination therapy in the present study. Metformin is a peripheral sensitizer of insulin and has beneficial effects on insulin resistance it's an important factor in the pathogenesis of type – 2 diabetes accordingly, metformin was reported as the first drug of choice for most of the patients with type 2 diabetes (Sultana G *et al.,* 2010). Metformin does not promote weight gain and help to prevent cardiovascular risk factors. This result contrasts the reports of some studies done in Indore (Sudha V *et al.,* 2008). In this study among second-generation sulphonylureas, glimepiride was most commonly prescribed. Glimepiride was prescribed for (6.47%) of total drugs. The main advantage of glimepiride was its long half-life and better compliance there for it reduces the risk of hypoglycemia. Among fixed drug combination the study was found that combination of metformin and glimepiride was the commonly prescribed regimen followed by metformin + sitagliptin (4.31%), glipizide + metformin (2.51), metformin + vildagliptin (1.43%), metformin + gliclazide (1.07%) ,metformin + miglitol (0.3%). Among three-drug combinations, the combination of metformin, glimepiride, and voglibose (1.07%), and metformin, glimepiride, and pioglitazone (1.07%) 5 was highly prescribed. Voglibose comes under alpha – glucosidase inhibitor that helps to lower the daily glycemic conversions and inhibits overwork of the pancreatic beta cells. Pioglitazone comes under thiazolidinedione's that help to increase insulin sensitivity to target tissues.

CONCLUSION

Prospective observational study for drug utilization evaluation on oral anti-diabetic was carried out on 110 patients in a tertiary care hospital. The females were higher in number 68 ie, 61.81% in the study. Majority of sample population belongs to an age group of 60-65years (21.81%).The family history of parents diabetic was noted in 59.09% patients. Majority of the respondents were from the urban area (51.81%). Most of the patients from post graduate level. Most of the patient had co-

morbid conditions along with diabetes. Most commonly seen co-morbid condition in this study was hypertension. Majority of prescriptions had a diabetic duration of 1-10 years.

Monotherapy was found to be predominant over combination therapy. The study has shown metformin as the predominantly prescribed oral anti-diabetic drug both as monotherapy as well as combination therapy. Glimepride + metformin combination was the most commonly prescribed combination. This study revealed that the pattern of antidiabetic prescription was rational and comply with NICE (national institute for health and clinical excellence) guidelines.

LIMITATIONS OF THE STUDY

It was a short-term research project; the restricted sample size restricts the generalization of findings. Therefore, similar studies need to be conducted in a larger number of populations to confirm our findings.

Certain information was recorded according to the statement of the respondents; as such the validity of the statement is questionable, the result depends upon the validity of the statement given by the respondent.

ACKNOWLEDGEMENT
Nil

CONFLICT OF INTEREST
No interest

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