



## DRUG USE PATTERN AMONG DIABETIC HOSPITALIZED PATIENTS MANAGED WITH ORAL HYPOGLYCEMIC DRUGS, INSULIN, BOTH ORAL HYPOGLYCEMIC DRUGS AND INSULIN IN TERTIARY CARE TEACHING HOSPITAL

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### ABSTRACT

To observe and document the drug use pattern in hospitalized diabetic patients. To determine the choice of therapy based on age, gender, complications, duration of the disease. To find out the commonly occurring adverse drug reactions associated with antidiabetics. The present study involves prospective observational study for patients with diabetes. The methodology involves collection and documentation of patients medical and medication history, blood glucose levels, and duration, choice of therapy with diabetes. During the period of study, a total of 143 cases were collected and reviewed, among that 91% cases were type 2 diabetes mellitus and 9 % cases were type 1 diabetes mellitus. In this study females were higher in range than males. Most of the patients were with the age group of 41 to 60 followed by the age group 61 to 70 was affected by diabetes mellitus. The overall study shows Insulin was used more in most of the prescriptions for both single as well as doublet therapy. Next, to that Metformin was used as first line agent all type2 diabetes patients. Sulfonylureas such as Glimpiride Glibenclamide were used as second line agent. Oral anti-diabetic drugs still dominate the drug prescribing pattern, but there was a little change in the study towards the use of Insulin preparations in the management of Type 2 diabetes mellitus because of the severe diabetic level and insulin deficiency. Insulin preparations were found to be more effective than oral anti-diabetics for hospitalized patients.

**Key words:** Diabetes, Anti-diabetic drugs, Single therapy, Combination therapy, OHA (Oral Hypoglycaemic Agents)

### INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder resulting from the deficiency of insulin secretion or may be excessive insulin secretion. It is one of the major health problems among the worldwide and leads to an increase in the cause of morbidity and mortality rate. Hospitalization was the major concern among diabetic patients due to the severity of the disease. Long-term treatment is not possible for the hospitalized patients because of a short-term stay in the hospital. The main goal for Diabetic inpatients was to prevent mortality and complications by normalizing blood glucose level. Diabetes is also a major risk factor for cardiovascular disease, stroke, and kidney failure. The prevalence rate of diabetes among worldwide was estimated to be 2.6% in 2000 and 4.4% in 2030. Diabetes mellitus requires continuous medical care and create awareness about the disease and improve patient education to prevent acute complications and to reduce the risk of long-term complications. The management of hospitalized diabetic patients differs from outpatients in terms of goals and treatment measures. Drug utilization studies are the most effective tool for evaluating the healthcare systems as well as to promote rational prescriptions. Poor glucose controls in diabetes mellitus can be controlled by rational use of Oral Hypoglycemic Agents (OHAs) and insulin. This study shows the drug use pattern among diabetic patients and analyzes the prescriptions according to WHO core drug prescribing indicators.<sup>1-6</sup> The irrational use of drugs is an another problem and it can be managed with WHO guidelines and it helps to promote the rational drug use. Irrational prescribing may cause failure in treatment and leads to make burden, distress, anxiety and increased costs.<sup>7</sup>

**Aim:** The main aim of the study is to study the anti- diabetics among inpatients in a tertiary care teaching hospital.

**Objectives:** To observe and document the drug use pattern in hospitalized diabetic inpatients. To determine the choice of therapy based on age, gender, complications, duration of the disease. To determine the most frequently used drugs in this study. To find out the commonly occurring adverse drug reactions associated with antidiabetics. To find out the possible therapeutic outcomes involved in patients with diabetes.

### MATERIALS AND METHODS

#### Study Area

The study was conducted at the rajah muthaih medical college Hospital (RMMCH), Annamalai Nagar, Chidambaram. It was 1350 bedded tertiary care teaching hospital

#### Study type

Prospective observational study

#### Study Population and Sample Size Determination

Diabetes mellitus patients who are registered and visited the Medicine wards of RMMCH were the subjects for the study. Their population from the inpatients of RMMCH Were Obtained from inpatients case sheets from medicine ward. The patient details were collected from the case sheets and reviewed. The size of the sample was 143. The adverse drug reaction related to

antidiabetics were monitored and documented in ADR monitoring form. **Data Collection**

**Study period**

3 months

**Ethical considerations**

This study was ethically approved by IHEC rajah muthaih medical college hospital, Annamalai University with issue number IHEC/0300/2017.

The first step in the study was to design a data collection form and prescription analysis form. The patient data collection form was used to collect all the details like inpatient number, patient name, age, sex, date of admission, date of discharge, chief complaints, history of present illness, past medication history, laboratory data, diagnosis, dose, route of administration, the frequency of the therapeutic management. A total of 143 prescriptions of diabetic cases were collected to obtain other relevant information required in the data collection form.

**Table-1: Demographic characteristics**

S.no.	Characteristics	Type 1	Type 2	Total
1.	<b>Gender wise distribution:</b>			
	Males	06	62	68 (47.55%)
	Females	07	68	75(52.45%)
2.	<b>Age wise distribution:</b>			
	Less than 40	08	21	29(20.27%)
	41 to 60	05	65	70(48.95%)
	61 to 70	-	39	39(27.28%)
	>70	-	05	05(3.50%)
3.	<b>History wise distribution:</b>			
	Known case	09	27	36(25.20%)
	Newly diagnosed	04	103	107(74.80%)
4.	<b>Duration of diabetes:</b>			
	1-5 years	5	18	32(22.40%)
	6-10 years	6	74	64(44.75%)
	11-20 years	2	38	47(32.85%)

**Table-2: Drug wise distribution antidiabetics**

Therapy	Drugs	No's	%	Total
Oral hypoglycaemic drugs	Metformin	14	9.8%	50 (35%)
	Glimepiride	08	5.6%	
	Glibenclamide	05	3.5%	
	Voglibose	03	2.1%	
	Metformin +Glimepiride	09	6.3%	
	Voglibose + Metformin	05	3.5%	
	Metformin + Glibenclamide	06	4.2%	
Oral hypoglycaemic drugs + Insulin	Metformin + insulin	26	18.1%	43(30%)
	Glimepiride + insulin	17	11.9%	
Insulin	Human Actrapid	17	12.1%	50 (35%)
	Human Monotard	11	7.6%	
	Human Mixtard	12	8.4%	
	Glarjine	10	6.9%	

**Table-3: Therapy wise distribution antidiabetics**

Therapy	Drugs	No's	%	Total .No's (%)
Single therapy	Metformin	14	9.8%	80(56%)
	Glimepiride	08	5.6%	
	Glibenclamide	05	3.5%	
	Insulin's	50	35%	
	Voglibose	03	2.1%	
Doublet therapy	Metformin +Glimepiride	09	6.3%	63(44%)
	Metformin +Insulin	26	18.1%	
	Voglibose + Metformin	03	2.1%	
	Metformin +Glibenclamide	06	4.2%	
	Glimepiride + Insulin	17	11.9%	

Table-4: Type of therapy used

S.No.	Characteristics		Patients	Therapy type	
				Singlet	Doublet
1.	Newly diagnosed diabetes	Type 1	9	4.9%	1.4%
		Type 2	94	40%	26%
2.	Already existing diabetes	Type 1	4	2.2%	0.6%
		Type 2	36	8.4%	16.7%

Table-5: Therapy choice based on age, gender, complications, duration of the disease

S.No.	Characteristics	Therapy type			
		OHA's only (n=50)	OHA+ Insulin (n=50)	Insulin only (n=43)	Total (n=143)
1.	<b>Gender wise:</b>				
	Males	29(58%)	16(32%)	23(53.5%)	68
	Females	21(42%)	34(68%)	20(46.5%)	75
2.	<b>Age wise:</b>				
	Less than 40	11(22%)	12(24%)	06(14%)	29
	41-60	29(58%)	18(36%)	23(53.5%)	70
	61-70	10(20%)	20(40%)	09(21%)	39
	>70	-	-	05(11.5%)	05
3.	<b>Duration wise:</b>				
	1-5yrs	09(18%)	15(30%)	08(18.6%)	32
	6-10yrs	28(56%)	23(46%)	13(30.2%)	64
	11-20yrs	13(26%)	12(24%)	22(51.2%)	47
4.	<b>History wise:</b>				
	Known case	12(24%)	05(10%)	19(44%)	36
	Recently diagnosed	38(76%)	45(90%)	24(56%)	107
5.	<b>Complications :</b>				
	CAD	15(30%)	18(36%)	04(9.3%)	37
	Dyslipidaemia	04(8%)	08(16%)	-	12
	Diabetic foot	11(22%)	17(34%)	05(11.5%)	33
	UTI	03(6%)	-	07(16.2%)	10
	Anaemia	02(4%)	-	09(21%)	11
	CVA	09(18%)	02(4%)	12(28%)	23
	Hypokalaemia	06(12%)	05(10%)	06(14%)	17

OHA- oral hypoglycaemic agents

Table-6: Adverse Drug Reactions observed in patients with Diabetes treated with Antidiabetics N= 9

S.No.	Adverse drug reaction	Drugs No's			
		Metformin	Glimepiride	Insulin	Glibenclamide
1.	Hypoglycaemia	-	1	-	1
2.	Diarrhoea	-	-	-	-
3.	Vomiting	-	-	-	-
4.	Giddiness	-	-	-	-
5.	Gastric distension	3	-	-	-
6.	Lactic acidosis	-	-	-	-
7.	Allergic reactions	2	-	-	2

Table-7: Outcomes of therapy

Parameters	At Hospital Admission (mmhg) MEAN± S.D			At Hospital Discharge (mmhg) MEAN± S.D		
	FBG	RBG	PPG	FBG	RBG	PPG
OHA users	187± 17.9	284 ± 31.9	273 ± 39.2	117±13.1	126±20.7	140±14.9
Insulin users	279± 70.2	294 ± 35.5	283 ± 41.8	121 ±19.3	139 ±16.4	141±13.9
OHA+Insulin	270 ± 67.9	335± 46.1	308 ± 55.6	124 ±18.6	137.1±18.3	144±16.1

## RESULTS

During the period of study, a total of 143 cases were collected and reviewed, among that 91% cases were type 2 diabetes mellitus and 9 % cases were type 1 diabetes mellitus. In this study females (58.8%) were higher in number than males (41.2%). Most of the patients were with the age group of 41 to 60 (54%) followed by the age group 61 to 70 (30%) were affected by diabetes mellitus. In this study, the known case of Type 2 Diabetes Mellitus was found to be more with (90.9%). The demographic characteristics of the patients in the current study are shown in Table 1.

The current study was categorized into three groups they are as follows 1. Oral hypoglycaemic agents users 2. Insulin users 3 both OHA+ Insulin users.

The overall study shows total numbers of 50 cases were **oral hypoglycaemic agents' users**. Among that males were mostly found with (58%) and females with (42%). The mostly affected age group were 41-60 with (58%) cases. The duration of the disease were found to be more in 6-10 years with (56%) followed by 11-20 years with (26%). The known case of Type 2 Diabetes Mellitus was found to be more with (86%) in OHA's

users. The major complication associated with OHA's users were coronary artery disease (30%) followed by diabetic foot ulcer with (22%). Prescriptions with (58%) were mostly in generic names for the patients with OHA's users. The therapy wise characteristics of the patients in the current study are shown in Table 6.

The same study conducted for **(oral hypoglycaemic agents +Insulin users)** with 50 cases was mostly females with (68%) and males with (32%). In this case the mostly affected age group were 61-70 with (40%) cases followed by age group between 41-60 with (36%). The duration of the disease was found to be more in 6-10 years with (46%) followed by 1-5 years (30%) and 11-20 years with (24%). In this group most of the cases were recently diagnosed type 2 Diabetes Mellitus patients with (90%). The major complication associated with OHA's+ insulin users were coronary artery disease with (36%), diabetic foot ulcer with (34%) followed by dyslipidaemia (16%). In this study also 54% of the Prescriptions were prescribed in generic names.

**Insulin users** with 43 cases were mostly females (46.5%) were lesser than (53.5%) males. In this case the mostly affected age group were 41-60 with (53.4%) cases followed by age group between 61-70 with (21%). The duration of the disease were found to be more in 11-20 years with (51.2%) followed by 6-10 years with (30.2%). In this group most of the cases were recently diagnosed type 2 Diabetes Mellitus patients with (58%). The major complication associated with OHA's+ insulin users were cerebro vascular accident with (28%).

## DISCUSSION

Uncontrolled diabetes in hospitalized patients with or without prior diagnosis is associated with serious outcomes and increased the duration of stay in the hospital. The main aim of the study is to describe the current trends in prescribing pattern and possible outcomes involved in hospitalized diabetic patients in a tertiary teaching care hospital, Tamilnadu. In this study out of 143 patients who were both type 1 and type 2 were treated with insulin and oral hypoglycemic medications. This data obtained is similar to the other studies shown in India and other countries. Among that females were more in number than males. Most of the diabetic cases in this study had severe uncontrolled blood glucose level. In effect to that, Insulin was prescribed in a majority of the prescriptions. As per American diabetic association guidelines, Insulin treatment is recommended for many diabetic patients under hospitalization. It is administered as bolus form with reference to the sliding scale to obtain glycaemic level in control. In this study, we observe Insulin is more commonly used to control glycaemic levels in uncontrolled type 2 diabetes patients. According to American diabetic association, the glycaemic target set for hospitalized diabetic inpatients for fasting blood glucose is below 140 mg/dl and post prandial below 180 mg/dl. In addition to that oral anti diabetic agents were also preferred after the patient achieves good glycaemic control. Although combination therapy is especially given with insulin and oral agents at bedtime and it may be preferred as the optimal approach for establishing glycaemic control in most patients with severe type 2 diabetes<sup>8</sup>. And therefore most of the hospitalized diabetic patients need insulin and it is recommended by most physicians. Regarding insulin administration, the initial step is the combination of insulin together with the already administered oral hypoglycemic agents for uncontrolled type 2 diabetic patients<sup>9</sup>. The most commonly prescribed oral antihyperglycemic drugs were Biguanides (Metformin) which was used as single therapy as well as Combination therapy. Metformin is preferred for both type 1 and type 2 diabetes, due

to their prolonged absorption and its time profile over 24 hours. Metformin is mostly considered as an ideal first-line agent for the treatment of Type 2 diabetes<sup>13</sup>. Apart from that the cost of metformin is very low when compared with other hypoglycemic drugs and is affordable. Next to that sulfonylureas (Glimepiride, Glibenclamide) were seen in all prescription. The most commonly used combination drug therapy in this study was Metformin+ Glimepiride followed by insulin+ insulin. The study also shows a higher number of newly diagnosed type 2 diabetes cases than type 1 diabetes<sup>10-12</sup>. And consequently, the type 2 diabetes patients with singlet therapy are wider than type 1 diabetes. Adverse drug reactions were found to be very low in our study. The common ADR associated with metformin was gastric distension, hypoglycemia with glimepiride, followed by allergic complaints with metformin and Glibenclamide. Most of the drugs were prescribed in generic names in all prescriptions. The main outcome followed by drug use pattern involved in this study practice for diabetic patients was achieving the glycaemic level in control. The glycaemic level was under control at discharge when compared with hospital admission. Initially, the patients were at high glycaemic level later it was brought under control due to the frequent use of oral hypoglycemic agents and insulin administration.

## CONCLUSION

Studies on drug prescribing pattern of anti-diabetic drugs appear to be lacking in part of developing countries. Oral anti-diabetic drugs still dominate the drug prescribing pattern, but there was a little change in this study towards the use of Insulin preparations in the management of Type 2 diabetes mellitus because of the severe diabetic level and insulin deficiency. Insulin preparations were found to be more effective than oral anti-diabetics for hospitalized patients. The current study reported that females were affected more than males with type 2 diabetes. Insulin plays a major role in controlling blood glucose level. Human insulin is very well effective in type 1 as well as type 2 diabetes. Combination therapy with insulin may provoke good results in attaining glucose level under control for diabetic patients. Fewer rates of adverse drug reaction were found with antidiabetics. And finally, at the end of hospital discharge, many of them attained glucose level under control. In the end, we concluded the people involved in this study lack awareness about the disease, an irregular doctor visits and irregular check up on lab values. Majority of the patients required counselling regarding their medication use, dietary management and was unaware of the severity of the disease and its complications. This study doesn't focus on cost analysis of the patients. In future we will target to focus on cost analysis, followed by major complications of diabetes and creating awareness to the patients.

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