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Research Article

**A PROSPECTIVE OBSERVATIONAL STUDY ON
PRESCRIPTION PATTERN DRUG UTILIZATION AND AUDIT
FOR THE TREATMENT OF DIABETES MELLITUS IN A
TERCIARY CARE HOSPITAL IN ANDHRA PRADESH.**

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Abstract:

Introduction: Diabetes is the most common metabolic disorder in Indian community. It is a silent disease that has become more prevalent with increased age. Despite the advances in understanding the disease and its management, the mortality and morbidity of the disease is increasing. **Objective:** The objective of the study is to evaluate the prescription pattern, drug utilization and audit for the treatment of diabetes mellitus in a tertiary care hospital in Rajahmundry. **Methodology:** The study design is a prospective observational study. A total of 150 cases related to anti diabetic treatment were investigated in a tertiary care hospital in Rajahmundry, Andhra Pradesh. Inclusion and Exclusion Criteria include patients with diabetes mellitus admitted as in-patients in the hospital and Patients with age group 20-70 years of both men and women are included. Pregnant and lactating women are excluded from the study and Patients who are unconscious/mentally retarded and who were suffering with psychiatric diseases are excluded from the study. The data sources include patient case sheets, prescriptions issued and discharge medication sheet, WHO guidance on essential drugs and by interacting with physicians and patients. **Results and Conclusions:** The diabetes is more prevalent among women than in men. Patients in the age group 51-60 years are more prone to diabetes than other age groups. The comorbid diseases in diabetic patients majorly include Hypertension, Hyperlipidemias, Thyroid, and Obesity. Cataract, Chronic foot ulcer, Neuropathy and Mild hypoglycemia are the major clinical manifestations in diabetic patients. Mono drug therapy in 36.6% cases, two drug therapies in 44.6% cases and three drug therapies in 18.6% cases is followed for the treatment of diabetes in the hospital. WHO suggested 18 drugs for mono therapy and 6 two drug combinations for diabetes. Only three drugs (Insulin, Metformin, Glimepiride) out of 18 suggested were used in mono therapy and only one 2 drug combination was used among the 6 suggested by WHO. Three 2 drug combinations other than those suggested by WHO are also used in the hospital. Anti diabetic drugs other than those suggested by WHO are also used to a large extent in the hospital. Hence, it is suggested that the WHO suggested Essential drugs be prescribed in the hospital for better patient care, safety and efficacy.

Key words: Prospective observational study, Prescription pattern, Drug utilization, Prescription audit, Anti-diabetic drugs.

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INTRODUCTION:

In 2008, an estimated 347 million people in the world had diabetes and the prevalence is growing, particularly in low and middle income countries. India had 69.2 million people living with diabetes (8.7%) as per the 2015 data. Of these, it remained undiagnosed in more than 36 million people [1]. Diabetes is the most common metabolic disorder in Indian community. It is a silent disease that has become more prevalent with increased age. Despite the advances in understanding the disease and its management, the mortality and morbidity of the disease is increasing. Many causes have been postulated for this rise, such as poverty, non-compliance, and poor follow-ups. Poorly controlled diabetes mellitus leads to damage of end organs such as kidneys, heart, brain and eyes. This not only affects the quality of life of the patient but also increases the health expenditure to the individual and at large to the society [2].

The health problems associated with diabetes mellitus are arterial hypertension, overweight, ischemic cardiopathy; cardiac infarction, cerebrovascular accidents, diabetic foot ulcers, blindness, and secondary chronic renal failure. Chronic complications such as blindness, renal failure and amputations influence the quality of life in Diabetes Mellitus patients [3].

The objective of the study is to evaluate the prescription pattern, drug utilization and audit for the treatment of diabetes mellitus in a tertiary care hospital in Rajahmundry.

METHODOLOGY:

The study design is a prospective observational study. A total of 150 cases related to treatment of diabetes mellitus were investigated in a tertiary care hospital in Rajahmundry, in Andhra Pradesh. The study is conducted during January 2017 to April 2017.

Inclusion and Exclusion Criteria:

1. Patients with diabetes mellitus admitted as inpatients in the hospital are enrolled.
2. Patients with age group 20-70 years of both men and women are included.
3. Pregnant and lactating women are excluded from the study.
4. Patients who are unconscious/mentally retarded and who were suffering with psychiatric diseases are excluded from the study.

Sources of Data:

The data sources include patient case sheets, prescriptions issued and discharge medication sheet, WHO guidance on essential drugs and by interacting with physicians and patients. The study protocol is approved by Institutional Animal Ethics Committee (IAEC).

RESULTS AND DISCUSSION:

The objective of the study is to evaluate the prescription pattern, drug utilization and audit for the treatment of diabetes mellitus in a tertiary care hospital in Rajahmundry. Audit is a review and the evaluation of the health care procedures and documentation for the purpose of comparing the quality of care which is provided with the accepted standards. Prescription audit consists of monitoring, evaluating and if necessary, suggesting modifications in the prescribing practices of medical practitioners⁴. A total of 150 cases related to diabetes mellitus were studied in a tertiary care hospital in Rajahmundry. The demographic details and medical history of the diabetic patients observed are given in Table 1.

The diabetes is more prevalent among women (54%) than in men (46%). Patients in the age group 51-60 years are more prone to diabetes (36%) than other age groups. The comorbid diseases in diabetic patients majorly include Hypertension (74%), Hyperlipidemias (37%), Thyroid (14%), and Obesity (2.6%).

Table 1: Demographic Details and Medical History of Diabetic Patients

S.no	Item	No. of Cases (%)
1.	Gender: Men Women	69 (46) 81 (54)
3.	Age(years): 21-30	—
4.	31-40	9 (6)
5.	41-50	47 (31.3)
6.	51-60	54 (36)
7.	61-70	40 (26.6)
8.	Comorbidities: Obesity	4 (2.6)
9.	Thyroid	21 (14)
10.	Hyperlipidemias	56 (37)
11.	Hypertension	112 (74)

The clinical manifestations and complications observed in diabetic patients are listed in Table 2 along with their percentage of occurrence. The major manifestations observed are cataract (46.6%), chronic foot ulcer (30.6%), neuropathy (19.3%) and Mild hypoglycemia (18%).

Lab investigations carried out on diabetic patients include HbA1c, FBS, PPBS, ALT, Total cholesterol,

HDL Cholesterol, LDL Cholesterol, Triglycerides, Sodium, Potassium, Creatinine and Albumin:Creatinine Ratio (Table 3). In majority of the lab investigations like PPBS, FBS, HbA1c, and LDL Cholesterol abnormally higher values were observed in about 73.3-79.3% cases indicating severity of the disease diabetes.

Table 2: Clinical Manifestations and Complications Observed in Diabetes Patients

S.no	Clinical Manifestations	No. of Cases (%)
1.	Glaucoma	10 (6.6)
2.	Cataract	70 (46.6)
4.	Neuropathy	29 (19.3)
5.	Amputation	3 (2)
6.	Gangrene	9 (6)
7.	Chronic foot ulcer	46 (30.6)
8.	Nephropathy	7 (4.6)
9.	Liver disease	7 (4.6)
10.	Severe hypoglycemia	6 (4)
11.	Mild hypoglycemia	27 (18)

Table 3: Abnormal Cases in Lab Investigations

S.no	Lab Investigations	No. of Cases With Abnormal Values (%)
1.	HbA1C	115 (76.6)
2.	FBS	118 (78.6)
3.	PPBS	119 (79.3)
4.	ALT	53 (35.3)
5.	Total Cholesterol	72 (48)
6.	HDL Cholesterol	72 (48)
7.	LDL Cholesterol	110 (73.3)
8.	Triglycerides	70 (46.6)
9.	Sodium	51 (34)
10.	Potassium	32 (21.3)
11.	Creatinine	60 (40)
12.	Albumin: Creatinine Ratio	45 (30)

HbA1c- Glycated hemoglobin; FBS-Fasting Blood Sugar;
 PPBS- Post Prandial Blood Sugar; ALT-Alanine Amino Transferase;
 HDL Cholesterol- High Density Lipid cholesterol;
 LDL Cholesterol - Low Density Lipid Cholesterol.

Table 4: Anti diabetic Drugs Used in the Prescriptions

S.no	Drug Prescribed	Dose	No. of cases (%)
1.	Mono therapy (36.6%): Insulin Metformin Metformin Glimepiride Glimepiride	25/75 500mg 1000mg 1mg 2mg	11 (20) 8 (14.5) 14 (25.4) 9 (16.3) 13 (23.6)
6.	Two-Drug therapy (44.6%) Insulin 25/75+metformin Metformin + Glimepiride Canagliflozin/Metformin Sitagliptin/Metformin	25/75,500; 25/75,1000 500/1,500/2,1000/1,1000/2 50/850,50/1000 2.5/1000mg, 5/500	17 (25.3) 13 (19.4) 21 (31.3) 16 (23.8)
10.	Three-Drug therapy (18.6%) Insulin 25/75+metformin+glimepiride Insulin 25/75+metformin+glimepiride Metformin+glimepiride+sitagliptin	25/75,500,2mg 25/75,1000,1mg 500,2,2.5mg	7 (25%) 9 (32.1%) 12 (42.8%)

Table 5: Other Drugs Prescribed in Antidiabetic Patients

S.no	Other Drugs	No.of cases (%)
1.	Enam(5mg,10mg)	14 (9.3)
2.	Aten(25mg,50mg,100mg)	43 (28.6)
3.	Telma(20,40,80)	18 (12)
4.	Atorfit(10,20,40,80)	35 (23)
5.	Ecospirin(75,325)	64 (42.6)
6.	Rantac(75,150,300)	20 (13.3)
7.	Calcium(500)	110 (73.3)
8.	Amldac/Amlong(2.0mg,5mg, 10mg)	139 (92.6)
9.	Levothyroxine(25mcg,50mcg,100mcg,200mcg)	21 (14)

The anti diabetic drugs used in the hospital along with the doses and percentage usage of each drug are given in Table 4. In 36.6% cases single drug therapy, in 44.6% cases two drug therapy and in 18.6% cases three drug therapy is followed. In mono drug therapy three drugs namely Insulin, Metformin and Glimepiride are used in different doses. Among the three drugs Metformin (1000mg) was prescribed largely in 25.4% patients. The two drug combinations include Insulin and Metformin, Metformin and Glimepiride, Canagliflozin and Metformin, Sitagliptin and Metformin. Among the two drug combinations Canagliflozin and Metformin combination is prescribed in majority of the cases (31.3%). The three drug combinations include i)Insulin (25/75), Metformin (500mg), Glimepiride(2mg) ii) Insulin (25/75), Metformin (1000mg), Glimepiride(1mg) and iii) Metformin (500mg), Glimepiride(2mg), Sitagliptin (2.5mg). Among the three drug

combinations Metformin, Glimepride and Sitagliptin combination is prescribed largely (42.8%).

Other categories of drugs prescribed along with anti-diabetic drugs are given in Table 5.

A comparison of WHO suggested Essential drugs for diabetes and drugs used in the hospital is shown in Table 6.

WHO suggested 18 drugs for mono therapy and 6 two drug combinations for diabetes . In the hospital where the study was conducted only three drugs were used in mono therapy and only one 2 drug combination was used among the 6 suggested by WHO. Three 2 drug combinations other than those suggested by WHO are also used in the hospital. All the anti diabetic drugs used at doses suggested by WHO. However, anti diabetic drugs other than those suggested by WHO are also used to a large extent in the hospital. Hence, it is suggested that the WHO suggested Essential drugs be prescribed in the hospital for better patient care, safety and efficacy.

Table 6: Comparison of WHO Essential Drugs and Drugs Prescribed in the Hospital

S.no	WHO Essential Drug List	Drugs Prescribed in Hospital
1.	Monotherapy: Tab 6.25mg, 12.5mg, 25mg.	—
2.	Linagliptin Tab 5mg	—
3.	Saxagliptin Tab 2.5mg, 5mg	—
4.	Alogliptin Sitagliptin Tab 25mmg, 50mg, 100mg	—
5.	Canagliflozin 100mg, 300mg	—
6.	Dapagliflozin Tab 5mg, 10mg	—
7.	Empagliflozin Tab 10mg, 25mg	—
8.	Chlorpropamide Tab 100mg, 250mg	—
9.	Gliclazide Tab 40mg, 80mg	—
10.	Glimipride Tab 1mg, 2mg, 3mg, 4mg	Glimipride Tab 1mg, 2mg, 3mg, 4mg
11.	Glibenclamide/Gliburide Tab 2mg, 5mg	—
12.	Pioglitazone Tab 15mg, 30mg, 45mg	—
13.	Rosiglitazone Tab 4mg, 8mg	—
14.	Nateglinide Tab 60mg, 120mg, 180mg	—
15.	Repaglinide Tab 500mcg, 1mg, 2mg	—
16.	Acarbose Tab 50mg, 100mg	—
17.	Metformin Tab 500mg	Metformin Tab 500mg
18.	Insulin Products(Aspartate, detemir, regular, NPH)	Insulin products (Aspartate, NPH, detemir, regular)
19.	Two-Drug therapy: Alogliptin/Metformin 12.5/500mg, 12.5/800, 12.5/1000	—
20.	Linagliptin/Metformin 2.5/500mg, 2.5/850, 2.5/1000	—
21.	Saxagliptin/Metformin 2.5/1000mg, 5/500, 5/1000	—
22.	Sitagliptin/Metformin 50/500mg, 50/850, 50/1000, 100/1000	Sitagliptin/Metformin 50/500mg, 50/850, 50/1000, 100/1000
23.	Dapagliflozin/Metformin 5/850mg, 5/1000mg	—
24.	Empagliflozin/Metformin 12.5/850mg, 5/850, 12.5/1000, 5/1000	—
25.	—	Insulin 25/75+metformin 25/75, 500; 25/75, 1000
26.	—	Metformin+glimipride 500/1,500/2,1000/1,1000/2
27.	—	Canagliflozin+Metformin 50/850, 50/1000

CONCLUSIONS:

- The diabetes is more prevalent among women than in men. Patients in the age group 51-60 years are more prone to diabetes than other age groups.
- The comorbid diseases in diabetic patients majorly include Hypertension, Hyperlipidemias, Thyroid, and Obesity.
- Cataract, Chronic foot ulcer, Neuropathy and Mild hypoglycemia are the major clinical manifestations in diabetic patients.
- Mono drug therapy in 36.6% cases, two drug therapies in 44.6% cases and three drug therapies in 18.6% cases is followed for the treatment of diabetes in the hospital.

- WHO suggested 18 drugs for monotherapy and 6 two drug combinations for diabetes.
- Only three drugs(insulin, metformin, glimepride) out of 18 suggested were used in monotherapy and only one 2 drug combination was used among the 6 suggested by WHO.
- Three 2 drug combinations other than those suggested by WHO are also used in the hospital.
- Antidiabetic drugs other than those suggested by WHO are also used to a large extent in the hospital. Hence, it is suggested that the WHO suggested Essential drugs be prescribed in the hospital for better patient care, safety and efficacy.

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CONFLICT OF INTEREST:

Authors declared there is no conflict of interest.

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