A Prospective Study on Prescribing Pattern in Type II Diabetes Mellitus with Their Co-Morbidities

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ABSTRACT

Introduction: Diabetes Mellitus (DM) is a group of metabolic disorder characterized by Hyperglycemia and abnormalities in carbohydrate, fat and protein metabolism. DM with comorbid conditions constitute a major health problem in worldwide. **Objectives:** Study the prescribing pattern in type II Diabetes Mellitus with their co-morbidities **Methodology:** It was a Prospective and Observational study carried out for a period of six months at Apollo Multi-Speciality hospital. After obtaining approval from Institutional Ethical Committee and based on the criteria, patients were enrolled in the study. Suitable statistical tool were used to evaluate the data. **Results:** Of 300 prescription assessed, majority (202) were males. Most of the patients (179) were in the age group of >60 years. Hypertension was the most common comorbidity seen. Most (34.83%) of patients were on oral Hypoglycemic agents dual therapy and among patients on Insulin therapy, 73.22% received insulin monotherapy. Most of the patients had well controlled Glycosylated haemoglobin, 65.25% and moderately controlled general random blood sugar levels, 54.33%. **Conclusion:** Patients with Type 2 DM were characterized by a high number of comorbidities. Metformin was the most commonly utilized oral anti-diabetic agent along with regular insulin as the benefit clearly outbalance the risk of severe side effects. Most of the patients had well controlled blood glucose levels and hence the therapy was found to be effective.

INTRODUCTION

Diabetes Mellitus is a pandemic disease that has struck each and every corner of the world[1].

The number of people with diabetes is increasing due to population growth, aging, urbanization, and increasing prevalence of obesity and physical inactivity[2].

According to the statistics from the International Diabetes Federation (IDF), India has more diabetics than any other nation of the world. Current estimates peg the number of diabetics in the country at about 62 million and increase of over 10 million from 2011 when estimate suggested that about 58.8 million people in the country were suffering from the disease. By the year 2030, over 100 million people in India are likely to suffer from Diabetes[3].

According to WHO, the term Diabetes Mellitus is defined as a metabolic disorder characterized by Hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both [4].

Treatment of type II DM broadly includes: oral Hypoglycaemic agents and insulin therapy.

Oral Hypoglycemic agents includes Sulfonylureas (first generation eg: Tolbutamide, Chlorpropamide; second generation: Glibenclamide, Glipizide, Gliclazide, Glimepiride), Biguanides (eg; Metformin), Meglitinide / Phenylalanine analogues (eg: Repaglinide, Nateglinide), Thiazolidinediones (eg: Rosiglitazone, Pioglitazone),α Glucosidase inhibitors (eg: Acarbose, Miglitol) and Insulin therapy includes (eg: Insulin Lispro, Insulin Aspart).

Co-morbidity is defined as the occurrence of one or more chronic conditions in the same person with an index-disease, occurs frequently among patients with diabetes. *Hypertension* (85%), *Nephropathy* (41.6%), *Neuropathy* (40.6%), *Hyperlipidemia* (88%), *Retinopathy* (16.9%), *Vertigo* (23.3%), *Allergic Rhinitis* (18.3%), *Calcium Deficiency* (40.9%), *Gastritis* (9.2%), *Anemia* (16%), *Mood Disorder* (24.7%), *Parkinson's Disease* (12.4%) and *Thyroid* (16.9%) are the major comorbidities associated with diabetes [5].

The main objective is to study the prescribing pattern in type II Diabetes Mellitus with their co-morbidities. This study is a component of medical audit that does monitoring and evaluation of the prescribing practice of the prescribers as well as recommends necessary modifications to achieve rational and cost-effective medical care and it helps to evaluate and

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suggest modifications in prescribing practices of medical practitioners so as to make medical care rational.

Since there is an increase in the number of newly diagnosed diabetes over the past few years, the amount of interest in the management of diabetes and its co-morbidities has increased tremendously. This is the need of the hour to utilise the data generated by so many prescription pattern monitoring studies done on every drug so that the main aim of promoting rational use of drugs is fulfilled. The pre-requisite for the management of diabetes and its comorbidities is to understand the demography and detailed management of type II DM. In this study, we try to evaluate the prescribing pattern in the management of type II DM and its comorbidities which may help us in better understanding of DM.

MATERIALS & METHODS

Study site:

The study was conducted in Apollo Multi Specialty Hospital and Research Center, Bengaluru.

Study design:

This was a prospective and observational study performed on 300 patients to assess the prescribing pattern in type II Diabetes Mellitus patients with their co-morbidities.

Study period:

The study was conducted over a period of 06 months starting from November 2018 to April 2019.

Ethical approval:

Ethical committee clearance was obtained by the Institutional Ethical Committee of Apollo Multi Specialty Hospital and Research Center.

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Study procedure

1. Patient Enrollment

A hospital based prospective study was conducted in Medicine and Endocrinology department of Apollo Multi Specialty Hospital and Research Center. The study was conducted on 300 patients who met the requirements of criteria. Patients who were not willing to give their consent, pregnant and lactating women were excluded from the study.

2. Method of Data Collection

Pro-forma was used for data collection, which includes medication information (name, dose, frequency, route etc) and patient information details (name, age, sex), socioeconomic parameters, past medical history, disease diagnosed and duration of treatment. The anti-diabetic medications used in the diabetes patients were recorded along with the other required laboratory details in a data collection form (Annexure) designed for the study. Data was evaluated using suitable statistical tools.

3. Determination of prescribing pattern:

After the diagnosis was confirmed as DM, the entire relevant details were collected. Therapeutic data such as name of drugs, dose, route of administration, duration and other laboratory data were collected and documented in a suitably designed data collection form. Frequently used OHA and insulin were found by using statistical tools. Prescription was analyzed for anti-diabetic agents and was evaluated for the choice of drugs given, their class, type of therapy i.e, monotherapy/combination therapy and therapeutic category.

Statistical Methods: Descriptive statistical analysis has been carried out in the present study. Chi-Square test has been used to find the significance of study parameters on categorical findings among different groups.

P value or significant considerations: Actual range (0.01<0.05<0.1)

*Strongly significant if P value is = 0.01.

*Moderately significant if P value is 0.01-0.05.

*Significant if P value is >0.05 to 0.1.

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*Non-Significant if P value is >0.1.

Statistical Software:

The statistical software called SPSS (IBM) version 25 was used for the analysis.

Microsoft Word and Excel are used to generate tables and graph respectively.

RESULT AND DISCUSSION

Table No. 01: Gender distribution of patients (n=300):

Gender	No .of patients	Percentage
Male	202	67.33
Female	98	32.67
Total	**300**	**100**

As shown in table 01, a total of 300 patients were included in our study out of which males were higher (67.33%) than females (32.67%) indicating that the prevalence of DM is high in males.

Table No. 02: Age distribution of patients (n=300):

Age (years)	Male	Female	Total	Percentage
≤ 30	2	0	2	0.67
31-40	4	2	6	2
41-50	25	11	36	12
51-60	50	27	77	25.66
> 60	121	58	179	59.67
Total	**202**	**98**	**300**	**100**

As shown in table 02, the age distribution of the given population showed that 0.67% of patients belong to the age group of ≤30 years, 2% in 31-40 years, 12% in 41-50 years, 25.66% in 51-60 years and 59.67% of the total population are in the age group of >60 years.

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Table No. 03: Distribution of comorbidities associated with DM (n=346):

Co-morbid conditions	Gender		Total	Percentage
	Female	Male		
Hypertension	87	90	177	51.15
Ischemic heart disease	23	31	54	15.60
Unstable angina	6	12	18	5.20
Hypothyroidism	9	5	14	4.04
Asthma	4	8	12	3.46
Acute coronary syndrome	5	6	11	3.17
Anemia	6	3	9	2.60
Chronic obstructive pulmonary disorder	3	3	6	1.73
Urinary tract infection	5	3	8	2.31
Diabetic foot sepsis	2	3	5	1.44
Tuberculosis	1	4	5	1.44
Lower respiratory tract infection	4	1	5	1.44
Seizure disorder	2	3	5	1.44
Multiple myeloma	1	2	3	0.86
Stroke	1	2	3	0.86
Parkinsonism	0	2	2	0.57
Otitis media	1	1	2	0.57
Breast Carcinoma	2	0	2	0.57
Lung cancer	0	1	1	0.28
Carcinoma larynx	1	0	1	0.28
Cervical cancer	1	0	1	0.28
Liver cirrhosis	0	1	1	0.28
Gout	1	0	1	0.28
Total	**165**	**181**	**346**	**100**

P=0.16, Non-Significant, Chi-Square test

According to table 03, the distribution of comorbid conditions among the patients showed that, the most commonly seen co-morbidity in DM patients was HTN (51.15%), followed by

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cardiovascular disorders like IHD (15.60%) and Unstable angina (5.20%). Based on the result, it's found that patients with DM are highly associated with cardiovascular risk due to altered metabolism.

Analysis of glycemic control and efficacy of treatment based on laboratory parameters tested at admission and discharge (as per American Diabetes Association):

Table No. 04a: HbA1c distribution in the study population (n=164)

HbA1c%	At Admission		At Discharge		Total	Percentage
	Male	**Female**	**Male**	**Female**		
</= 7% (Controlled)	6 (3.65%)	11 (6.70%)	58 (35.36%)	32 (19.51%)	107	65.25
>7% (Uncontrolled)	11 (6.70%)	12 (7.31%)	18 (10.97%)	16 (9.75%)	57	34.75
Total	**17 (10.36%)**	**23 (14.02%)**	**76 (46.34%)**	**48 (29.26%)**	**164**	**100**
P value	0.66		0.71			

Non-Significant, Chi-Square test

The above table 04a showed that the test was advised to 164 patients who had uncontrolled blood glucose levels or other co-morbidities or diabetes associated complications. The distribution and evaluation of HbA1c ranges at the times of admission and discharge were studied from the above table. The efficacy was tested using the same comparing to ADA (American Diabetes Association) treatment targets and guidelines. This showed that 65.25% of patients had controlled blood glucose level and 34.75% of patients had uncontrolled levels while comparing admission and discharge HbA1c values. Hence, the treatment was found to be effective.

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Table No. 04b: Distribution of GRBS in the study population (n=300):

GRBS (mg/dl)	At admission			At discharge		
	Male	**Female**	**Total**	**Male**	**Female**	**Total**
</= 160 (Controlled)	12 (4%)	9 (3%)	21 (7%)	86 (28.66%)	32 (10.66%)	118 (39.33%)
161-200 (Moderately controlled)	114 (38%)	43 (14.33%)	157 (52.33%)	107 (35.66%)	56 (18.66%)	163 (54.33%)
>200 (Uncontrolled)	76 (25.33%)	46 (15.33%)	122 (40.66%)	9 (3%)	10 (3.33%)	19 (6.34%)
Total	**202 (67.33%)**	**98 (32.66%)**	**300 (100%)**	**202 (67.33%)**	**98 (32.67%)**	**300 (100%)**
P value	0.49			0.37		

Non-Significant, Chi-Square test

The above table 04b shows that all the patients were tested for GRBS levels both at admission and discharge. Out of 300 patients, 118 (39.33%) had controlled blood glucose levels, 163 (54.33%) had moderate control and 19 (6.34%) had uncontrolled levels.

Inference: This implies that majority of the patients have moderate control over the blood glucose levels and poor glycemic control in rest of the patients may be due to presence of co-morbid conditions, other concomitantly taken drugs or unchanged lifestyle. Therefore, overall evaluation concludes that the treatment was effective.

Table No. 05: Pattern of anti-diabetic agents prescribed in the study population (n=300):

Anti-diabetic agents	Male	Female	Total	Percentage
OHA	75	42	117	39
Insulin	83	39	122	40.67
OHA + Insulin	44	17	61	20.33
Total	**202**	**98**	**300**	**100**

P=0.94, Non-Significant, Chi-Square test

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Table 05 represents that, out of 300 patients, 40.67% of patients were prescribed with insulin followed by OHA (39%) and OHA along with insulin (20.33%) for the management of diabetes.

Table No. 06: Classification of OHA prescribed to the patients (n=178):

Class of OHA	Drug name	Age (years)					Gender		Total	Percentage
		</=30	31-40	41-50	51-60	>60	Male	Female		
Sulfonylurea	*Glimepiride*	4	1	4	9	6	16	8	33	18.53
	Gliclazide	0	1	1	2	3	3	4		
	Glyburide	0	0	0	1	1	1	1		
DPP-IV Inhibitors	*Vildagliptin*	0	1	1	4	9	7	8	35	19.67
	Teneligliptin	0	0	0	5	6	8	3		
	Linagliptin	0	0	0	0	3	2	1		
	Sitagliptin	0	0	0	4	2	4	2		
Biguanides	*Metformin*	11	4	14	32	33	57	37	94	52.81
Alpha glucosidase inhibitors	*Acarbose*	0	0	0	0	1	1	0	16	8.99
	Voglibose	2	0	0	3	10	6	9		
Total		**17**	**7**	**20**	**60**	**74**	**105**	**73**	**178**	**100**

P=0.42, Non-Significant, Chi-Square test

Based on table 06, evaluation of OHA prescribed to the patients showed that majority (52.80%) of patients are prescribed with metformin of biguanide class, among which the patients of age group 51- 60 (32) and >60 (33) years had higher requirements and males (57) are prescribed more than females (37). Other frequently prescribed drugs were glimepiride of *sulfonylureas* class (24) followed by *vildagliptin* of DPP-IV Inhibitors class (15), *voglibose* of *alpha-glucosidase* inhibitors class (15), *teneligliptin* of DPP-IV Inhibitor class (11), gliclazide of sulfonylureas class (7) and the least prescribed drug was acarbose(1) from alpha-glucosidase inhibitors.

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Table No. 07: Classification of Insulin prescribed to the study population (n=183):

Class of Insulin	Drug name	Age (years)					Gender		Total	Percentage
		</=30	31-40	41-50	51-60	>60	Male	Female		
Rapid acting	Insulin Lispro	3	1	1	2	5	9	3	26	14.23
	Insulin Aspart	2	1	1	0	2	2	4		
	Insulin Glulisine	2	0	1	0	1	1	3		
	Human Insulin	2	0	0	1	1	2	2		
Short acting	Regular Insulin	24	33	8	45	12	79	43	122	66.67
Intermediate acting	Insulin aspart protamine	1	2	0	1	1	3	2	15	8.19
	Biphasic isophane insulin	0	1	7	1	1	6	4		
Long acting	Insulin Glargine	1	3	3	2	8	7	10	17	9.28
Ultra-long acting	Insulin Degludec	0	0	1	1	1	2	1	3	1.63
Total		**35**	**41**	**22**	**53**	**32**	**111**	**72**	**183**	**100**

P=0.39, Non-Significant, Chi-Square test

Based on the table 07, Out of 300 patients, 183 were prescribed with insulin and majority (66.67%) of patients were prescribed with short acting insulin, among which the patients of age group 31- 40 (33) and 51-60 (45) years had higher requirements and males (79) were prescribed more than females (43). Other class of insulins following short acting insulin were rapid acting insulin (14.23%), long acting insulin (9.28%), intermediate acting insulin (8.19%) and ultra-long acting insulin (1.63%).

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Table No. 08: Type of OHA therapy in the study population (n=178):

Therapy	Drug given	No. of patients	Percentage
Monotherapy	Metformin	34	19.10
	Glyburide		
	Glimepiride		
Combination therapy	Metformin + Voglibose	59	33.14
	Metformin + Glimepride		
	Metformin + Vildagliptin		
	Metformin + Tenegliptin		
	Metformin + Sitagliptin		
Dual therapy	Metformin, Gliclazide	62	34.83
	Glyburide, Linagliptin		
	Metformin, Tenegliptin		
	Metformin, Glimepiride		
	Metformin, Vildagliptin		
Triple therapy	Metformin, Glibenclamide, Tenegliptin	23	12.93
	Metformin, Glimepiride, Tenegliptin		

P=0.66, Non-Significant, Chi-Square test

According to table 08, evaluation of OHA therapy in the sample revealed that majority (34.83%) of patients were on dual therapy where patients received two different drugs belonging to same or different OHA class, 33.14% of patients were on combination therapy, where two drugs of same or different OHA class are combined in a single formulation, 19.10% of patients on monotherapy and 12.93% of patients receive triple therapy, in which, 3 drugs are given separately, taken simultaneously or non-simultaneously.

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Table No. 09: Pattern of Insulin therapy in the study population (n=183):

Therapy	Drug given	No. of patients	Percentage
Monotherapy	Insulin Isophane	134	73.22
	Regular Insulin		
	Insulin Glargine		
Dual therapy	Insulin Regular, Insulin Isophane	49	26.78
	Insulin Lispro, Insulin Glargine		
	Insulin Aspart, Insulin Dgludec		
	Insulin Glargine, Regular Insulin		

P= 0.21, Non-Significant, Chi-Square test

Table 09 revealed that 73.22% of patients were on monotherapy, which means only one insulin formulation in a prescription and 26.77% of patients were on dual therapy, where two same or different class of insulin preparations are prescribed.

Fig - 01

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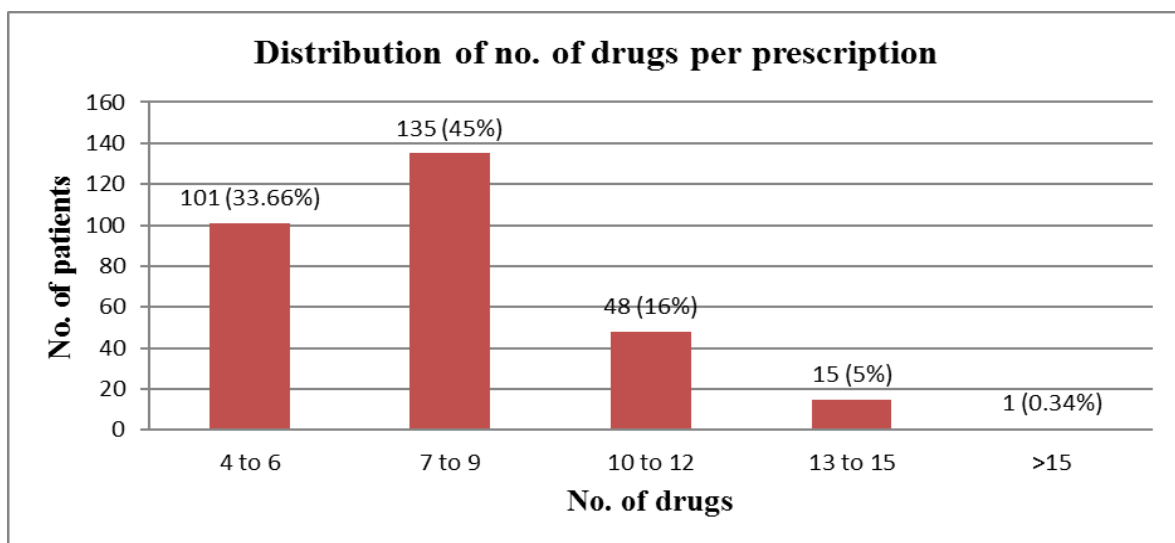
From Fig 01, the evaluation of average number of drugs per prescription among the study population shows that 45% of patients were on 7-9 drugs, 33.66% of patients were using 4-6 drugs, 16% of patients on 10-12 drugs, 5% on 13-15 drugs and remaining 0.34% were using >15 drugs. On an average, every patient was receiving approximately 8 drugs per prescription. Various factors influencing polypharmacy are co-morbidities, age and gender.

DISCUSSION

In this study, we attempt to describe the current prescribing pattern of anti-diabetic drug therapy along with its effectiveness to maintain an optimal glycemic levels in DM patients and statistically analyzed the prescription for the following factors:

- Prevalence of type 2 DM according to different age groups

- Prevalence of type 2 DM according to sex

- Analysis of prescription showing prevalence with other diseases

- Prescribing pattern of major pharmacological drug classes

- Assessment of various lab parameters

Table No. 01 and 02 represents that, in the current study, males predominated over females in the exposure of type 2 DM, hence prevalence of type 2 DM was higher in males and the age distribution of the given population implies the higher incidence of type 2 DM in the elder i.e., above 60 years of age and thereby treatment necessities are required in elderly people to have a good glycemic control and to prevent further complications. Similar findings were found in a study conducted by **Mahmood M *etal*.[6]** in which 62.97% were males and 37.02% were females indicating that males predominated over females and majority of the patients were elderly (>60 years). According to table 03, the distribution of comorbid conditions among the patients showed that the most commonly seen co-morbidity in DM patients was HTN (51.15%). Based on the result, it is found that the patients with DM are highly associated with cardiovascular risk due to altered metabolism. Similar findings were observed in a study conducted by **Hui C *et al*.[7]** which showed that hypertension was the most common co-morbidity associated with T2DM.

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As per the HbA1c % distribution from table no. 04a, it was found that the test was advised to 164 patients who had uncontrolled blood glucose levels (>7%) or other co-morbidities or diabetes associated complications. The distribution and evaluation of HbA1c ranges at the times of admission and discharge were studied from the table. The efficacy was tested using the same comparing to ADA (American Diabetes Association) treatment targets and guidelines. This showed that 65.25% of patients had controlled blood glucose level (</=7%) and 34.75% of patients had uncontrolled levels (>7%). Hence, the treatment was found to be effective. **Mathew C et al.[8]** conducted a similar study and found that the majority of patients (60%) attained HbA1c level <7%, 40% of patients had uncontrolled levels (>7%) and therefore had controlled blood glucose level. The table 04b showed that all the patients were tested for GRBS levels both at admission and discharge and it implies that majority of the patients had moderate control over the blood glucose levels and poor glycemic control in rest of the patients may be due to the presence of co-morbid conditions, other concomitantly taken drugs or unchanged lifestyle. Therefore, overall evaluation concludes that the treatment was effective. Similar observations were made in a study conducted by **Thakare V et al.[9]** which showed that patients were having GRBS in the range of 140-200mg/dl (moderately controlled) which supports our study results. Table 05 represents that, out of 300 patients, 40.67% of patients were prescribed with insulin, 39% of patients with OHA and 20.33% with OHA along with insulin which concludes that insulin(40.67%) was the most commonly prescribed anti-diabetic agent followed by OHA(39%) and OHA + insulin (20.33%). Similar findings were observed that there was a higher percentage of use of insulin (50%) compared to OHA (35%) in Type 2 diabetes in a study conducted by **Agarwal et al.[1]**Based on table 07, evaluation of OHA prescribed to the patients showed that majority (52.80%) of patients are prescribed with metformin of biguanide class, among which the patients of age group 51- 60 (32) and >60 (33) years had higher requirements and males (57) are prescribed more than females (37). Similarly, based on a study conducted by **Rani J et al.[10]**, it was revealed that among individual drugs, metformin (20%) and glimepiride (16.6%) were the maximum prescribed drugs, metformin of biguanides class being the most commonly prescribed OHA. According to table 08, evaluation of OHA therapy in the sample revealed that majority (34.83%) of patients were on dual therapy where patients receive two different drugs belonging to same or different OHA class, 33.14% of patients were on combination therapy, where two drugs of same or different OHA class are combined in a single formulation, 19.10% of patients on monotherapy and 12.93% of patients receive triple therapy, in which, 3 drugs are given separately, which are taken at once or at different time intervals. **Aparna A et**

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al.[11] conducted a similar study and found that, among all patients, 34.7% (249) of patients were treated with dual therapy and concluded that most of the patients were receiving dual therapy. Table 09 revealed that 73.22% of patients were on monotherapy, which means only one insulin formulation in a prescription and 26.77% of patients were on dual therapy, where two same or different class of insulin preparations are prescribed. Similar findings were observed in a study conducted by **Manjusha S *et al*.[12]** showing that among 83 patients on insulin treatment, 66 patients were using only one insulin formulation (monotherapy) while the remaining 17 patients were using two insulin formulation (dual therapy). Fig 01, the evaluation of average number of drugs per prescription among the study population shows that on an average, every patient was receiving 7.74 (approx-8) drugs per prescription which shows polypharmacy. Various factors influencing polypharmacy are comorbidities, age and gender It is most common in the elderly and the majority of the patients in our study were above 60 years of age. Similar observations of polypharmacy in elderly patients with type 2 DM were observed in a study conducted by Marianna N et al which showed that 57.1% of the study population were prescribed more than 5 drugs.
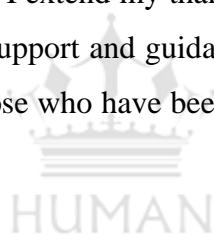
CONCLUSION

Our study was conducted to assess the effectiveness of the drug therapy and prescription pattern in the diabetic patients and we found that the prevalence of type 2 DM was higher in males than females. The maximum age distribution was seen in patients above 60 years of age and the least distribution of age was seen in patients $\leq$30 years of age. Hypertension, ischemic heart disease and unstable angina were the most common co-morbidities. The treatment was based on the HbA1c and GRBS levels of the patients which were monitored frequently by using OHA and insulin or by the combination of both depending on the glycemic swings. The most commonly prescribed drugs were Metformin of Biguanides class with or without the combination of other drugs based on the requirements of mono/dual/triple therapy and insulin. The most commonly used insulin was short acting (regular insulin) followed by rapid acting insulin and long acting insulin. On an average, every patient was receiving approximately 8 drugs per prescription which showed polypharmacy. By comparing the GRBS, and HbA1c, levels at the time of admission to that of at the time of discharge, we concluded that majority of the patients were controlled well with their glucose levels and the therapy was assessed to be effective.

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The study revealed that the most commonly prescribed drugs were Metformin of Biguanides class and regular insulin of short acting insulin class. Study results revealed that blood glucose levels of majority of the patients were well controlled and the therapy was found to be effective.

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