Prescription Pattern Analysis of Type II Diabetes Mellitus Inpatients and Associated Co-Morbidities

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ABSTRACT

Background: The present study was planned to assess the prescription pattern analysis of Type II Diabetes Mellitus and associated co-morbidities. As per WHO, the worldwide prevalence of DM will reach 366 million by 2030. Evaluating drug prescription pattern is a major aspect of patient care, which is used as a measure of the quality of care provided. Objectives: Primary objectives of the study were to highlight the current prescription pattern trends in patients having diabetes mellitus with or without other co-morbid conditions, to ensure safety and rational use of prescribed regimen. And the secondary objectives of the study were to analyse the demographic information of the enrolled patients and also to identify and analyse the prescriptions with polypharmacy. Materials and Methods: A prospective observational study was conducted to analyse the prescribing pattern of anti-diabetic drugs. The study incorporated 100 Type II DM inpatients having co-morbid conditions. The study has been conducted with the help of WHO prescribing indicator scale. It is used to analyse drug class, generic and branded drugs, fixed dose combination and dosage form. Patient data was collected and medical data records were analysed daily till discharge from hospital. Results: It was found that most of the drugs have been prescribed are purely from Karnataka Essential Medicine list (KEML). And percentages of medicines prescribed on their generic name were 76%. About 51% of patients were treated only with oral hypoglycemic agents. Whereas, 38% were treated with Insulin and 11% were treated with both oral hypoglycemic agents and Insulin. Conclusion: Improved rational use of prescription by using Essential Medicine List (EML). And also ensured the appropriateness of prescription by using WHO scale. Several Adverse Drug Reactions (ADR) have been reported and which leads to improved prescription pattern.

Keywords: Type II Diabetes Mellitus, Prescribing Indicator, Co-Morbidities.

INTRODUCTION

DM is defined as a heterogeneous metabolic disorder characterised by chronic hyperglycaemia with disturbance of carbohydrate, fat and protein metabolism. Metabolic syndrome such as insulin resistance syndrome can increase the risk of DM.[1]

Diabetes symptoms are frequent urination, excessive thirst, blurred vision, sweating, sudden weight loss, slow healing sores and fatigue. Organ damage and dysfunctions etc. are the after effects of type II DM.[1-2]

Diabetes are of 3 types: Type I, Type II, and Gestational diabetes.

If DM is not treated properly or is for long-term then it can leads to shock, cardiovascular disease, chronic kidney disease and permanent damage to the eyes. DM patients should manage daily dietary intake because the patient have to take oral hypoglycaemic agents. Without taking proper diet, the patient can suffer from hypoglycaemia. Instead of eating a large meal at single time, the patient can have small meals 4 to 5 times a day.[3]

Type II DM comprises of about 80% cases of DM. It was called earlier as maturity onset diabetes or Non-Insulin Dependent Diabetes Mellitus (NIDDM).[5]

Major risk factors for Type II DM are Family history, habitual physical inactivity, Obesity, previous identification of impaired fasting glucose, race, hypertension, history of gestational diabetes or delivery of baby heavier than 4kg, dyslipidaemia, Poly Cystic Ovarian Syndrome (PCOS), History of vascular disease.[1,4]

Pathogenesis of Type II DM can be explained only through certain types of factors and those are, Genetic Factors, Constitutional Factors, Insulin Resistance, Impaired Insulin Secretion, Increased Hepatic Glucose Synthesis.[3]
Anthypoglycemic agents in hospitalized patients include, Insulin therapy, Noninsulin therapy include Dipeptidyl Peptidase (DPP4) inhibitors or in combination with Insulin, Sulfonylurea and Metformin.[9]

The first line treatment for type II DM will always be lifestyle modifications. In case of obese patients with Type II DM, Bariatric surgeries is an effective treatment.[5]

Comorbidity refers to presence of at least one extra chronic disease for 6 months or longer. In some cases, diabetic patients with clinical complexity are more likely to receive high quality care.[5]

DM is associated with carbohydrate, fat and protein metabolism abnormalities which can results in chronic microvascular, macrovascular and neuropathic disorders.[7]

Retinopathy with potential blindness, neuropathy with kidney failure and neuropathy with risk of foot ulcers, amputation and sexual dysfunction are the long term complications of DM. 75% of patient deaths are reported due to macro vascular events.[2]

Most common comorbidities are, Retinopathy, Neuropathy, Nephropathy, Peripheral Vascular disease and foot ulcer, Coronary Artery Disease, Hypertension and Transplantation.

Treatment for various comorbidities primarily includes glycemic control. [5]

Pharmacological treatment for various comorbidities in diabetic patients is as follows:

1. Hypertension
   - Maintain the blood pressure less than 140/80 mmHg.
   - Angiotensin Converting Enzyme (ACE) inhibitors and Angiotensin Receptor Blockers (ARBs) are the drug of choice.
   - Calcium channel blockers (CCB) or diuretics may be considered as a first line agent in some cases.
   - Beta blockers as second and third line agent.

2. Coronary Vascular Disease
   - Aspirin therapy
   - Clopidogrel, if allergic to aspirin
   - Beta blockers for protection from recurrent chronic heart disease.

3. Dyslipidemia
   - Statins
   - Fibrates (its use is controversial)
   - Fibrates, niacin and Statins for hypertriglyceridemia.

4. Diabetic foot
   - Ciclosporin is useful for reducing claudication symptoms.
   - Revascularisations
   - Appropriate foot wear and foot care for foot lesions.[6,10]

Foot ulcers are one of the serious medical problems. It exhibits a high rate of recurrence and it is extremely difficult to heal in case of DM patients.

In case of general population coronary heart disease is the most common cause of death in patients having diabetic End Stage Renal Disorder (ESRD) 25-47% of persons having DM with hypertension as comorbidities are having insulin resistance or impaired glucose tolerance.[8]

Prescribing Indicators:

WHO core prescribing indicators were used to analyse prescription patterns. Evaluating drug prescription pattern is a major aspect of patient care, which is used as a measure of the quality of care provided. In the developing countries systematic analysis is prevalent due to irrational dispensing, prescribing and administration of medications. Such kind of irrational prescribing is unethical and can leads to adverse effects incidence, drug resistance, drug interactions etc. As per WHO more than half of all medicines are prescribed, dispensed or sold inappropriately. Prescription pattern studies can be used as a better tool for accurate prescribing, dispensing and distribution of drugs. Thus aim of these kinds of studies is to provide rational use of drugs. The drug use indicators were developed by WHO for rational use of drugs.

Prescription monitoring studies are crucial to bridge the areas such as rational use of drugs. It is very essential to conduct studies regarding prescribing patterns in every state in India and should use the data that has been collected through these studies for improving the quality of patient care with the main aim of improving rational drug use. [11]

MATERIALS AND METHODS

As per the study criteria those patients fulfilling the inclusion criteria were enrolled in the study and those met the exclusion criteria were excluded.

The study design was Prospective, observational study for 6 months duration.

Ethical clearance was obtained from institutional ethics committee for initiation of study. 100 diabetes patients were enrolled within the study from the Department of General Medicine, KCG hospital. Prescription pattern analysis of Type II DM patients with comorbidities has been conducted with the help of WHO core prescribing indicators. Thereby found out weather the treatment is rational or irrational.

Patient data was collected and medical data records were analysed daily till discharge from hospital. Prescription pattern analysis has done regularly with the help of World Health Organisation (WHO) prescribing indicators.

Patients aged more than 18 years were only included in the study. Patients diagnosed with diabetes along with other co-morbidities were selected. And those are on treatment with oral hypoglycemic agents and Insulin therapy was also incorporated in the study.

Patients with conditions such as poisoning and accident case, Pediatric patients and Patients with gestational diabetes were excluded. Patients visiting outpatient departments with or without diabetes mellitus were also be excluded.

Statistical Analysis was done with the help of Microsoft Excel.

RESULTS

To assess the prescription pattern of type II Diabetes mellitus in-patient, the data has been collected from 100 patients admitted to KCG Hospital and observations are as follows:
1. WHO Prescribing Indicators:

| S.N. | Prescription Indicators                                      | Frequency |
|------|--------------------------------------------------------------|-----------|
| 1    | Total number of prescriptions analysed (n)                   | 100       |
| 2    | Total number of medicines used in the study (n)              | 63        |
| 3    | Average number of medicines per prescription (n)             | 7         |
| 4    | Percentage of medicines prescribed on their generic name (%) | 75.36%    |
| 5    | Percentage of drugs prescribed with antibiotics (%)          | 17.17%    |
| 6    | Percentage of prescription contains injectable preparations (%) | 90%        |
| 7    | Percentage of medicines recommended from KEML (%)            | 100%      |

- Patients with co-morbidities were also included in the present study.
- Number of prescriptions contain polypharmacy were more among studied population as 67% prescriptions contain greater than 5 drugs.

Number of drugs per prescription:

| S.N. | Number of drugs per prescription (n) | Percentage of prescription |
|------|-------------------------------------|---------------------------|
| 1    | Less than Five drugs                | 33%                       |
| 2    | More than Five drugs                | 67%                       |

Table 3: Number of drugs among both genders

| Gender | Male | Female | Male | Female |
|--------|------|--------|------|--------|
| Less than five drugs | 20 | 13 | 20% | 13% |
| More than Five Drugs | 43 | 24 | 43% | 24% |

2. Prescription pattern of Anti-Diabetic drugs

About 51% (n=51) of patients were treated only with oral hypoglycaemic agents whereas, 38% (n=38) were treated with Insulin and 11% (n=11) were treated with both oral hypoglycaemic and Insulin.

Maximum numbers of anti-diabetic drugs per prescription were 2, which include both Insulin and oral hypoglycaemic agents. Among that, oral hypoglycaemic agents are most commonly used. (Metformin, Glibenclamide, Glimepiride) Human Actrapid were the drug of choice of Insulin preparation among enrolled patients.
Table 4: Anti-Diabetic drugs used

| SLNO. | Anti-Diabetic drugs used                  | Number of patients (n) | Percentage of prescriptions |
|-------|------------------------------------------|------------------------|----------------------------|
| 1     | Metformin 500mg                          | 20                     | 20%                        |
| 2     | Glibenclamide 5mg                        | 4                      | 4%                         |
| 3     | Glimepiride 1mg                          | 10                     | 10%                        |
| 4     | Metformin(500mg) + Glimepiride(2mg)      | 9                      | 9%                         |
| 5     | Metformin + Glibenclamide                | 10                     | 10%                        |
| 6     | Insulin + Metformin                      | 6                      | 6%                         |
| 7     | Insulin                                  | 38                     | 38%                        |
| 8     | Metformin + Glimepiride + Insulin        | 2                      | 2%                         |
| 9     | Exenatide                                | 1                      | 1%                         |

3. Prescription Pattern of Diabetes Associated Co-Morbidities

- Diabetes associated co-morbidities $\rightarrow$ 52% patients.
- Diabetes associated co-morbidities with other non-diabetes associated co-morbidity $\rightarrow$ 32% patients.
- Diabetes with other co-morbidities such as thrombocytopenia or pneumonia etc. $\rightarrow$ 14% patients.
- Only diabetes without any other co-morbidities $\rightarrow$ 2% patients.

![Figure 2: Co-Morbid Conditions](image)

- Hypertension, diabetic foot(52%) $\rightarrow$ Most common comorbidity.
- Maximum number of drugs used to treat hypertension $\rightarrow$ One
- Amlodipine $\rightarrow$ Commonly used medicine for hypertension.
- Symptomatic treatment has been given to diabetic patients with chronic kidney disease which include Lasix for oedema and electrolyte replacement for electrolyte imbalance etc.
- Diabetes mellitus patient with diabetic foot are mainly hospitalised as an inpatient for amputation and injectable antibiotic preparation mostly prescribed for postoperative surgical site infections.
- Ceftriaxone, Amikacin and Metronidazole are used together for minimum of five days or maximum to seven days to prevent surgical site infection.
4. Sex Distribution

The study participants enrolled in the study, majority of the participants were males 64(64%) followed by females 36(36%).

![Figure 3: Gender Distribution](image)

Table 5: Number of Patients

| S.N. | Gender | Number of Patients(N) | Percentage |
|------|--------|-----------------------|------------|
| 1.   | Female | 36                    | 36%        |
| 2.   | Male   | 64                    | 64%        |

5. Age wise distribution

Among 100 participants, majority of age group between 50-60 years (30%) and least were in the age group between 30-40 years (7%). Male patients were more affected in this age group (50-60 years).

![Figure 4: Age Distribution](image)

Table 6: Number of patients in different age groups

| S.N. | Age(years) | Number of patients (n) | Percentage of patients |
|------|------------|------------------------|------------------------|
| 1.   | 30-40      | 7                      | 7%                     |
| 2.   | 41-50      | 21                     | 21%                    |
| 3.   | 51-60      | 32                     | 32%                    |
| 4.   | 61-70      | 26                     | 26%                    |
| 5.   | >70        | 14                     | 14%                    |

DISCUSSIONS

As per the study conducted by Manjusha S et al, it is found that 83.81% patients were suffering from concurrent illness where hypertension was the most common co-morbidity followed by hypertension with atherosclerotic heart disease where in our study Hypertension was the common co-morbidity.[11]

In our study, out of 100 patients,

- Diabetes associated co-morbidities $\rightarrow$ 52% patients
- Diabetes associated co-morbidities along with other comorbid conditions $\rightarrow$ 2% patients
- Diabetes with other co-morbidities $\rightarrow$ 24% patients
- only diabetes without any co-morbidities $\rightarrow$ 2% patients

Prescription pattern of anti-diabetic drugs were studied and out of 100 patients,

- Metformin mono therapy $\rightarrow$ 29% prescriptions
- Insulin therapy $\rightarrow$ 28% prescriptions
- Oral sulfonylureas which include both Glimepiride and Glibenclamide $\rightarrow$ 14% prescriptions.
- Combination of Metformin and Sulfonylureas $\rightarrow$ 19% prescriptions.

These information were comparable to the study done by Kevin M Pantolone et al.[12] It is found that Metformin and Sulfonylureas are commonly prescribed oral hypoglycaemic agents and patients receiving only Metformin monotherapy in 2018 & 2013 were 63 % and 67% respectively. Whereas, in another study by Manjusha et al. shows that 58% patients were under monotherapy and 41.9% were under combination of oral hypoglycemic agents. Metformin is widely regarded as first line treatment for most of the Type II diabetes patients. Our study also supports the same, 56% patients has been prescribed with Metformin with other oral hypoglycemic agents or insulin preparation. Age distribution of patient with DM with or without associated co-morbidities cases in age group 50-60 constituted 32% following by 21% in 40-50 age group, this corresponds to finding by Mohd Mahmood et
al, where majority were of age group between 41-60 (45.53%) and least were in the age group of 20-40 (6.38%). In our study prevalence of type II DM were high in male (63%) which also correlate the result of various other study across India.

CONCLUSION

The study concluded that anti-diabetic drugs are prescribed purely from KEML that show rational prescribing pattern. Metformin and oral Sulfonylureas were widely used oral hypoglycemic agent as monotherapy or combination of those among studied population. According to the result obtained from the study, Male patients are more prone to DM when compared to female patients and more number of diabetes patients were in between 51-60 years of age due to various comorbid conditions like hypertension, diabetic foot etc.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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