**Original Article**

# AN INVESTIGATIONAL EXAMINATION OF DRUG PRESCRIBING DESIGN, COST ANALYSIS AND REPORTING ARD'S AMONG PATIENTS WITH DIABETES IN A MULTISPECIALITY HOSPITAL OF HYDERABAD

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## ABSTRACT

Diabetes is a disease that occurs when your blood glucose, also called blood sugar, is too high. Blood glucose is your main source of energy and comes from the food you eat. To determine the most prescribed anti diabetic drugs and its Prescription patterns, Cost analysis, Adverse Drug Reactions. Average number of drugs per prescription (encounter), Percentage of drugs prescribed by generic name, Percentage of prescriptions with an antibiotic prescribed, Percentage of prescriptions with an injection prescribed, Percentage of drugs prescribed from an Essential Medicine List , Average drug cost per prescription or encounter. Data were analyzed using the Statistical Package for Social Sciences SPSS for windows. Patients in the age group of 50–69 years have more incidences of diabetes mellitus than the other age group, this incidence is more as observed in the other study (59.89%), followed by, 40–49 years and less than 30-39 years and more than 70 years. The mean +SD age of the patients is 56.9 +12.55 years. It has been seen that 78.68% patients of diabetes mellitus have co-morbid which is higher than as observed in (70.33%). Co-morbid conditions like CVDs and nephropathy is less while asthma is more as observed by (76.42%, 1.13% and 1.13% respectively). DM patients were commonly encountered with restlessness (42.0%), peripheral neuropathy (36.0%), liver disorder (22.0%), rashes (18.0%), and other nervous system disorders (40.0%). Other frequent ADRs that have been experienced were nausea, vomiting, arthralgia, drowsiness, and pain in back and limbs.

**Key Words**: Prescription patterns, Cost analysis, Adverse Drug Reactions, arthralgia, drowsiness.

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## 1. INTRODUCTION

DM happens all over the world, but is more usual in the more advanced countries. The greatest rise in incidence is, however, occurring in low- and middle-income countries [1-4] including in Asia and Africa, where most sufferers will perhaps be found by 2030.[5-7] The rise in occurrence in evolving countries follows the Global nutrition transition, marked by enlarged intake of diets that are high energy-

dense but nutrient-poor often high in sugar and saturated fats, occasionally referred to as the Western pattern diet.[1] [8-11] The risk of getting type 2 diabetes has been widely found to be associated with lower socio-economic position across countries.

The classic indications of non-treated diabetes are loss of weight, polyuria, polydipsia, and polyphagia.[12-14]Indications may progress quickly weeks or months in type 1 DM, while they usually grow much more gradually and may be subtle or absent in type 2 DM.

Numerous other signs and indications can mark the start of diabetes although they are not specific to the illness.[15-18]. In accumulation to the known ones above, they involve blurry vision, headache, slow healing of cuts, fatigue, and itchy skin.[19-21]. Lengthy high blood glucose can cause glucose absorption in the lens of the eye, which leads to alterations in its shape, resulting in vision variations. No. of skin rashes that can happen in diabetes are jointly known as diabetic dermatomes

Absolute bioavailability.[22-24] depends on dosage. Food slightly lowering the bioavailability (a decrease of about 6% is seen when the 40-mg dose is administered with food). Highly bound to plasma proteins (>99.5%), mainly albumin and a1-acid glycoprotein. Binding is not dose-dependent.[25].

The aim of the study is to determine the most prescribed anti diabetic drugs and its Prescription patterns, Cost analysis, Adverse Drug Reactions

## 2. EXPERIMENTAL SECTION

A prospective drug utilization study was conducted in PRIME Hospital, Ameerpet, Hyderabad. Which is 700 bedded multispecialty hospitals. The study was carried out for the total period of 8 months in between November 2016 to July 2017. The study was carried out in Endocrinology department and General Medicine department in 62 populations. Case notes of both Diabetes outpatients and inpatients treated November 2016 and July 2017. Diabetes OPD and IPD, male and female, between 20 and 90 years of age. Diabetic patients visiting the OPDs and IPDs of the hospital and patients who gave written informed consent to analyze their prescription after photocopy.

**Exclusion Criteria like** Patients whose case notes recorded <3 visits to the clinic. Patients whose case notes did not record laboratory investigations. Patients who are admitted with, pregnancy induced diabetes mellitus and pediatric diabetic patients, patients who have surgery of

pancreas (pancreatectomy) and recently got operation for any other surgery.

## PATIENT DATA COLLECTION

I. Demographic details of the Patients:

a. Average age of the patients

b. Sex (male and female ratio)

c. Co-morbid conditions prevalent in diabetic patients

II. To study the pattern of drug prescribing among diabetic outpatients

III. To analyze the prescription as per the WHO Prescribing Indicators

The following are the parameters:

Average number of drugs per prescription (encounter), Percentage of drugs prescribed by generic name, Percentage of prescriptions with an antibiotic prescribed, Percentage of prescriptions with an injection prescribed, Percentage of drugs prescribed from an Essential Medicine List , Average drug cost per prescription or encounter. Approval of the Institutional Ethics Committee was obtained prior to the commencement of the study. This study was approved by the Institutional ethical committee (IEC).

Data were analyzed using the Statistical Package for Social Sciences (SPSS for windows. Version 16.0.SPSS Inc. 2007.Chicago, USA) software. Continuous data were presented as mean ± standard deviation (SD) while categorical data were presented as percentages and by using graph pad prism software.

## 3. RESULTS AND DISCUSSIONS

### I. Subject Characteristics:

A total of 166 prescriptions were collected that contained 1824 drugs. There were patients of type 2 (n=56) and Type 1 diabetes mellitus (n=6). Among these diabetes patients Males and females were 48.34% and 51.66% respectively. Among these patients, the greatest number were in the age group of 60–69 years, followed by 50–59 years, 40–49 years, 30-39 years and more than 70 years respectively. The mean +SD age of the patients was 56.9 +12.55 years. Total of 62 patients were enrolled in the study in accordance with the inclusion and exclusion criteria, after giving the written consents. During the study

period, patients case files and medical records were reviewed. Out of 62 recruited subjects, 41.8% (28) were females and 58.2% (34) were males. The mean age of the subject was 52.48 years ± 13.69 years. The minimum age of the patient was 32 and the maximum age of the subject was 82 years.It has been seen that 78.68% patients of diabetes mellitus have co-morbid conditions like cardiovascular diseases (HT, CAD, stroke and peripheral vascular disease), dyslipidemia, GIT, diabetic foot, asthma, nephropathy etc.

**Table 1: Demographic profile**

| Age | Male | % age | Female | %Age | Total | % Age |
|-----|------|-------|--------|------|-------|-------|
| 30-39 | 7 | 20.5 | 5 | 17.8 | 12 | 19.35 |
| 40-49 | 6 | 17.6 | 4 | 14.2 | 10 | 16.12 |
| 50-59 | 7 | 20.5 | 6 | 21.4 | 13 | 20.96 |
| 60-69 | 9 | 26.4 | 11 | 39.2 | 20 | 32.25 |
| >70 | 5 | 14.7 | 2 | 7.14 | 7 | 11.2 |
| Total | 34 | 54.8 | 28 | 45.16 | 62 | 100 |

**Graph 1: Demographic profile of Diabetes Patients**
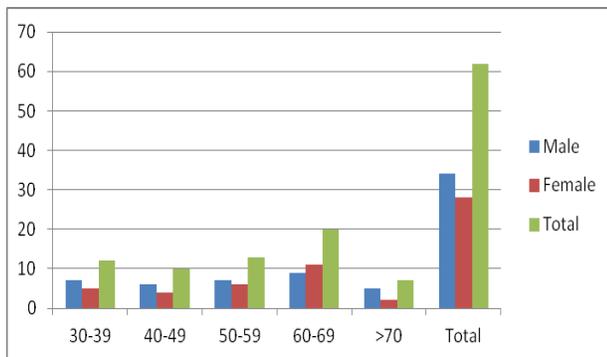


**Table 2: Co morbid condition prevalent in type 2 DM**

| Other diseases | No.of patients | % of patients |
|----------------|----------------|---------------|
| DM+HT | 11 | 35.48 |
| DM+CAD | 8 | 25.8 |
| DM+HT+CVA | 3 | 9.6 |
| DM+CVD+HT | 9 | 29.03 |
| **TOTAL DM+CVDs** | **31** | **100%** |
| Dyslipidemia | 11 | 26.82 |
| Asthma | 12 | 29.26 |
| Diabetic foot | 9 | 21.9 |

| | | |
|---|---|---|
| Nephropathy | 2 | 4.8 |
| GI disorders | 6 | 14.63 |
| Osteoporosis | 1 | 2.43 |
| **Total** | **41** | **100%** |

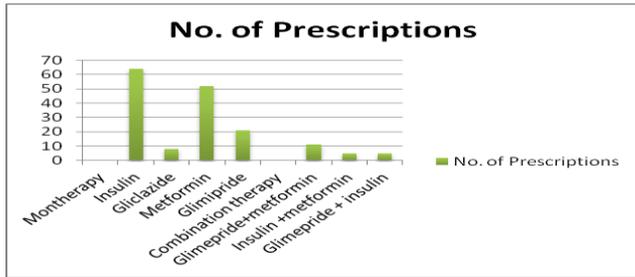**Graph.2: Co morbid condition prevalent in type 2 DM**
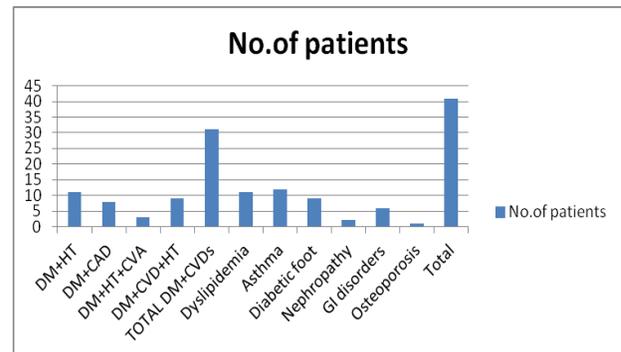


## II. Drugs prescribed from different groups among diabetic patients

It has been observed that 28.45% of the drugs belong to anti-diabetic groups (oral hypoglycemic and insulin) while 71.55% belong to other groups. Among oral anti-diabetic drugs 85.6 % of the drugs prescribed as monotherapy and combination therapy was 14.4% either two drugs or three drugs (10.4% and 4% respectively). Insulin is prescribed in 7.8% cases

**Table 5.3: Drugs prescribed from different groups**

| Classification of anti-diabetic drugs | No.of Prescriptions | Percentage of patients |
|----------------------------------------|---------------------|------------------------|
| **Monotherapy** | | |
| Insulin | 64 | 38.6 |
| Gliclazide | 8 | 4.8 |
| Metformin | 52 | 31.4 |
| Glimipride | 21 | 12.5 |
| **Combination therapy** | | |
| Glimepride+metformin | 11 | 6.4 |
| Insulin +metformin | 5 | 3.1 |
| Glimepride + insulin | 5 | 3.1 |

| 1 | Insulin | 64 |
|---|---|---|
| 2 | Meglitinides | 8 |
| 3 | Biguanide | 52 |
| 4 | Sulphonylureas | 21 |
| 5 | Sulphonylureas+biguanides | 17 |
| 6 | Insulin+biguanide | 5 |
| 7 | Sulphonylureas+insulin | 5 |



**Graph 3: Drugs prescribed from different groups**

**Table 4: Other drugs commonly used along with DM**

| Drugs group | No. of prescriptions | % of prescription |
|---|---|---|
| Ramipril | 45 | 26.9 |
| Enalapril | 69 | 41.4 |
| Telmisertan | 25 | 15.2 |
| Olmisertan | 12 | 7.3 |
| Losartan | 1 | 0.6 |
| Diuretics | | |
| Hydrochlorthiazide | 17 | 10.3 |
| Torsemide | 9 | 5.4 |
| Furosemide | 4 | 2.4 |
| Beta blockers | | |
| Metaprolol | 7 | 4.2 |
| Atenolol | 7 | 4.2 |
| Alpha blockers | 2 | 1.2 |
| Antiplatelets | 26 | 15.4 |
| Atorvastatin | 17 | 10.4 |
| Rosuvastatin | 90 | 54.1 |

**Graph 4: Other drugs commonly used along with DM**
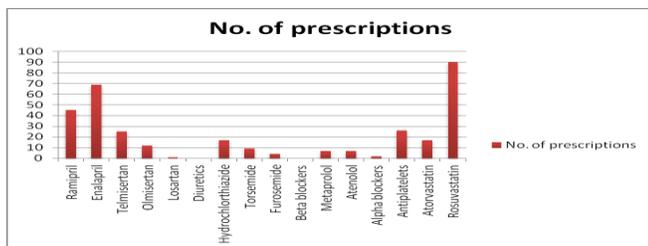


**Table 5: Most Frequently Prescribed Drug Molecule**

| Sl.No | Name of Drug | No of Prescriptions |
|---|---|---|

There were total of 7 different drug molecules prescribed in the study population. Out of which the most commonly prescribed molecule was insulin. This drug was prescribed total 64 times. This was followed by metformin and glimipride by 52 times and 21 times prescribed drug respectively. The least commonly prescribed drugs were insulin+metformin combination and Glimepride+insulin which were prescribed 5 times.

**Table 6: Antibiotics distribution among DM**

| Antibiotics | No. of Prescriptions | Percentage of patients |
|---|---|---|
| Nil | 89 | 53.1 |
| Yes | 77 | 46.9 |
| Augmentin | 7 | 9.09 |
| Cefixime | 37 | 48.05 |
| Cefotaxim | 24 | 31.16 |
| Ceftriaxone | 1 | 1.29 |
| Ciprofloxacin | 8 | 10.38 |

**Graph 6: Antibiotics distribution among DM**
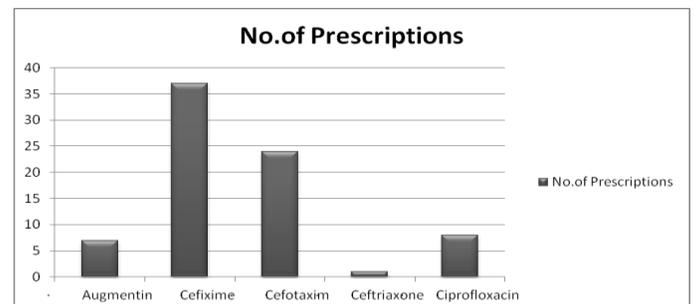
## Cost Benefit:

**Table 7: Different brands of drugs used and their cost.**

| Sr. No. | Brand | content | Price per tablet |
|---------|-------|---------|-----------------|
| 1 | Human Mixtard | 100IU | 38.14INR |
| 2 | Human Actrapid | 10ml | 159 INR |
| 3 | Glycomet | 500 mg | 3.3 INR |
| 4 | Glimipride | 2mg | 2.50INR |
| 5 | Glyciphage | 500 mg | 2.50 INR |
| 6 | Forson | 500 mg | 8.7INR |
| 7 | Novonorm | 1mg | 9.8INR |
| 9 | Amaryl-M | 2mg | 12.4INR |
| 10 | Glucotrol-MF | 5mg | 0.74INR |

The above table shows that the costliest drug which prescribed was Human Actrapid, having the cost of 159 INR per Injection. The cheapest drug prescribed was Metformin and Glipizide (Glucotrol-MF) combination having the cost of 0.74INR per tablet**.** Insulin and Biguanides are more are showed good efficacy and hence prescribed more frequently among all other antidiabetics

Insulin is prescribed for 64 times and Biguanides for 52 times.

Costly drugs (Insulin) are giving more benefit when compare to cheaper drugs (Glucotrol – MF). Among insulin's Human Mixtard is cost beneficial when compared to Human Actrapid. Among oral antidiabetics single drug treatment with Biguanides Glyciphage is cost beneficial and most frequently prescribed and in combination treatment Glucotrol –MF is cost beneficial.

The cost of Diabetes varies according to age groups; an earlier study cited in the review had concluded that people with diabetes spend at least 1.75% more on medical care than those without diabetes.

In this study we determined the cost of treating over a period of 8 months. It shows in below table.

**Table 8: Budgetary cost of treatment**

| | Cost in INR |
|---|---|
| Personnel | 57,000INR |
| Facilities | 15,978INR |
| Supplies and equipment's | 2,645INR |
| Fixed cost | 1,6401NR |
| **Total** | **77,263** |

**Graph 8:  Budgetary cost of treatment**
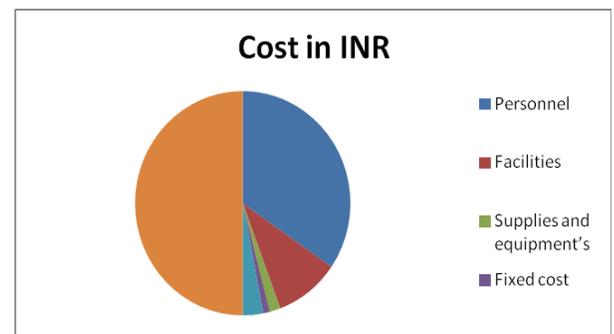


To accurately measure the benefits of using anti diabetic treatment of diabetes, we should compare it with the benefits of using other forms of treating the condition. The table below shows the benefits of using insulin, oral anti diabetics and combination therapies.

**Table 9: Health benefits of using insulin, oral anti diabetics and combination therapies**

| Health variables | % benefit with oral treatment | % benefit with insulin | % benefit with combination therapy |
|---|---|---|---|
| Hemoglobin(lower is better) | 8.5 | 10.00 | 9.5 |
| Triglycerides(high is not better) | 2.0 | 3.1 | 1.9 |
| Low density lipoprotein(optimal<2.6) | 2.5 | 3.2 | 2.5 |
| High density lipoprotein(optimal>1.5) | 1.2 | 1.0 | 1.1 |
| Spontaneous bacterial peritonitis (lower is better) | 102 | 110 | 120 |
| DBP( optimal <80) | 76 | 68 | 77 |

In the above table the benefits are not clear cut, out of six variables measured treatment using insulin showed better only in 3 instances, using oral hypoglycemic or a combination therapy would be better option.

A total of 15 patients presented with at least one ADR. The median duration (±SD) between onset of treatment and first-time adverse reaction occurrence was 25 days.

**Table 10: ADR incidence in patients:**

| ADR | ADR incidence n (%) | Onset time, days (median) | p value |
|---|---|---|---|
| Nausea and vomiting (ciprofloxacin) | 11 (26.0) | 12 (7–26) | 0.242 |
| Rashes(Sulphonyl ureas+Insulin) | 8 (24.0) | 16 (10–29) | 0.916 |
| Peripheral neuropathy(Ciprofloxacin) | 13 (36.0) | 1 (7–50) | 0.058 |
| Liver injury(Augmentin) | 9 (22.0) | 25 (17–54) | 0.51 |
| Restlessness (Sulphonylu reas) | 15 (42.0) | 10 (5–25) | <0.001*** |
| GI problem(Metformin) | 7 (14.0) | 12 (5–40) | 0.236 |
| Hypoglycemia( Insulin) | 2 (4.0) | 06 (3–10) | 0.001*** |
| Joint pain(Antibiotics) | 7 (14.0) | 20 (11–45) | 0.698 |
| Drowsiness(cephalosporins) | 5 (10.0) | 11 (5–27) | 0.319 |
| Back pain(Miglitinide) | 07 (14.0) | 37 (15–55) | 0.002** |
| Foot pain(Antibiotics) | 05 (10.0) | 30 (25–39) | 0.006* |
| Blurring vision(Antibiotics) | 01 (2.0) | 60 | 0.613 |

**Graph 10: ADR incidence in patients**
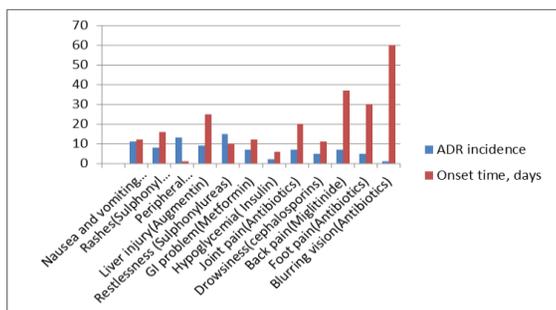


DM patients were commonly encountered with restlessness (42.0%), peripheral neuropathy (36.0%), liver disorder (22.0%), rashes (18.0%), and other nervous system disorders (40.0%). Other frequent ADRs that have been experienced were nausea, vomiting, arthralgia, drowsiness, and pain in back and limbs. All ADRs were mild to moderate. Rechallenge of suspected drug was not performed in most cases due to safety and practical necessity. Among the collected ADRs, restlessness,

hypoglycemia, back pain, and feet pain were significantly associated DM patients. The occurrence of other ADRs was not significantly different between the two groups as presented.

**DEMOGRAPHY DETAILS:**

The incidence of diabetic mellitus is slightly less in males than females which are contrast to as observed in which show higher incidence among male. Patients in the age group of 50–69 years have more incidences of diabetes mellitus than the other age group, this incidence is more as observed in the other study (59.89%), followed by, 40–49 years and less than 30-39 years and more than 70 years. The mean +SD age of the patients is 56.9 +12.55 years. It has been seen that 78.68% patients of diabetes mellitus have co-morbid conditions (like cardiovascular diseases (HT, CAD, dyslipidemia, GIT, diabetic foot, asthma, nephropathy etc) which is higher than as observed in (70.33%). Co-morbid conditions like CVDs and nephropathy is less while asthma is more as observed by (76.42%, 1.13% and 1.13% respectively). It has been observed that Dyslipidemia, diabetic foot and GIT disorders are also present in diabetes patients of this region as compared to studies in reviews.

There were total of 7 different drug molecules prescribed in the study population. Out of which the most commonly prescribed molecule was insulin. This drug was prescribed total 64 times. This was followed by metformin and glimipride by 52 times and 21 times prescribed drug respectively. The least commonly prescribed drugs were insulin + metformin combination and Glimepride+insulin which were prescribed 5 times. In this study the author determined the cost of treating over a period of 6 months. To get the net social benefits we have to calculate willingness to pay as the measure of benefits of treating DM. To measure the benefits of using anti diabetic treatment of diabetes we compared it with the benefits of using other forms of treating the condition out of six variables measured treatment using insulin showed better only in 3 instances, using oral hypoglycemic or a combination therapy would be better option.

**ADR REPORTING:**

DM patients were commonly encountered with restlessness (42.0%), peripheral neuropathy (36.0%), liver disorder (22.0%), rashes (18.0%), and other nervous system disorders (40.0%). Other frequent ADRs that have been experienced were nausea, vomiting, arthralgia, drowsiness, and pain in back and limbs. All ADRs were

mild to moderate. Rechallenge of suspected drug was not performed in most cases due to safety and practical necessity.

## 4. CONCLUSION

DM sufferers were usually encountered with restlessness, peripheral neuropathy, liver illness, rashes, and other nervous system illnesses. Other recurrent Adverse Drug Reactions that have been undergone were arthralgia, nausea, drowsiness, vomiting, and pain in back and limbs. All ADRs were mild to moderate. Rechallenge of supposed medicine was not conducted in most cases due to security and practical requirement.

In these trail sufferers in the age group of 50–69 years have more occurrences of diabetes mellitus than the other age group, this incidence is more as observed in the other study (59.89%), followed by, 40–49 years and less than 30-39 years and more than 70 years. This trail is only catalogues what other studies have analyzed over a single hospital. To measure the benefits of using anti diabetic treatment of diabetes we compared it with the benefits of using other forms of treating the condition out of six variables measured treatment using insulin showed better only in 3 instances, using oral hypoglycemic or a combination therapy would be better option.

In that regard, this is only a small step in advancing the use of economic models in health management. The findings should therefore not be taken as conclusive given that each hospital has its own peculiarities. The next step would be to collect more data from the PRIME and analyses to get a correct picture of the exact costs and benefits of treating diabetes mellitus using insulin.

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