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# ASSESSMENT OF EPIDEMIOLOGY, PRESCRIBING PATTERNS, MEDICATION ADHERENCE AND IMPACT OF PATIENT EDUCATION ON DIABETICS IN A RURAL COMMUNITY

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**Keywords:**

Diabetes, Counselling, Knowledge, Adherence

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**ABSTRACT: Background:** There is a rise in a number of diabetes mellitus patients globally, but awareness of the disease, symptoms, medication use, associated complications, and comorbidities are low among Indians. The objective of the study was to evaluate the epidemiology of diabetes, prescribing patterns, and medication adherence and the impact of patient education on diabetes in a rural community. **Methods:** A cross-sectional, descriptive, and community-based study was conducted on 100 randomly selected known diabetic patients by direct interview at their doorsteps using data collection form, glucometer, patient leaflet, and brief medication questionnaire. The data contained information about socio-demographic details, knowledge about the disease, medication use, adherence, lifestyle changes, complications and co-morbidities, and measurement of their random blood sugar levels before and after counseling. Data were analyzed using SPSS version 18. **Results:** There were 63% females and 37% males; the maximum number of patients was in the age group 51-60 years, and the mean age was 51.6 ± 11.1years. The most commonly used drugs were biguanides, followed by sulfonylureas. The Brief Medication Questionnaire (BMQ) showed patient medication adherence 32% with a non-adherence of 68%. There is a significant improvement among the patients' random blood sugar after patient counseling (p=0.0001). **Conclusion:** The obtained knowledge about the various aspects of care among diabetics at an individual level was inadequate, requiring periodic counseling for improving medication adherence and to obtain glycemic control.

**INTRODUCTION:** Diabetes mellitus is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced (WHO).

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The prevalence of diabetes is growing day by day, reaching an alarming rate. Type 2 diabetes mellitus (T2DM) is a worldwide epidemic, with a growing prevalence, creating a global healthcare burden. India stands second after China with the highest rate of diabetes [1].

In India, about 7.0% of adults were diagnosed with diabetes, according to the annual health survey 2017 [1]. WHO (World Health Organization) estimated 32 million diabetic people in India in 2002, which was analyzed to rise by about 80 million people by the year 2030 [3].

The higher percentage of the male population (7.1%) was observed with diabetes than the females (6.8%) and with a higher proportion in urban (9.8%) than rural (5.7%) areas. About 10.2% of adults were diagnosed with diabetes in Andhra Pradesh [1]. Deficiency of insulin results in increased concentrations of glucose in the blood, which in turn damage many of the body's systems, in particular the blood vessels and nerves. There are two types of diabetes mellitus are type-1, also known as insulin-dependent and type-2, known as non-insulin dependent.

Type-1 is majorly caused by the destruction of pancreatic beta cells due to autoimmune-mediated reaction, which leads to decreased insulin production. Type-2 is due to insulin resistance or abnormal insulin secretion, either of which is the major cause of [2].

T2 DM is a chronic progressive disorder that is incurable, with long term complications that can be diagnosed by various diagnostic tests like fasting blood glucose (FBG) levels, which indicates the possibility of diabetes (FBG≥126mg/dL) and postprandial blood glucose levels (PPBS≤140 mg/dL). An oral glucose tolerance test (OGTT≥ 200 mg/dL) is done generally for patients who are overweight and have more than one additional risk factor. Random blood sugar (RBS: 79-160 mg/dL) is generally done for diabetic patients to determine the efficacy of therapy, and another monitoring parameter is glycated hemoglobin (HbA1c > 6.5%) which gives the three months average of serum blood sugar levels [3].

The glycemic control can be achieved by dietary and lifestyle modifications along with the selection of medication [4]. Higher blood glucose can lead to micro and macrovascular complications that could be decreased with optimizing blood glucose levels [5].

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The glycemic control can be achieved by dietary and lifestyle modifications along with the selection of medication [4]. Higher blood glucose can lead to micro and macrovascular complications that could be decreased with optimizing blood glucose levels [5]. To avoid complications National Institute of Clinical Excellence (NICE), Indian Diabetes Management, and American Diabetes Association (ADA) recommends aggressive anti-diabetic therapy [6].

Metformin and sulfonylureas are the most commonly used first-line therapeutic agents in newly diagnosed type-2 diabetes patients [4]. These drugs act by the influx of calcium ions that, in turn, increase the release of insulin from the pancreatic beta cells [3]. Initially, these agents show an effective response to lowering glucose levels. However, some patients may experience intolerable side effects, and glycemic control is not achieved, then there is a requirement of alternative monotherapy or combination therapies [4]. Alternative mono-therapies include thiazolidinedione (TDZ), sodium-glucose cotransporter 2 inhibitors (SGLT2), dipeptidyl peptidase four inhibitors (DPP4), alpha-glucosidase inhibitors, and insulin-based therapy [4].

The anti-diabetic drugs currently used are very effective, but due to deficiency of clinical information, patient's noncompliance, decreased insulin receptor sensitivity, lack of physical activity and dietary modifications are leading to higher chances of uncontrolled hyperglycemia [7].

According to WHO, adherence is the extent to which a person's behavior, taking medication, following a prescribed diet, and executing lifestyle changes corresponds with agreed recommendations from the health care provider. Due to non-adherence, the safety and effectiveness of the treatment reduce, which can lead to morbidity and mortality, which are translated into direct and indirect costs to the health care system. Medication adherence scales are critical components in identifying ways for improvement and patient education [8]. The factors associated with non-adherence maybe therapy-related, patient-centric, or health care system related. Patient-centric factors include the demographic and psychological understanding of health care.

The therapy-related factors can be the route of administration, duration of therapy, type of medicine, and side effects of the therapy. The health care system-related factors include the availability and accessibility of health care [8]. Along with the dietary and lifestyle modifications for Type-2 diabetes, medication adherence is a major determinant for the achievement and optimization of glycemic control [4].

Currently, no gold standard medication adherence questionnaire is present; however, a brief medication questionnaire (BMQ) describes the adherence of patients towards medication and assesses barriers and self-efficacy [8].

The BMQ is a brief and easy tool to use for good sensitivity and ability to detect various barriers for adherence with the potential for self-administration by patients on multiple drugs [9].

BMQ has majorly three screens, regimen screen, which is a 5 item screen that measures adherence and behaviour for potential non-adherence. The belief screen that concerns about the efficacy and ADRs, which includes short term and long term and other bothersome features of the prescribed medications. The recall screen that measures the problems associated with remembrance of the doses and dosage regimens by asking the patient [9]. Effective improvement of diabetes can be managed with education, lifestyle modifications and blood glucose monitoring in parallel to pharmacological treatment [11]. Educational intervention and lifestyle modifications that include diet, physical activities are critical steps in treatment [12]. These are effective in improving knowledge of blood sugar levels in diabetic individuals [13].

**Objectives:**

- To evaluate the epidemiology of diabetes in a community
- To study the prescribing patterns
- To assess the medication adherence in patients using BMQ
- To study the impact of patient education

## MATERIALS AND METHODS:

**Study Site:** This study was conducted in the Gargaparu community, which is located in Palakoderu Mandal, West Godavari District, Andhra Pradesh, India. People of Gargaparu village speak Telugu. The total population is 5092, and the number of houses is 1477. About 66.9% of villagers are literates, and the female population is 50.1%.

**Study Design:** The study was a cross-sectional study.

**Study Period:** The study was carried out over a period of seven months from July 2018 to January 2019.

**Source of Data and Materials:**
**Method of Collection of Data:**

- Patient interview

**Method of Collection of Material:**

- Patient health-related quality of life documentation form (BMQ)
- Patient consent form
- The patient data collection form
- Patient information leaflet
- Measurement of patients RBS with the glucometer

**Study Criteria:**
**Inclusion Criteria:**

- Patients who are willing to participate in the study
- Patients diagnosed with diabetes mellitus

**Exclusion Criteria:**

- Patients who are not willing to give the consent form
- Pregnant/lactating women

**Study Procedure:**
**Method of Data Collection:** An approval for ethical clearance has been obtained from Institutional Ethical Committee IEC NUMBER-SVCP/IEC/18-19/7 prior to the initiation of the study. A Survey of the total number of subjects having diabetes in the area was done. Subjects who met the inclusion criteria were selected accordingly. The total population of 303 diabetics was randomly enrolled for the study. An informed consent form was obtained from the patient or the attendants of the patient.

A face to face interview was conducted for each patient at their doorstep. Details of the subject's duration of illness, medication use, and medication adherence according to the BMQ were obtained, medication adherence charts were given to the patients using more than two drugs, mobile alarms were set for patients using a single drug. The random blood sugar levels were checked by glucometer. Patient counseling was done with the aid of leaflets.

The leaflets contained information about the disease symptoms, when to seek medical advice, managing by self-care during hyperglycemic and hypoglycemic conditions, home remedies for reducing frequent attacks, medication adminis-tration, adherence, storage, and healthy dietary habits. The leaflet was printed in both English and Telugu (local language) for easy understanding by patients. The time spent on collecting data from each subject was varying from 15-30 min (average 20 mins).

Subjects were advised to follow the tips given during counseling for optimal glycemic control. A review of counseling and measurement of RBS was taken from subjects with a gap of about four months after initial counseling to know the impact of counseling on the health-related quality of life.

**Assessment of Medication Adherence:** According to the study design, the patient's medication adherence was measured by using the BMQ scale. The collection of patient medication adherence issues according to their quality of life was done by using appropriate questionnaires and assessed by using scores that have been included according to scales.

**Statistical Methods:** The prescribing patterns of anti-diabetic treatment were evaluated. To analyze the age, gender, duration of illness, and economic status Pearson's correlation test is used. The medication adherence evaluation of subjects was employed by the BMQ questionnaire. Descriptive statistical analysis of demographics and clinical variables included percentage, mean, and standard deviation. Mean values of random blood sugars before and after, along with mean changes, were calculated. A paired t-test was used to determine if the change is detected from before and after counseling was significant. The probability value of $\leq 0.05$ was set as significant and $\leq 0.001$ as highly significant. All the statistical analysis was performed by using SPSS statistical software, version 18.

**RESULTS:** A total of 303 people were identified with diabetes in an overall population of 5092 in the community. Out of the total identified population, 100 subjects were enrolled by randomization. Among the 100 sample females (63%) n=63 and males (37%) n=37, age group of 51-60 is about 34% followed by 61-70 (28%), 41-50 (24%), >71 (8%), 31-40 (4%), 21-30 (1%) and <20 (1%). Duration of illness of <5 years (56%) is mostly observed in the study population followed by 6-10 years (28%), 11-15 years(8%), 16-20 years (6%), and >20 years (2%). The percentage of the study population in the middle class is about 48, followed by poor 26 and rich 26. The percentage of type 2 diabetes (97%) is more in the study population than type 1 diabetes (3%).

**TABLE 1: DISTRIBUTION OF VARIOUS ANTI-DIABETIC DRUG CLASSES**

| S. no. | Class | Number | Percentage |
|---|---|---|---|
| 1 | Biguanides | 113 | 53.80 |
| 2 | Sulfonyl Ureas | 68 | 32.38 |
| 3 | Insulin | 11 | 5.23 |
| 4 | Thiazolidinediones | 9 | 4.28 |
| 5 | Alpha Glucosidase Inhibitor | 6 | 2.85 |
| 6 | DPP4 Inhibitors | 3 | 1.42 |

It represents biguanides (53.80%) are the most commonly prescribed class of drugs followed by sulfonylureas (32.38%), insulin (5.23%), thiazolidinediones (4.28%), alpha-glucosidase inhibitors (2.85%) and DPP4 inhibitors (1.42%).

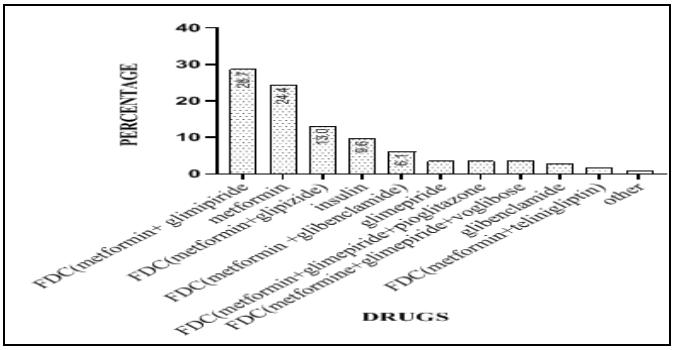


**FIG. 1: DISTRIBUTION OF MEDICATIONS PRESCRIBED TO THE PATIENT.** Fig. 1 represents FDC (glimepiride and metformin) (28.69%) is the most commonly prescribed medication followed by metformin (24.34%), FDC (metformin + glipizide) (13.04%), Insulin (9.56%), FDC (metformin + glibenclamide) (6.08%), glimepiride (3.47%), FDC (metformin + glimepiride + pioglitazone) (3.47%), FDC (metformin + glimepiride + vogilbose) (3.47%), gibenclamide (2.60%), FDC (metformin + telinigliptin) (1.7%), vogilbose (0.8%), teneligliptin (0.8%), glipizide (0.8%) and FDC (metformin + vogilbose) (0.8%)

**TABLE 2: COMPARISON OF RBS VALUES BEFORE AND AFTER COUNSELLING**

| | Paired Differences | | | | | T | Degree of freedom | Sig. (2-tailed) |
|---|---|---|---|---|---|---|---|---|
| | Mean difference | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference | | | | |
| | | | | Lower | Upper | | | |
| RBS Before - RBS After | 27.25 | 73.07 | 7.31 | 12.75133 | 41.74867 | 3.729 | 99 | 0.0001 |

It represents the comparison of the RBS using paired t-test; the difference in the RBS is measured statistically to observe the improvement among the patients. Comparing the actual t value (t=1.98) with the obtained value (t=3.729) at 95% confidence interval, the hypothesis states that there is a significant improvement in the patients' RBS after the counseling (P=0.0001).

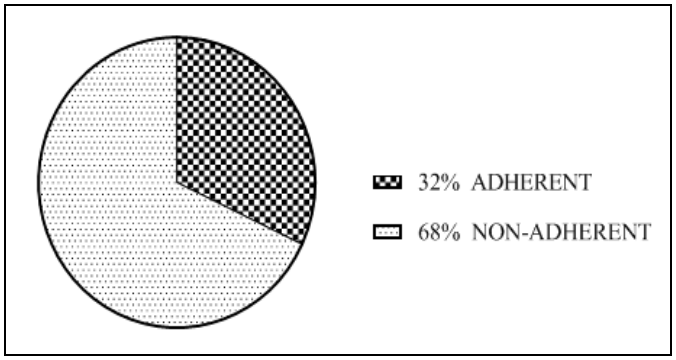


**FIG. 2: DISTRIBUTION OF STUDY POPULATION BASED ON MEDICATION ADHERENCE.** It represents the major study population is non-adherent (68%) to the medication prescribed than adherence (32%).

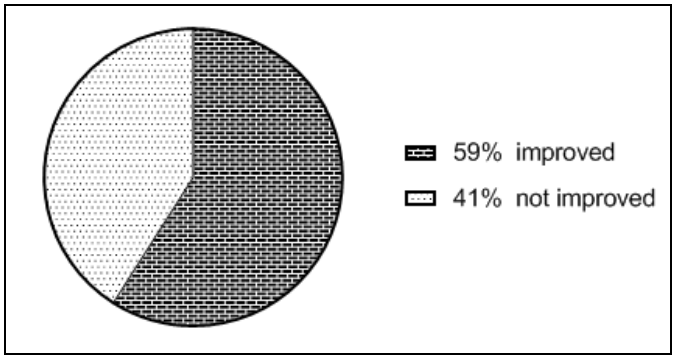


**FIG. 3: IMPROVEMENT IN THE CONDITION AMONG THE STUDY POPULATION (BLOOD GLUCOSE) AFTER COUNSELLING.** It represents an improvement in the condition among the study population (Blood Glucose) after counseling compared with those non-improved in the remaining population.

**DISCUSSION:** This study was conducted to analyze the epidemiology of diabetes mellitus in a community, prescribing patterns, patient medication adherence, and to evaluate the impact of patient education by the measurement of random blood glucose.

**Age and Gender Distribution of Diabetes Mellitus:** The total number of subjects enrolled under the study group was (n=100), the distribution of females (63%) is greater than males (37%).

The subjects were in the age group between 18 to 90 years. The maximum number of subjects were in the age group of 51-60 years (34%), mean age was 51.6 ± 11.1 years which fell within the range of the previous study by Dhanaraj *et al*., in 2013 (55 ± 10); Agarwal *et al*., in 2014 (58.12±10.5); Shwetha *et al*., in 2017 (56.5 ± 11.6) [6, 7, 13].

**Prescribing Patterns in Diabetes Mellitus:** Among the drugs prescribed for the treatment of diabetes mellitus in our study, biguanides were the most commonly prescribed class of drugs followed by sulfonylureas, insulin, thiazolidinediones, alpha-glucosidase inhibitors, and DPP4 inhibitors. Observations reported by other studies by Nithin *et al*., in 2018; Agarwal *et al*., in 2014, showed the most common prescription of sulfonylureas [5,7]. This study shows that fixed-dose combination (glimepiride + metformin) (28.69%) is the most commonly prescribed medication followed by metformin (24.34%), FDC (metformin + glipizide) (13.04%), insulin (9.56%), FDC (metformin + glibenclamide) (6.08%), glimepiride (3.47%), FDC (metformin + glimepiride + pioglitazone) (3.47%), FDC (metformin + glimepiride + voglibose) (3.47%), glibenclamide (2.60%), FDC (metformin + telinigliptin) (1.7%), voglibose (0.8%), teneligliptin (0.8%), glipizide (0.8%) and FDC (metformin + voglibose) (0.8%).

Similar observations reported by Agarwal *et al*. in 2014 where sulfonylureas (34.14%) were the most commonly prescribed class followed by biguanides (31.65%) among the different classes of OHA and their fixed-dose combination (FDC) accounted for 20.25%. Metformin (biguanide) was the most common individual OHA to be prescribed 31.65%, followed by glimepiride (sulfonylurea) 20.25%, followed by FDC of glimepiride plus metformin 11.40%. Other classes of OHA prescribed were thiazolidinediones 6.33%, alpha-glucosidase inhibitor 3.8%, and dipeptidyl peptidase four inhibitors (DPP 4 inhibitors) 2.5%, respectively [7].

Another study conducted by Dhanaraj *et al*., in 2013 showed that metformin was the most commonly prescribed anti-diabetic drug (70%) in general, followed by insulin (53 %), sulfonylureas (44 %), and thiazolidinedione (28 %) [6].

The majority of the diabetic patients were on combination therapy (62%) followed by monotherapy (38%), which fell within the range in the study by Dhanaraj *et al*., in 2013 (70%) [6]. Insulin preparations accounted for 10.2% of the total anti-diabetic drugs, which was lower than that reported by Agarwal *et al.*, in 2014 (43.6%) [7].

**Medication Adherence in Diabetes Mellitus:** In our study, the major study population is non-adherent (68%) to the medication than adherence (32%). These findings are comparable with past studies by Bagonza *et al*., in 2015, where the reported adherence is about 83.3% [8]. Another study by Caetano *et al*., in 2017, reported adherence of 34.4% [11].

**Patient Counselling in Diabetes Mellitus:** Patient counseling for the subjects was done at their doorstep, along with the measurement of Random blood sugar levels. The counseling was done with the aid of leaflets. The leaflets contain information about the disease symptoms, when to seek medical advice, managing by self-care during hyper-glycemic and hypoglycemic conditions, home remedies for reducing frequent attacks, medication administration and adherence; medication adherence charts were given to the patients with more than two drugs, mobile alarms were set for patients using a single drug, storage and healthy dietary habits. The leaflet was printed in both English and Telugu (local language) for easy understanding by patients.

Subjects were advised to follow the tips given during counseling for optimal glycemic control. A review of counseling and measurement of RBS was taken from subjects with a gap of about four months after initial counseling to know the impact of counseling on the health-related quality of life. The mean difference between random blood sugar before and after counseling was 27.25. The difference in means is highly statistically significant (P=0.0001). This shows that there was an improvement in random blood sugar after counseling. The study was in accordance with studies conducted by S. Chai *et al*., in 2018 in which a total of 118 patients were randomly assigned to two groups (education group, n = 63; control group, n = 55). Compared to control group, fasting blood glucose (6.78 mmol/L *vs*. 7.70 mmol/L, P < 0.001), postprandial blood glucose (7.90 mmol/L *vs*. 10.58 mmol/L, P < 0.001) and glycosylated haemoglobin A1C level [6.20 (5.80, 6.60)% *vs*. 6.70 (6.40, 7.30)%, P < 0.01] significantly decreased after the sixth month in education group [12].

**CONCLUSION:** India has observed the most devastating increase in the burden of diabetes in the contemporary era. This cross-sectional study was carried to assess the epidemiology, prescribing patterns, medication adherence, and impact of patient education among diabetic patients. The study reveals a higher prevalence of diabetes among females and the age group of 51-60 years. Due to a lack of epidemiological studies in India, this study recommends the need for such studies to establish prevalence.

A combination of metformin and glimepiride was most commonly used in the community, followed by metformin. There is a dominance of oral anti-diabetic drugs in the prescribing patterns. Intensification of current drug therapy and planning multiple drug interventions would prevent diabetic complications.

The study population was non-adherent to the medication and lack knowledge of the disease and its complications. There was a statistical improvement of RBS before and after the counseling among the study population. Thus the study suggests the need for continuous education on diabetes, anti-diabetic drugs, administration, improvement of knowledge on newer drugs among doctors, which lead to the achievement of rational drug therapy and optimal glycemic control.

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