

DRUG UTILIZATION STUDY AND EFFECTIVENESS OF ANTI-DIABETIC DRUGS IN PATIENTS ATTENDING A TERTIARY CARE HOSPITAL OF UPPER ASSAM

Diabetology

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ABSTRACT

Introduction: The rate of diabetes mellitus in India is consistently high. Studies on drug use assist in determining the extent of drug use, compliance with accepted norms, and the rationality of drug use. **Aim And Objectives:** To ascertain the medication use pattern and efficacy of Anti-diabetic medicines in individuals with diabetes mellitus. **Materials And Procedures:** This six-month prospective observational study was conducted at the AMCH's Medicine Department in conjunction with the Pharmacology Department. Included were the diabetic patients who came to the outpatient department of medicine. Following institutional ethical committee approval, structured data Demographic information, a complete prescription, and other pertinent data needed for the study were gathered using a collecting form. The pattern of drug use was identified. Anatomical therapeutic classification (ATC) was used to classify the medications, and WHO criteria were used to determine DDD/1000 inhabitants/day. The best successful medication/combination in this area was found to be among all Anti-diabetic medications. **Results:** The average number of all medicines prescribed per encounter is 5.9 ± 2.0 , % of medicine prescribed by generic name names is 56.2%. The majority of the patients were in the 40–60 age range for males (175;46%) and females 205 (53.94%) out of the 516 prescriptions that were evaluated; A Total of 286 (55.42%) were females and 230 (44.57%) were males. Among co-morbidities, hypertension was the most prevalent. 4.26 medications were prescribed on average, with anti-diabetics being among them. DDD/1000 inhabitants/day for metformin (A10BA02), glimepirides (A10BB12), glibenclamide (A10BB01), and pioglitazone (A10BG03) was 12.5, 9.6, 10.2 and 3.1. Only 128 of the 200 newly diagnosed diabetes mellitus patients who were involved in the trial were effectively followed up. Combinations of metformin, sulfonylureas, and other medications demonstrated effective fasting management. **Conclusion:** Metformin was the most utilized drug followed by glimepiride. Dual combination therapy is the most frequent when compared to monotherapy in which metformin+glibenclamide is the most commonly prescribed one. So by understanding the current prescribing patterns attempts can be made to improve rational prescribing.

KEYWORDS

Drug utilization study, Effectiveness, Anti-diabetic drug, Diabetes mellitus, ATC

INTRODUCTION

The prevalence of type 2 diabetes mellitus (T2DM) globally among individuals aged ≥ 20 years was estimated at 171 million in 2000 and is projected to reach 366 million by the year 2030. The World Health Organization (WHO) has forecasted that the number of individuals with T2DM in India will reach 79.4 million by 2030. Currently, T2DM affects 26% of the elderly population in India. The escalation of T2DM worldwide in the 21st century is attributed to increasing urbanization, an aging population, and sedentary lifestyles^[1]. Elderly individuals are at a higher risk of complications due to the progressive decline in bodily functions such as hepatorenal as they age. Numerous studies have highlighted the significance of optimal glycemic control and the management of complications as fundamental aspects of T2DM care^[2]. The choice of anti-diabetes drug (ADD) largely depends on target glycosylated hemoglobin (HbA1C), drug safety and efficacy profile, and therapy cost-effectiveness. However, a significant proportion of elderly patients with T2DM are on concomitant drugs for various comorbidities (hypertension, ischemic heart disease, and neuropathy). This principle of "polypharmacy" is sometimes irrational and even detrimental, hence requires strict therapeutic vigilance^[3].

Study Rationale

The primary objective of research endeavors in drug utilization (DU) is to support the concept of "rational drug prescribing." The idea of "rational" drug usage for individual patients involves administering a well-documented medication at an optimal dosage for the correct indication, along with appropriate information, at an affordable cost^[4]. The absence of insight into prescription and usage patterns makes it challenging to promote rational drug prescription practices and recommend strategies to modify prescribing behaviors for the better^[15]. This investigation seeks to evaluate the utilization pattern of anti-diabetic drugs in a tertiary care hospital of upper Assam, gauge its proximity to optimal care, identify influencing variables, and assess the impact of this practice on health outcomes by examining metabolic parameters. While numerous studies have explored urban settings, there is a paucity of data reflecting rural trends, despite over 60% of the Indian population residing in such areas with limited access to specialized healthcare. This study fulfills this gap and provides

valuable insights for healthcare policymakers^[6].

Objective

This study aims to examine the prescription pattern of anti-diabetic drugs (ADD) patients with Type 2 Diabetes Mellitus (T2DM) in Upper Assam. This analysis will be based on the international levels of the 2016 World Health Organization (WHO) Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) Index. The ATC/DDD Index is a widely used tool in drug utilization research, serving as a means to enhance the quality of drug usage and facilitate comparisons of drug consumption data. Effectiveness studies are employed to evaluate the optimal pharmaceutical agent within the realm of existing drug therapies. Consequently, this investigation was conducted with the following aims:

1. Ascertaining demographic characteristics, including age and gender, of diabetic subjects encompassed in the study.
2. Examining the utilization trends of anti-diabetic agents.
3. Assessing the efficacy of various extant anti-diabetic drug options.

MATERIAL AND METHODOLOGY

Study Setting: This investigation constituted a prospective, observational, study inquiry spanning 6 months after receiving approval from the Institutional Ethics Committee at Assam Medical College Hospital, Dibrugarh. Utilizing prescription records of individuals diagnosed with T2DM [Age > 20 years] of either sex who were attending the outpatient clinic for follow-up, and admitted to the Medicine Department of Assam Medical College and Hospital from January to July 2023. Before commencing the study, explicit informed consent was procured from all participants, except those with gestational diabetes. The acquired data was meticulously organized and categorized in alignment with the 2016 ATC/DDD WHO Index. In addition, parameters reflecting patient care and prescribing trends were thoroughly evaluated. Evaluation of metabolic indicators was conducted under the 2015 American Diabetes Association (ADA) guidelines. Patients with co-existent causes of hyperglycemia [e.g. Cushing syndrome, pancreatic cancer, or hormone-secreting tumors] were excluded from the study.

Study Design:

Following ethical approval from The Ethics Committee of the Hospital, this prospective, observational, open-labeled study was conducted. Five hundred sixteen [516] prescription sheets that contained at least one anti-diabetes medicine issued by the health facility are screened for the study. For effectiveness, the tentative sample size fixed was 200 patients. Among 200 patients only 128 members were successfully followed up and 72 cases were excluded due to lack of follow-up data. The guidelines for Strengthening the Reporting of Observational Studies in Epidemiology [STROBE] were used in designing the protocol and manuscript.

Research Instrument:

The instruments employed in the study encompassed a validated data collection proforma, prescribing indicators from the World Health Organization and the International Network for Rational Use of Drugs (WHO-INRUD), the 2023 edition of the online WHO Collaborating Centre for Drug Statistics list of Defined Daily Doses (DDD).

Data Collection:

The categorization of anti-diabetic medications was conducted based on the Anatomic Therapeutic Chemical (ATC) classification system. Various details were extracted from the prescription sheets, encompassing patient demographics such as age and sex, the total count of prescribed medications, the number of medications prescribed using generic names, the quantity of anti-diabetes drugs prescribed, as well as the number of essential anti-diabetes medications prescribed and dispensed. Furthermore, information regarding the specific antidiabetes medication names, classes, routes of administration, dosage forms, strengths, doses, frequencies, and durations was also abstracted. In addition, Defined Daily Doses (DDDs) were acquired from the online database of the WHO Collaborating Centre for Drug Statistics, and incorporated into the data collection form. This process aimed to establish the outcome measure for the study.

Outcome Measure:

The categorized data were organized and grouped being inputted by Microsoft 2007 Excel software. Identification was made for all anti-diabetic medications that were assigned a Defined Daily Dose (DDD) by the WHO Collaborating Centre for Drug Statistics Methodology. The number of tablets for each anti-diabetic drug with ATC code A10 in every prescription was transformed into DDDs and subsequently subjected to analysis. The values of the anti-diabetes medicine utilization indicators were calculated as

$$\text{DDD}/1000 \text{ inhabitants/day} = \frac{\text{Total amount of antidiabetic medicines used [mg/units]} \times 1000}{\text{DDD[mg/units]} \times 365 \text{ days} \times \text{sample size}}$$

Statistical Analysis:

The identical iteration of Microsoft Excel (2007) was employed for structuring, refining, and conducting the statistical examination of the data. The conduction of descriptive statistics was executed, with continuous variables being delineated as mean $\pm$ standard deviation (SD), as well as in numbers and percentages. A comparison of the consumption of anti-diabetic medications [ADD/1000 INHABITANTS/DAY] based on age, anti-diabetic medications [ADD/1000INHABITANTS/DAY] based on gender was carried out using the Z-test [calculated p-value for two sample mean], whereby the level of significance was established at $p < 0.05$.

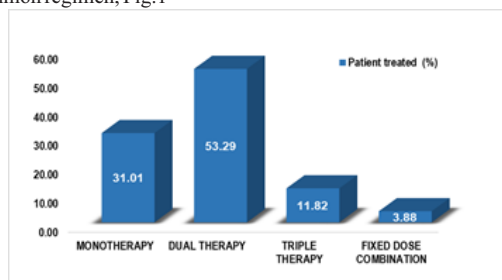
RESULTS

Out of 516 patients, 286 were females who were more when compared to males 230. The majority of patients were found in between the age group of 40-60 years of which 175 are males, and 205 are females, in between the age group 20-40 years 35 are males, 49 are females and 20 are males, 32 are females of >60 years of age were tabulated in Fig. 1. In the study the average age of the male population was 49.75 ± 9.08 years and that of the female population 52.68 ± 10.2 years.

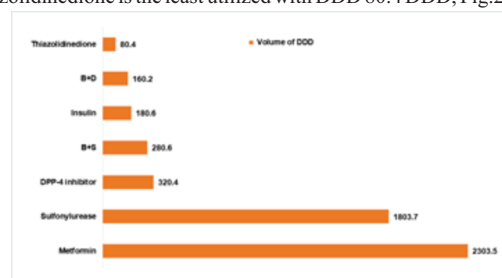
Table.1: Distribution according to age

Age in years	MALE	%	FEMALE	%	TOTAL
20-40	35	41.66	49	58.33	84
40-60	175	46.05	205	53.94	380
>60	20	38.46	32	61.53	52
Total	230	44.57	286	55.26	516

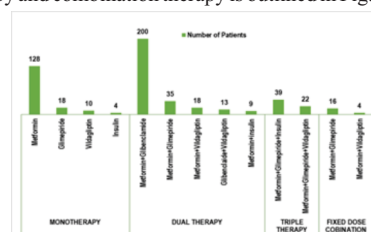
Out of a comprehensive count of 780 medications that were recommended for the examined patients, dual therapy emerged as the most commonly utilized treatment regimen, accounting for (53.29%) of the prescriptions, while triple therapy was identified as the least common regimen, Fig.1

**Fig.1: Percentage distribution of type of ADD prescribed**

According to DDD as a unit of medicine utilization, Metformin, which accounted for 2303.7 DDD, made it the most utilized individual anti-diabetes medicine followed by sulfonylureas with 1803.5 DDD, while thiazolidinedione is the least utilized with DDD 80.4 DDD, Fig.2

**Fig.2: Antidiabetes class utilized ranked by volume of DDD**

Upon assessment of individual anti-diabetic medications that were prescribed, it was observed that metformin (80%) emerged as the most frequently recommended mono-therapy, while metformin in combination with glibenclamide (72%) and metformin in conjunction with glimepiride (12%) were the prevailing dual anti-diabetic medication regimens. The study also identified fixed-dose combinations of anti-diabetic drugs, notably metformin plus glibenclamide (80%) and metformin plus vildagliptin (20%). The distribution of individual antidiabetic medications prescribed as monotherapy and combination therapy is outlined in Fig. 3.

**Fig. 3: Percentage distribution of different combination of ADD prescribed**

When assessing the consumption of anti-diabetic medications about gender, it was observed that metformin emerged as the most widely utilized anti-diabetic drug, exhibiting nearly equivalent usage rates among both male and female individuals (16.9 vs 16.5 DDD/1000 Diabetes Patients/Day). A higher prevalence of glibenclamide (10.3 vs 8.2 DDD/1000 Diabetes Patients/Day) and vildagliptin (1.4 vs 0.8 DDD/1000 Diabetes Patients/Day) was noted among male patients compared to their female counterparts, although these differences were not statistically significant. Conversely, a substantially greater consumption of glimepiride was observed in males in comparison to females; however, this variance did not reach statistical significance (9.2 vs 0.88 DDD/1000 Diabetes Patients/day).

When the consumption of anti-diabetic medications was analyzed about age, it was observed that individuals with diabetes between the ages of 40 and 60 exhibited notably higher usage of metformin, glibenclamide, and glimepiride in comparison to those below 40 years old and those aged 60 years or above, as illustrated in Figure 5

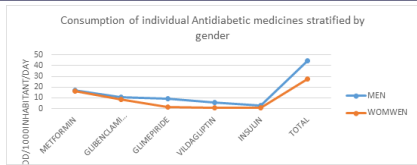


Fig 4. Consumption of individual Anti-diabetic medicines stratified by gender

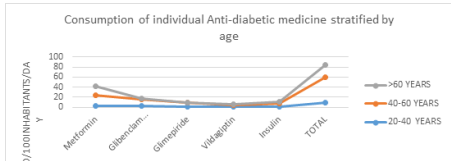


Figure:5 Consumption of individual anti-diabetic medicines stratified by age

For effectiveness, a total of 200 patients were recruited among them 128 patients who were followed up successfully. The effectiveness of various available anti-diabetic agents calculated based on fasting blood glucose that is noted pre and post-usage of respective drugs and data is represented below FIG.6

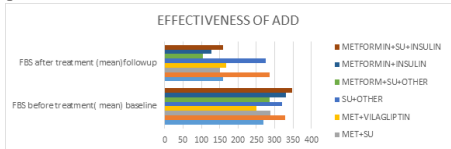


Figure:6. effectiveness of different combinations of add based on fbs value (fasting blood glucose)

Co-morbidities Associated With Diabetes Mellitus

The most common co-morbidity associated with DM was hypertension (56.33%), followed by hypertension with chronic heart disease (23.16%), details which is presented in the figure below

DM=DIABETS MELLITUS
HTN=HYPERTENSION
CAD=CORONARY ARTERY DISEASE
COPD=CHRONIC OBSTRUCTIVE PULMONARY DISEASE
HYPOTH=HYPOTHYROIDISM

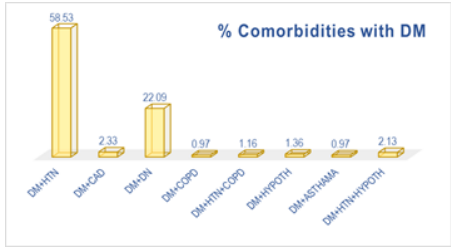


Fig. 4: Co-morbidities associated with DM

Table 3 depicts the roster of Anti-diabetic agents that are categorized in accordance with the WHO ATC system of classification, while also showcasing the consumption of each individual drug in Defined Daily Doses (DDD). The utilization of drugs in DDD/1000 inhabitants per day reveals that metformin emerged as the most frequently consumed drug, registering a consumption rate of 12.5 DDD/1000 inhabitants

Table:3, Distribution Of Add With Atc Code And Ddd By Who

ATC CODE	ADD	DDD/1000 INHABITANT /DAY [mg]	DDD [WHO]	PDD	DDD/ PDD
AT10BA02	Metformin	12.5	2g	1.54 g	1.29
A10BB12	Glimepiride	9.6	2mg	1.08mg	1.85
A10BB01	Glibenclamide	10.2	10mg	10 mg	1
A10BG03	Pioglitazone	3.1	30mg	30 mg	1
A10BH02	Vildagliptin	6.9	50 mg	-	
A10BF03	Voglibose	1.7	0.6 mg	0.44 mg	1.36
A10AD30	Premixed insulin	5.4	40 u	42.5 u	0.941
A10AE04	Insulin Glargine	3.1	40 u	30 u	1.33

A10AB05	Insulin Aspart	2.9	40 u	36 u	1.11
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The average number of all medicines prescribed per encounter is 5.9±2.0,% of medicine prescribed by generic name names is 56.2%.

DISCUSSION

Diabetes mellitus (DM) is an escalating public health issue in developing nations. Numerous studies on the utilization of anti-diabetic drugs have been conducted within the healthcare sector across different regions globally, providing valuable insights into the appropriate use of medication in diabetic patients. This investigation focuses on analyzing the patterns observed in anti-diabetic drug usage in 2021 as presented by Hannan et al^[7]. The significance of drug utilization research in clinical practice cannot be overstated, as it lays the groundwork for policy modifications in drug distribution at both local and national levels. Furthermore, by facilitating the development of efficient strategies for resource allocation in healthcare, such studies play a crucial role, particularly in countries like India where patients bear 72% of the healthcare burden.

In the investigation conducted by our team, it was noted that glibenclamide and exhibited a PDD/DDD ratio of 1. Conversely, glimepiride, metformin, vildagliptin, insulin glargine, insulin lispro, and insulin aspart demonstrated ratios exceeding 1, while premixed insulin showcased a ratio below 1. A deviation of the PDD/DDD ratio from one could imply inappropriate drug utilization, either insufficient or excessive. Nevertheless, it is crucial to recognize that PDD might be subject to variations based on individual patient characteristics and disease factors. Discrepancies in PDDs may also be evident across different regions; for instance, PDDs frequently tend to be lower among Asian populations compared to Caucasian counterparts. Moreover, the Defined Daily Doses (DDD) obtained from the World Health Organization's Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) platform are designed for moderately severe medical conditions and are derived from a global dataset. Consequently, WHO advocates for countries to establish their own DDD reference list utilizing local information. Our research endeavors are aiding in the accumulation of such data, with a specific focus on India.

Premixed insulin utilization was discovered to be inadequate within our particular healthcare environment. Conversely, Kalra et al ^[8]. identified through a comprehensive review that premixed insulin is the predominantly prescribed and utilized form of insulin within the Asian region. This trend could be attributed to the challenging nature faced by physicians when confronted with conflicting recommendations, leading to a dilemma in selecting between basal and premixed insulin. Nevertheless, the current investigation substantiates the necessity for an increased prescription of premixed insulin. Furthermore, the study at hand incorporated participants within the geriatric age bracket, a demographic that might exhibit a preference for non-insulin therapeutic regimens, consequently resulting in the underutilization of premixed insulin.

Pioglitazone is utilized optimally, potentially due to a predilection for oral hypoglycemic regimens over insulin among patients. Its utilization is not excessive, taking into account its adverse effects. Metformin alone and in combination was the most frequently prescribed anti-diabetic medication in this particular investigation, consistent with the findings of Orlando and colleagues^[12] as well as Das et al. Their research also indicated metformin as the most commonly prescribed medication. Interestingly, our outcomes differ from those of Ramesh and colleagues, Chiang et al. ^[11], and Al Khaja et al. ^[10], where sulfonylureas were the predominant anti-diabetic treatment. This variation could be attributed to differences in the demographics of the cohorts examined in these studies. Among second-generation sulfonylureas in our study, glibenclamide was frequently prescribed alongside metformin, aligning with a study conducted in Nigeria by Jimoh et al. The prevalence of metformin prescription aligns with its recognition as the preferred anti-diabetic agent according to current clinical recommendations, such as those of the American Diabetes Association (ADA).

It was noted that the prevalence of comorbidities is higher in diabetic individuals, with conditions such as hypertension (58%), diabetic neuropathy (22%), cardiovascular disorders (2.32%), hypothyroidism (1.35%), and asthma (5%), chronic obstructive pulmonary disease(1.16%) frequently reported in the present study area. This pattern of comorbidities aligns with findings from Hannan *et al.*'s study

that focused on analyzing prescriptions in patients with type 2 diabetes mellitus.

This investigation was carried out within the Medicine department of a tertiary care hospital, where the consultants specialize. Nevertheless, in numerous regions of India, diabetic patients are under the care of general practitioners. When these medical practitioners are faced with such circumstances, the concept of "clinical inertia" becomes apparent. It denotes "A consultation in which a therapy modification based on a diabetes-related factor was recommended but not implemented". This results in inappropriate prescription practices and incorrect utilization of these drugs^[16]. To prevent this, governmental bodies should formulate and rigorously implement regulations. Although our study revealed both the instances of under- and overutilization of anti-diabetic medications, such information could be utilized by governmental and non-governmental entities to craft regulations and suggestions to promote the proper utilization of these drugs. While it may not be feasible for countries like India to have specialists at every tier of the healthcare system, it may be compulsory for current healthcare personnel to undergo training to ensure the proper use of medications, particularly for managing chronic ailments like^[17].

Strength And Limitation

The investigation carried out within a government healthcare facility may exhibit sampling bias due to the tendency of patients from a lower socioeconomic status to seek treatment there^[18]. Moreover, the absence of face-to-face patient interviews impeded the assessment of patient adherence. There is a need for a more extensive investigation to address these shortcomings. The study's methodology presented certain constraints that could be mitigated through a well-planned prospective study. The sample size of the study was deemed sufficient. The utilization of Electronic Medical Records (EMR) helped in minimizing Hawthorne bias. EMR, being an integral part of the national surveillance infrastructure, enhanced the reliability and accuracy of the collected data.

Glycosylated hemoglobin proves to be a more dependable indicator for evaluating glycemic regulation across a span of three months. However, due to the limited duration of our follow-up and the inclusion of exclusively newly diagnosed patients for the assessment of efficacy, this parameter was not utilized in the present investigation. Consequently, solely fasting blood sugar levels were juxtaposed pre- and post-treatment to gauge the efficacy of oral hypoglycemic agents^[20].

CONCLUSION

Among all patients, females outnumber males. The demographic group aged between 40-60 years shows a higher susceptibility to diabetes mellitus. It has been observed that diabetic patients are typically prescribed medication for longer durations compared to other patient groups. Metformin emerges as the most frequently utilized anti-diabetic drug, particularly in comparison to other options, while Glimepiride stands out as the most commonly prescribed drug within the Sulfonylureas class. Presently^[5], both Metformin alone and combinations of Metformin with other anti-diabetic drugs are widely prescribed to diabetic patients. In the current healthcare landscape, combination therapy is favored to regulate the fasting blood sugar levels of patients. Notably, the utilization of 2-drug combinations prevails over 3-drug combinations, with the combination of Metformin, Glimepiride, and Pioglitazone being the most frequently prescribed. A study involving 200 patients was conducted to evaluate the effectiveness of Anti-diabetic drugs. Combinations of Metformin, Sulfonylureas, and other agents exhibit superior control over fasting blood sugar levels when compared to Metformin alone, Sulfonylureas alone, or combinations of Metformin with Sulfonylureas or other agents. Therefore, a comprehensive comprehension of prevailing prescription practices can pave the way for enhancing the efficacy and quality of drug therapy^[19]. In addition to establishing standards and evaluating quality, efforts can be directed toward optimizing drug therapy outcomes.

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