Monitoring Of Adverse Effects For Commonly Prescribed Anti-Diabetic Drugs In A Tertiary Care Hospital Of West Bengal

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Abstract

Objective: Non-communicable diseases rapidly growing in india due to rapid industrialization, urbanization, and changing lifestyles. Diabetes is a predominant concern, with 77 million affected individuals, proclaiming india the second most impacted country globally. Evaluating adverse drug reactions (adrs) to anti-diabetic medications is critical for optimizing patient care and ensuring drug safety. This study uses standardized causality assessment methods to assess adrs associated with commonly prescribed anti-diabetic drugs in a tertiary care hospital.

Methodology: A cross-sectional was conducted over six months, involving 307 diabetic patients from the outpatient department of the college of medicine, jnm hospital, kalyani, west bengal. Data on demographic profiles, prescribed medications, and adrs were collected and analyzed.

Results: Metformin was the most frequently prescribed drug and was primarily associated with gastric disturbances, mouth ulcers, and folic acid deficiency. A small subset of male patients reported erectile dysfunction. Teneligliptin was linked to adverse effects, including gastric discomfort, skin rashes, headaches, and nasopharyngitis. Overall, the female population represented the majority of diabetic patients visiting the hospital.

Discussion: The study highlights the predictable adrs of metformin and teneligliptin, including gastrointestinal and mild systemic effects, with no novel events reported. A higher prevalence of diabetes in females suggests a need for targeted interventions addressing socio-economic and gender-specific factors to improve treatment outcomes and enhance diabetes management in diverse populations.

Keywords: Diabetes, Adverse Drug Reactions, Metformin, Teneligliptin.

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INTRODUCTION:

Due to industrialization, social and economic development, rapid urbanization, change of age-structure, lifestyle, India is facing a growing burden of non-communicable diseases. Among various non-communicable chronic disease like diabetes and hypertension are found to be predominant among the Indian Population [1,2,3,4].

There are currently over 62 million people in India who are being diagnosed with diabetes, making the condition quickly becoming an epidemic. . Recently, International Diabetes Federation, estimated 463 million are living with the condition across the world, 80% of whom live in low- and middle-income countries [5]. India is the second most affected country in the whole globe, behind China, with an estimated 77 million individuals (1 in 11 Indians) officially diagnosed with diabetes. The number is projected to grow by 2045 to become 134 million per the International Diabetes Federation [6] .

The 1961-62 thalidomide tragedy, causing teratogenic effects in 10,000 children, led to the WHO's International Drug Monitoring Programme in 1968, now involving 86 countries for ADR reporting. India's pharmacovigilance began in 1986 with a proposed 12-center ADR monitoring system. In 1997, India joined the WHO's Uppsala program, but it failed [7].

The WHO-sponsored National Pharmacovigilance Program, operational since 2005, is overseen by CDSCO, with two zonal and 26 peripheral centers, aiming to foster reporting, engage professionals, and benchmark global drug monitoring [8].

Monitoring ADRs is crucial for chronic diseases like diabetes, which are often asymptomatic and require

long-term therapy, increasing ADR risks. Proper monitoring and reporting of adverse reactions from antidiabetic and antihypertensive drugs enhance patient safety [9].

Monitoring of ADRs is more critical in the case of chronic ailments such as Diabetes [10]. These disorders are often asymptomatic and require long-term therapy, predisposing them to adverse drug events [11,12,13,14,15].

The study aims to expand the spectrum of drug safety for the treatment of Diabetes using anti- diabetic drugs prescribed. It targets to evaluate the current status of Antidiabetic drugs prescribed in tertiary care hospitals of West Bengal. It also investigates the possibilities of new ADR/s.

METHODOLOGY

Study design: Cross-Sectional study[16,17,18,19]

Setting : College of Medicine JNM Hospital, Kalyani, West Bengal, India.

Participants : Patients attending the outpatient department of COMJNMH, Kalyani, West Bengal, India.

Study type: Observational study [20,21,22,23],

IEC Reference Number: F-24/PR/COMJNMMC/IEC/22/869

Study population: Diabetic patients were selected based on the following inclusion and exclusion criteria.

Inclusion criteria:

Patients of 18 years and above of both sexes diagnosed with type 1 and type 2

Diabetes Mellitus were subjected to insulin and/or Oral Antihyperglycemic drugs for at least a period of one month or above without co-morbidities.

Exclusion criteria:

The pediatric patients aged < 18, subjected to insulin or/and Oral

Antihyperglycemic drugs for less than one month, and Gestational diabetic patients are excluded from the study. Any patients with hypertension complications are to be excluded. Patients suffering for more than 10 years are excluded from study [24].

Study Duration: 6 Months [25],

Sample size: The prevalence of ADR Reporting from Antidiabetic drugs was obtained from a literature survey as 27.6% (0.276) [18]. Based on the prevalence report sample size was calculated as below in Table 01.

Table 01: Calculation of Sample size based on prevalence (P) [18]

% Prevalence (P)	(1-P)	Sample size (n) = $[Z^2.P(1-P)]/d^2$
0.276	0.724	307

Where,

Z (*Z statistic for a level of confidence) = 1.96*

d (*precision (in proportion of one; if 5%, d = 0.05)*

Procedure:

Study protocol prepared and presented for IEC

Study protocol submitted to SRC and IEC for approval

Theprotocol was explained to the participants, fitting the inclusion criteria, and written consent was taken.

Information regarding health complaints, medication history, health status, and adverse events will be noted

Confirmation of adverse events made by the resident doctor.

RESULTS:

Patient Demography

a. *Gender Demography:*

Out of total data collected from 307 patients visited the OPD. Among them 186 (60.5%) were reported females the remaining were males reported 121 (39.4%).

b. *Age Demography:*

Age wise distribution as shown in Table 2 and figure 1 shows geriatrics patients were found to be more in number. The age range of 50 - 60 years reported the highest number for patients (111, 36.6%).The least reported were > 40 followed by 40-50 , as shown in the Table 3 below.

Table 02 : Age Demography of the Patients Under study

Gender	Frequency	Percentage (%)
< 40	22	7.17
40 - 50	55	17.92
50 - 60	111	36.16
60 - 70	67	21.82
>70	52	16.94

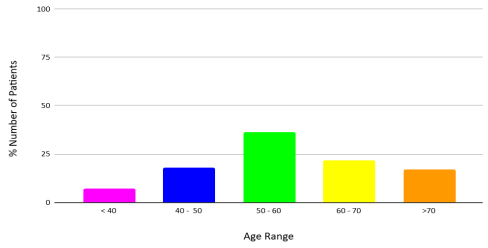

Figure 01: Demography of the age of Patients Under study

Drug Utilization pattern of Anti Diabetic Drug

From the study as shown in Table 3 it was observed that 100 % were prescribed with Biguanides namely Metformin, followed by DPP4 Inhibitor as Teneligliptine (50%) and Sulfonylurea namely Glimipride (10%).Both Teneligliptine and Glimipride were given in combination to Metformin. 40% of the patient sample were exposed to Monotherapy where 60% were treated with Multi Drug Therapy.

No other antidiabetic drugs were found in the prescription. Metformin was prescribed in two doses 500 mg and 1000 mg. Teneligliptine and Glimipride were given in combination to Metformin. The combination of Metformin and Teneligliptine were more preferred over Metformin and Glimipride because Glimipride is often associated with severe hypotension,weight gain and risk associated with renal impairment which are absent in Teneligliptin making it a safer drug of choice in combination to Metformin [24]. . Metformin in combination with Teneligliptin reduces HbA1C sustainably longer than Metformin-Glimipride combination [26,27,28,28,30,31].

Table 03: Drug utilization pattern for Prescribed Anti Diabetic Drug/s

Name of the Drug	% Patient Prescribed without combination	% Patient Prescribed in combination	Total % Patient prescribed
Metformin	32.24	67.76	100
Teneligliptin	-	50.16	50.16
Glimipride	-	10.09	10.09

Occurrence of ADR

As observed in Table 4 and demonstrated in Figure 2, among 307 patients 110 (36.6%) patients experienced ADR and out of that 20 (6.5%) patients had more than multiple ADR. The most commonly identified ADRs were with Metformin is 87 (27.36%) followed by Glimipride is 18 (5.86%) , and Teneligliptin 8(2.67%).

Table 4 : Drug wise occurrence of ADR

Name of the Drug	ADRs Reported	Number of patients with ADR reported	Cumulative ADR , % ADR
Metformin	Gastric intolerance Mouth Ulcer Anemia Hypoglycemia Erectile Dysfunction	57 08 10 07 04	84 (27.36%)
Glimipride	Hypoglycaemia Weight gain Gastric irritation	12 4 2	18 (5.86%)
Teneligliptin	Oedema	8	8 (2.67%)

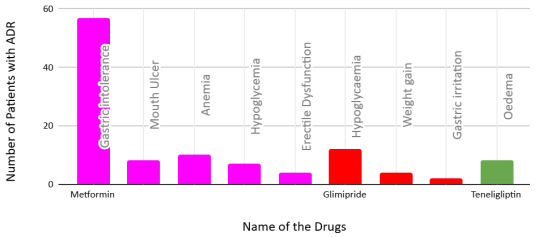

Figure 02: ADR distribution based upon drug

Gender wise distribution of ADR

The study as shown in Table 6 revealed that the number of female population 69 predominated over male patients 41 in ADR.

Age wise distribution of ADR

Table 5 and Figure 3 displays the age-wise distribution, indicating that the occurrence rate of ADR was 48 (43.6%) in the 50–60 age group and 32 (29.09%) in the 60–70 age group.

Table 5 : Distribution of ADR based on Age Distribution.

Age	Number of Patients reported	Number of ADR reported	ADR reported (Male)	ADR reported (Female)
< 40	22	5	1	4
40 - 50	55	12	5	7
50 - 60	111	48	19	29
60 - 70	67	32	10	22

>70	52	13	3	10

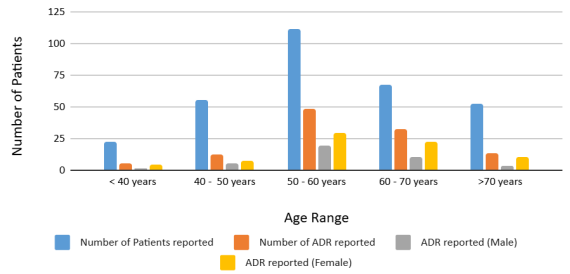

Figure 03 : Distribution of ADR based upon age.

Statistical Data Analysis

The data were entered into the program Microsoft Excel and further imported into the software Statistical Package for Social Science (SPSS 25.0), IBM. Descriptive statistics were expressed as frequencies, percentages and means where appropriate. The Chi-square tests of association were presented. To compare the incidence of ADRs versus gender, a 2 (gender) x 2 (ADRs present/absent) contingency table was used and tested with Chi-square test of independence as shown in Table 6.

Table 6: Gender-wise Distribution of Patients with and without Adverse Drug Reactions

Gender	ADR Present (n)	ADR Absent (n)	Total (n)	ADR Incidence (%)
Female	69	117	186	37.1
Male	41	80	121	33.9
Total	110	197	307	35.8

To compare the difference in age-groups, a 5x2 contingency table (age-Groups and ADRs present/absent) was used as shown in Table 7 and tested with Chi-square goodness-of-fit test using the null hypothesis*: distribution of ADRs will be proportional to the number of patients within each age group.*

Table 7 : Age-wise Distribution of Patients with and without Adverse Drug Reactions

Age Group (years)	ADR Present (n)	ADR Absent (n)	Total (n)	ADR Incidence (%)
< 40	5	17	22	22.7
40 - 50	12	43	55	21.8
50 - 60	48	63	111	43.2
60 - 70	32	35	67	47.8
> 70	13	39	52	25
Total	110	197	307	35.8

All 2x2 comparisons between age groups (pair-wise post-hoc analysis) were performed with 2x2 chi-square tests with Yates correction. $p < 0.05$ was statistically significant. Bonferroni correction was used for multiple pair-wise comparisons.

DISCUSSION:

In India, there were 77 million instances of diabetes mellitus in 2019, and by 2045, that number will have grown to 134 million.The elevated prevalence (11.7%–28%) in urban West Bengal, specifically Kalyani, is caused by hereditary factors, obesity, and changes in lifestyle [32,33,34,35,36,37,38]. According to a research conducted in Kalyani, the prevalence of diabetes was around 12%, which is in line with urban trends in Kolkata (12%) and Howrah (13%)[39].The National Family Health Survey (NFHS-5) highlights low awareness and control rates[40]. The high diabetes burden and polypharmacy in Kalyani's tertiary care hospitals necessitate ADR monitoring of antidiabetic drugs like metformin,Telnigliptine and Glimipride to ensure treatment safety [41,42,43].

Patients aged ≥18 years, both sexes, diagnosed with type 1 or type 2 diabetes mellitus, treated with oral antihyperglycemic drugs for ≥1 month, and without comorbidities were included. These criteria ensure an adult population [44], account for sex-based ADR differences [45], cover both diabetes types [46], allow sufficient drug exposure for ADR detection [47,48] , and minimize confounding by excluding comorbidities [49,50].The study, which was carried out in a tertiary care facility in eastern Bengal, complies with local pharmacovigilance standards [51].

The study suggests a female-to-male ratio of 1.5:1.This could reflect a true higher prevalence or a sampling bias due to higher female attendance at diabetes clinics [21,22]. Further analysis of data suggests that the majority of the female patients visiting OPD were House Wives that numbers 112 (36.4%) with no professional involvement.Low physical activity, a key risk factor, was prevalent among females, particularly housewives, due to household responsibilities, supporting their predominance in OPD visits[24] .

The 50–60 age group is a peak period for Type 2 Diabetes diagnosis in India, as this age range often coincides with peak obesity rates, declining metabolic function, and increased healthcare-seeking behavior in OPD settings[25,26].

The age groups are mostly associated with the detection of Type 2 Diabetes Mellitus.Thus the ADRs

are mostly detected to occur during the early phase of disease propagation till it gets adjusted to the body. Below 50 years the diagnosis is relatively lower and 60 - 70 or beyond is due to stabilization of the dosage regime adjusting it to the body. The above facts are justified and validated from the works done by Kumar et.al (2017) [32],Bhowmic et. al (2018) [33], Sharma et. al (2020)[34], Gupta et. al (2023)[35]. Gastric intolerance[57] was the ADR seen maximum (27.36%), in keeping with worldwide as well as Indian data, where GI complaints [bloating, diarrhea & nausea] are experienced by 20-75% of cases and may lead to drug withdrawal in 5-46%. Further, this again shows dose-dependence [more with 1000 mg than with 500 mg with lower stratification for the latter], and card these complaints are worse in Indian diets, rich in carbs. Extended-release formulations, dose-titration & Co-administration with probiotics may help, as recent meta-analyses support reduced GI risk with these.It was also observed specifically that the ADR associated with erectile dysfunction was found in males all within the age of 40 - 50 years range during the intake of Metformin after primary identification of diseases. Patel et al. (2017) [52] and Tseng (2022)[53] provide detailed insights regarding Metformin's effects on endothelial function and testosterone, which may contribute to erectile dysfunction , applicable to middle-aged men.Teneligliptin is showing a low ADR rate (2.67% with edema mentioned most but others including gastric discomfort, rash, headache and nasopharyngitis) so longterm combination safety is encouraging, given it is in your cohorts preferred combination with metformin rather than glimepiride because of its relatively lower risk of hypoglycemia/weight gain. Its observed that ADR, 36.6% (6.5% multi-drug) which is higher than in some Indian tertiary care hospital reports (10-30%), still indicative of active pharmacovigilance in actual OPD scenario of a busy hospital, which also shows under-reporting in routine pharmacovigilance systems, at hospitals. Multi-drug therapy (60%) could be responsible. Rational prescribing, monitoring for interactions needed.

No significant gender effect was seen in ADRs reported (2 =0.204, df=1, p=0.651) and the attributable higher number of ADRs in females (69 vs. 41) was statistically explained by the over representation of females in the out patient database (60.5%) rather than by gender specific predisposition. Similar finding was seen in line with female preponderance of attendance for Diabetes Clinic largely driven by socio-cultural, consensus and behavioral factors. However, the analysis of the age-group proved there to be a statistically significant relation between age and occurrence of ADR 2 = 15.793, df=4, p=0.0033. The age groups 50–60 years and 60–70 years had ADR incidences of 43.2% and 47.8% respectively which was significantly different from the in proportion observed (goodness-of-fit 2 = 10.134, df=4, p=0.038).

Although the post hoc pairwise comparisons suggested a trend for increased ADR burden among middle-aged group compared to the younger and very elderly groups, the post hoc pairwise comparisons for these age groups did not remain significant after bonferroni correction. This trend perhaps coincides with the convergence of peak time of diagnosis of type 2 diabetes, higher prevalence of obesity, metabolic deterioration and the commencement of first line therapy in middle-aged Indians. Therefore the statistical result shows the importance of doing surveillance on the age-stratified ADRs in management of diabetes mellitus in the first 1~2 year of the management, for the patients of 50~70 years.

CONCLUSION:

A study in a West Bengal tertiary care hospital monitored adverse drug reactions (ADRs) in patients aged ≥18 years, both sexes, with type 1 or type A study in a West Bengal tertiary care hospital monitored adverse drug reactions (ADRs) in patients aged ≥18 years, both sexes, with type 1 or type 2 diabetes, treated with insulin and/or oral antihyperglycemic drugs (e.g., metformin) for ≥1 month, without comorbidities. Notably, erectile dysfunction was observed in males aged 40–50 years using metformin, consistent with reports linking metformin to testosterone reduction and increased risk. Other potential ADRs of oral antihyperglycemic drugs, such as hypoglycemia or gastrointestinal issues, were not detailed but are commonly reported. These findings highlight the importance of vigilant ADR monitoring in diabetic patients to ensure treatment safety. Further studies should explore ADRs across a broader range of anti-diabetic drugs, include diverse age groups, and assess long-term outcomes to enhance pharmacovigilance in Indian tertiary care settings.

AUTHOR CONTRIBUTIONS

Khandekar Hussan Reza conceptualized the study, conducted the literature review, performed the experiments, analyzed the data, and drafted the manuscript.

Pranabesh Chakraborty, Chowdhury Mobaswar, Hossain and Anjan Adhikari supervised the research work, contributed to study design, provided critical revisions, and approved the final version of the manuscript.

All authors read and approved the final manuscript**.**

CONFLICTS OF INTEREST

The authors declare no conflicts of interest, financial or otherwise.

FUNDING .

No funding was involved either during the research or while preparing the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

IEC Reference Number: F-24/PR/COMJNMMC/IEC/22/869 obtained from College of Medicine JNM Hospital, Kalyani, West Bengal, India

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