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Original Article

Pharmacology Section

Pattern of Antidiabetic Prescription and Prevalence of Hypoglycaemic Events in Individuals Aged above 65 Years: A Cross-sectional Study

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ABSTRACT

Introduction: Diabetes Mellitus (DM) is a global health issue with micro- and macrovascular complications. With a rapidly rising population and increasing life expectancy, the prevalence of diabetes also increased. Hypoglycaemia represents the major barrier to optimal glycaemic control at any age, with elderly individuals being especially vulnerable owing to the burden of co-morbid diseases.

Aim: To analyse the prescription pattern and prevalence of hypoglycaemia associated with antidiabetic medications in individuals aged above 65 years.

Materials and Methods: A cross-sectional study was conducted at the Endocrinology Outpatient Department of SDM College of Medical Sciences and Hospital, Shri Dharmasthala Manjunatheshwara University, Dharwad, Karnataka, India, from April 2022 to March 2023. A total of 400 elderly diabetic patients who were on antidiabetic drugs for at least one year were included in the study. Parameters like age, gender, height, weight and Body Mass Index (BMI) were recorded. Baseline parameters like Fasting Blood Sugar (FBS), Glycosylated Haemoglobin (HbA1c), lipid profile, urine analysis, creatinine, microvascular (neuropathy, nephropathy, and retinopathy) and macrovascular {Coronary Artery Disease (CAD), stroke and peripheral arterial disease} complications were recorded. The prescription pattern of antidiabetic drugs, including oral antidiabetic drugs and injectables, was analysed. Statistical analysis was done by using Chi-square test and Fisher's-exact test. A p-value <0.05 was considered statistically significant.

Results: The study included 400 elderly diabetic patients (260 males and 140 females) and demonstrated significant differences in selected anthropometric and biochemical parameters. Hypoglycaemia was reported in 74 (28.5%) males and 39 (27.9%) females, with no significant difference (p-value= 0.502). The sulfonylureas 303 (75.8%) and metformin 281 (70.3%) were the most prescribed drugs. In males, longer duration of diabetes, lower Systolic (SBP), lower FBS, higher HbA1c, and higher sodium predicted hypoglycaemia; in females, lower FBS and haemoglobin were predictors. Less frequent blood glucose monitoring was significantly linked to hypoglycaemia in males but not females.

Conclusion: In the present study, sulfonylureas and metformin were the most commonly prescribed agents. While the overall incidence of severe hypoglycaemia was low, nearly one-fourth of patients reported level 1 hypoglycaemia. The study identified gender-specific predictors of hypoglycaemia, highlighting the importance of individualised therapy. The significant association between less frequent self-monitoring and hypoglycaemia in males further emphasises the need for education and behavioural interventions.

Keywords: Diabetes mellitus, Glycosylated haemoglobin, Hypoglycaemia, Thyroid stimulating hormone

INTRODUCTION

Diabetes Mellitus (DM) is a serious, long-term condition that occurs when raised levels of blood glucose occur because the body cannot produce enough of the hormone insulin or cannot effectively use the insulin it produces. Type 2 Diabetes Mellitus (T2DM) is the most common type of diabetes, accounting for over 90% of all diabetes worldwide. An estimated 537 million adults aged 20-79 years worldwide, (10.5% of all adults in this age group) have diabetes. By 2030, 643 million, and by 2045, 783 million adults aged 20-79 years are projected to be living with diabetes. According to the data from 2011, approximately 5.3% of the Indian population was aged over 65 years [1]. The number of people with diabetes in India in 2021 was 74.2 million. Prevalence is lowest among adults aged 20-24 years (2.2% in 2021). Among adults aged 75-79 years, diabetes prevalence is estimated to be 24.0% in 2021 and predicted to rise to 24.7% in 2045. The ageing of the world's population will produce an increasing proportion of those with diabetes being over the age of 60 years [2].

Diabetes management in older adults requires regular assessment of medical, psychological, functional, and social domains. When assessing older adults with diabetes, it is important to accurately categorise the type of diabetes as well as other factors, including diabetes duration, the presence of complications, and treatment-related concerns, such as fear of hypoglycaemia. Screening for diabetes complications in older adults should be individualised and periodically revisited, as the results of screening tests may impact treatment goals and therapeutic approaches [3-5]. Older adults with diabetes have higher rates of functional disability, accelerated muscle loss, mobility impairment, frailty, and coexisting illnesses, such as hypertension, chronic kidney disease, coronary heart disease, stroke, and premature death, than those without diabetes. At the same time, older adults with diabetes also require greater caregiver support and are at greater risk than other older adults for several common geriatric syndromes, such as cognitive impairment, depression, urinary incontinence, injurious falls, persistent pain, and frailty, as well as polypharmacy [6]. These conditions may impact older adults' diabetes self-management abilities and quality of life if left unaddressed [7]. In the long-term, hyperglycaemia causes damage to tissues and organs and exacerbates existing diabetic complications, other comorbidities, and the ageing process [8].

Glucose Regulating Agents (GRA), which include metformin and sulfonylurea derivatives, are primarily used to treat T2DM. Numerous newer GRA have entered the market in recent years; Glucagon-Like Peptide-1 (GLP-1 analogues (2005), Dipeptidyl Peptidase-4 (DPP4) inhibitors (2006), and Sodium-Glucose Cotransporter-2 (SGLT2) inhibitors (2012). The introduction of these newer GRA provides more therapeutic options, resulting in changes in the treatment of type 2 diabetes. Little is known about the extent to which these agents are prescribed to older people, especially to frail older people [9].

Agents with a low risk of hypoglycaemia are generally preferred; however, a high prevalence of renal insufficiency among the elderly frequently precludes the use of many of the newer agents. Study from hospitalised older adults with hyperglycaemia can help guide diabetes treatment goals and management in older adults. Further studies regarding local regional resources and cost factors are needed to frame protocols as per the local needs. Despite being required by the Indian Council of Medical Research, inadequate pharmacovigilance reporting is failing to prevent adverse drug reactions. Elderly patients' quality of life will be enhanced by competent pharmacovigilance, which will also assist treating physicians in providing safe and efficient medical treatment [10]. Hence, the current study intends to study the prescription pattern in the elderly in our region, which will help to frame protocols for the management of diabetes in the elderly. Therefore, the study aimed to analyse hypoglycaemia events and the prescribing pattern of oral antidiabetic medications in the elderly.

MATERIALS AND METHODS

This was a cross-sectional study conducted at SDM College of Medical Sciences and Hospital, Shri Dharmasthala Manjunatheshwara University, Dharwad, Karnataka, India, from April 2022 to March 2023. The study was approved by the Institutional Ethics Committee with IEC number SDMIEC/2022/179. Written informed consent was obtained from all the participants.

Sample size calculation: With 95% confidence level and 90% power, and based on the expected proportion reported by Pushpa VH et al., where the proportion of drugs prescribed by generic name was 41.78%(p-value=0.4178) [11].

$n=Z^2x\ p(1-p)\ /\ d^2$,

where, Z=1.96 for 95% confidence interval, p=expected proportion and d=desired absolute precision (0.05).

$n = 1.96^2 \times 0.4178(1-0.4178)/(0.05)^2 = 392.6$

Considering an approximate 2% non response rate, the sample size was rounded off to 400 participants.

Inclusion criteria: Patients above 65 years of age with T2DM and on antidiabetic drugs for at least one year were included.

Exclusion criteria: Patients with Chronic Kidney Disease (CKD) stage 3-5 [12], acute illness, DM patients with diabetes managed exclusively with lifestyle modification and not receiving pharmacotherapy were excluded from the study.

Study Procedure

Baseline parameters include FBS, Postprandial Blood Sugar (PPBS) and HbA1c, Lipid profile, urine analyses, serum creatinine, microvascular (retinopathy, nephropathy, and neuropathy) and macrovascular {CAD, Peripheral Vascular Disease-(PVD), stroke} complications and hypoglycaemia events were recorded. The treatment decision was taken by the treating physician and as per the routine standard of care. Patient's prescription details, like class of antidiabetic drug, compliance, and hypoglycaemic events, were recorded. Blood glucose levels less than 70 mg/dL were recorded by the patient by self-monitoring or hospital or clinic-based recorded values were considered as hypoglycaemia. The frequency of hypoglycaemic events was noted and compared with different variables like duration of diabetes, HbA1c, creatinine, estimated Glomerular Filtration Rate (eGFR), sodium, haemoglobin, etc., using binary logistic regression analysis. The severity of hypoglycaemia was classified into three levels-

- Level 1 is blood glucose < 70 mg/dL.
- Level 2 is blood glucose < 55 mg/dL.
- Level 3 is a severe event characterised by altered mental and/or physical status requiring assistance for treatment of hypoglycaemia, irrespective of glucose level [13].

STATISTICAL ANALYSIS

A Statistical Package for Social Sciences (SPSS) version 21.0 was used to perform the analysis. Categorical variables were analysed using frequencies and proportions and compared using Chi-square tests and Fisher's-exact test. A p-value<0.05 was considered significant. The predictors of hypoglycaemia were analysed with different variables using binary logistic regression analysis.

RESULTS

The study included 260 males and 140 females. There was a significant height difference (p-value<0.001), weight (p-value<0.001), serum creatinine (p-value=0.011), serum TSH (p-value=0.007) and haemoglobin levels (p-value<0.001) between the two groups [Table/Fig-1]. There were no significant differences in age, duration of diabetes, BMI, Blood pressure, FBS, HbA1c, urine microalbumin and electrolytes between the two groups.

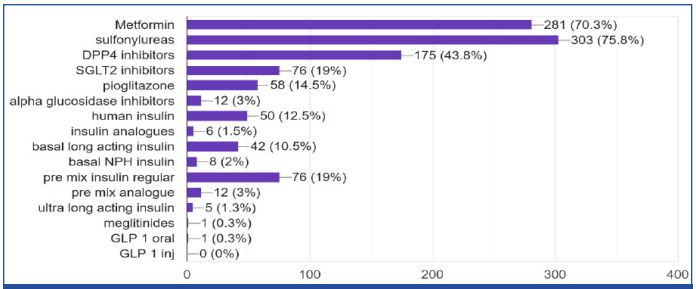
Parameters		Males (n=260)	Females (n=140)	t-value	p-value
Age (years)		71.21 + 4.91	70.93 + 4.49	0.576	0.577
Duration of diabetes (years)		12.04 + 7.55	11.09 + 6.56	1.309	0.210
Height (cm)		170.1 + 4.2	162.3 + 4.5	16.921	<0.001
Weight (kg)		67.2 + 8.8	61.3 + 11.1	5.436	<0.001
BMI (kg/m^2)		23.19 + 2.6	23.23 + 3.94	-0.108	0.904
Systolic BP (mm of Hg)		138.3 + 18.4	140.6 + 21	-1.094	0.265
Diastolic BP (mm of Hg)		78.8 + 10.2	79.8 + 10.1	-0.941	0.320
FBS (mg/dL)		160.1 + 66.7	161.6 + 67.6	-0.213	0.832
HbA1c (%)		8.56 + 1.97	8.83 + 1.93	-1.325	0.189
Serum creatinine (mg/dl)		1.34 + 0.96	1.10 + 0.74	2.779	0.011
eGFR (mL/min/1.73m^2)		66.11 + 23.43	62.21 + 22.64	1.623	0.109
Urine microalbumin spot (mg/g)		39.63 + 113.2	37.95 + 78.07	0.174	0.875
Serum sodium (mEq/L)		135.4 + 3.2	135.7 + 3.2	-0.894	0.431
Serum potassium (mEq/L)		4.42 + 0.49	4.37 + 0.44	1.041	0.369
Haemoglobin (g/dL)		12.29 + 1.59	11.19 + 1.34	7.325	<0.001
Serum TSH (mIU/L)		2.81 + 1.31	3.25 + 1.67	-2.702	0.007
Serum AST (u/L)		19.7 + 11.5	17.9 + 8.7	1.757	0.096
Serum ALT (u/L)		20.2 + 13.5	18.3 + 10.7	1.542	0.154
Frequency of self-blood glucose monitoring(n)	Never	16	13	-	0.122
	Occasionally	126	80	-	
	Frequently	114	46	-	
	Daily	4	1	-	

[Table/Fig-1]: Baseline characteristics in males and females.
*An independent sample t-test was used; AST: Aspartate transaminase, ALT: Alanine aminotransferase, BMI: Body mass index, BP: Blood pressure, FBS: Fasting blood sugar, HbA1c: Glycated haemoglobin, eGFR: estimated Glomerular filtration rate, TSH: Thyroid-stimulating hormone

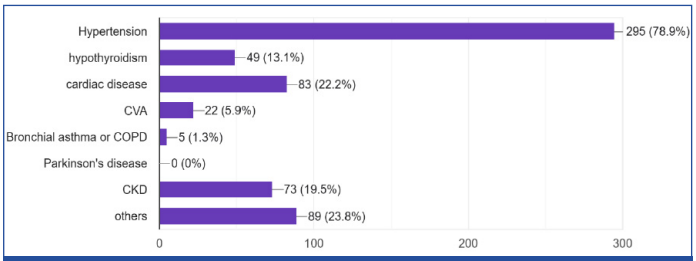
The most commonly prescribed medications were sulfonylurea (75.8%), followed by metformin (70.3%) and DPP4 inhibitors (43.8%) [Table/Fig-2].

The most commonly associated co-morbidity was hypertension (78.9%) followed by cardiovascular disease (22.2%) [Table/Fig-3].

Most participants, that is 71.5% of males and 72.1% of females, reported no hypoglycaemia. Level 1 hypoglycaemia (<70 mg/dL)



[Table/Fig-2]: Prescription pattern of antidiabetic medications.
X-axis: number of patients (%), Y-axis: Medication prescribed



[Table/Fig-3]: Associated co-morbidities in patients.
X-axis: number of patients. Y-axis: Co-morbidities; Abbreviation: CVA: Cerebrovascular accident; CKD: Chronic kidney disease; COPD: Chronic obstructive pulmonary disease

was reported by 22.7% of males and 24.3% of females. Level 2 hypoglycaemia (<55 mg/dL) occurred in 5% of males and 3.6% of females. Level 3 hypoglycaemia (requiring assistance) was seen in only 0.7% of males and none in females. No statistically significant association between gender and hypoglycaemia severity was observed (p-value 0.502) [Table/Fig-4]

Severity of hypoglycaemia	Male (n= 260)	Female (n=140)	Total (N=400)
No hypoglycaemia	186	101	287
Level-1 hypoglycaemia (<70 mg/dL)	59	34	93
Level-2 hypoglycaemia (<55 mg/dL)	11	5	16
Level-3 Hypoglycaemia (Requiring Assistance)	4	0	4

[Table/Fig-4]: Severity of hypoglycaemia with gender.
The Pearson's Chi-square test was used

The association between self-monitoring of blood glucose frequency and incidence of hypoglycaemia was assessed using the Chi-square test. Among females, no statistically significant association was observed (χ^2=5.901, df=3, p-value=0.117). In contrast, a significant association was found in males (χ^2= 17.618, df=3, p-value=0.001), suggesting that less frequent monitoring was related to hypoglycaemia occurrence in male participants.

Lower FBS and lower haemoglobin in females were significantly associated with increased odds of hypoglycaemia. Whereas in males, longer duration of diabetes, lower systolic blood pressure, lower FBS, higher HbA1c and higher sodium were significantly associated with increased odds of hypoglycaemia [Table/Fig-5].

Parameters	Male		Female	
	B	p-value	B	p-value
Age (in years)	-0.045	0.257	0.038	0.508
Duration of diabetes (years)	0.087	<0.001	0.006	0.875
BMI (kg/m^2)	-1.177	0.269	0.591	0.551
Height (cm)	-0.328	0.258	0.197	0.462
Weight (kg)	0.442	0.231	-0.265	0.484
Systolic BP (mmHg)	-0.025	0.044	-0.026	0.099
Diastolic BP (mmHg)	0.006	0.789	0.020	0.494
FBS (mg/dL)	-0.010	0.004	-0.016	0.001
HbA1c (%)	0.281	0.019	0.264	0.100
Serum creatinine (mg/dL)	1.384	0.043	0.358	0.601
eGFR (mL/min/1.73m^2)	0.014	0.452	-0.007	0.728
Serum sodium (mEq/L)	0.141	0.038	-0.056	0.478
Serum potassium (mEq/L)	0.538	0.165	0.096	0.860
Haemoglobin (g/dL)	-0.257	0.057	-0.419	0.041
Urine microalbumin (mg/g)	0.001	0.727	-0.002	0.613
Serum TSH (mIU/L)	0.054	0.688	-0.104	0.460
Serum AST (u/L)	-0.015	0.519	0.060	0.169
Serum ALT (u/L)	0.031	0.106	-0.009	0.805

[Table/Fig-5]: Regression analysis of variables with hypoglycaemia.
B- Regression coefficient; *binary logistic regression analysis

DISCUSSION

In the present study, sulphonylureas and metformin were the most commonly prescribed antidiabetic drugs. This pattern aligned with global prescribing trends, where there has been a shift toward increased use of safer medications like metformin and DPP-4 inhibitors, and a decline in sulfonylureas and thiazolidinediones [14,15]. Similar observations were reported in Canada from 2002–2013 [14], where metformin was prescribed to approximately 80% of patients, although a slight decrease occurred between 2006 and 2008. During the same period, prescriptions for DPP-4 inhibitors rose steadily sitagliptin from 0% to 10.1%, and saxagliptin from 0% to 2.1%. A notable decline in glyburide use (from 39.0% to 2.9%) with a rise in gliclazide prescriptions (0.3% to 11.7%) was also documented. Insulin use remained stable at around 7%, and thiazolidinedione prescriptions, though initially increasing, later declined. Prescriptions for other agents such as acarbose, acetohexamide, glimepiride, repaglinide, tolbutamide, nateglinide, and chlorpropamide remained consistently low (<5%) [14]. In a study by Dadibhanvi A et al., the most common fixed-dose combinations of medications were metformin + sulfonylureas in 26.2% of Inpatients (IP) and 36.1% of Outpatients (OP) [10]. Other combinations included metformin + alpha-glucosidase inhibitors in IP (0.9%) and OP (3.2%), metformin + sulfonylureas + voglibose in 3.2% of outpatients, and metformin + sulfonylureas + pioglitazone in 2.9% of both sample groups. In a study by Sridevi SA and Ganesh M the average number of antidiabetic medications per prescription was 1.8, while the number of Oral Hypoglycaemic Agents (OHAs) per prescription ranged from one to three [16]. This included 111 (61%) individuals on OHAs and 69 (39%) patients on insulin. The most often administered antidiabetic medications in this study were OHAs. The most often prescribed class was sulfonylureas (36%), followed by biguanides (32.5%).

Despite these shifts in medication patterns, hypoglycaemia remains a major concern, particularly in patients with long-standing diabetes and those using sulfonylureas or insulin [17,18]. The findings of this study parallel those of Mittal D and Mittal P, who reported that 23.7% of patients experienced 39 episodes of hypoglycaemia [17]. They found no significant difference in HbA1c levels between the hypoglycaemia and the no-hypoglycaemia groups. Random plasma glucose was slightly higher in the no-hypoglycaemia group, though not statistically significant. However, fasting plasma glucose was markedly lower in the hypoglycaemia group. They also reported higher sulphonylurea and insulin use among hypoglycaemia patients (9.6% and 52.2%) compared to the no-hypoglycaemia group (33.8% and 39.1%).

In the present study, hypoglycaemia was associated with lower FBS and lower haemoglobin in females, while in males, longer duration of diabetes, lower systolic blood pressure, lower FBS, higher HbA1c, higher creatinine, and higher sodium were linked with higher odds of hypoglycaemia. The study also highlighted the importance of regular blood glucose monitoring, as less frequent Self-Monitoring of Blood Glucose (SMBG) was associated with increased hypoglycaemia risk. Similar findings have been noted in previous literature, where

timely medication adjustment based on glucose readings has been emphasised. Although the overall proportion of patients experiencing hypoglycaemia-related hospital visits has declined [14], the impact on quality of life among insulin users remains comparable to that of non insulin users [18].

Despite the increasing availability of safer antidiabetic agents such as DPP-4 inhibitors used in 43.8% of patients in the current study, the continued high use of sulfonylureas indicates a gap between evidence-based recommendations and real-world practice. International guidelines and the American Geriatrics Society Beers Criteria advise minimising sulfonylurea use in older adults due to increased hypoglycaemia risk [19,20]. Consistent with the present findings, the GERODIAB cohort also reported a slow but persistent decline in sulfonylurea prescriptions, although usage remained relatively high over time [21]. These observations reinforce the importance of transitioning toward safer therapeutic options, particularly in elderly patients who are more vulnerable to adverse events.

The high prevalence of hypertension (78.9%) observed in this study is comparable with other Indian studies reporting similar comorbidity patterns among elderly diabetic patients [22]. This co-existence underscores the need for a more integrated, multidisciplinary approach to care, given the compounded cardiovascular risk. Although the majority of patients in the present study did not experience hypoglycaemia, the continued reliance on medications with known hypoglycaemic potential and the presence of gender-specific predictors highlight the need for individualised, evidence-based prescribing practices. Overall, the findings support broader recommendations advocating for safer antidiabetic drug classes, regular SMBG, and careful monitoring, particularly in older adults and other vulnerable subgroups.

Although serum sodium is not recognised as an established predictor of hypoglycaemia, the current study demonstrated a significant association between serum sodium levels and hypoglycaemia in male patients.

Limitation(s)

The present study has a few limitations. Firstly, it was conducted in a single centre, which may limit the generalisability of the findings to other settings or regions. Secondly, hypoglycaemia was self-reported by participants rather than confirmed through continuous glucose monitoring or laboratory verification, introducing potential recall bias, although blood glucose was checked at the time of hospital visit for those who did not monitor blood glucose at home. Lastly, despite analysing multiple predictors, other confounders such as cognitive status, frailty, and polypharmacy were not included, which could provide further insight into the observed gender-based differences.

CONCLUSION(S)

The sulfonylureas and metformin were the most commonly prescribed agents. While the overall incidence of severe hypoglycaemia was low, nearly one-fourth of patients reported level 1 hypoglycaemia. Logistic regression revealed gender-specific predictors, highlighting the importance of individualised therapy. The significant association between less frequent self-monitoring and hypoglycaemia in males further emphasises the need for education and behavioural interventions. Despite widespread guideline recommendations, the use of high-risk medications such as sulfonylureas remains prevalent. These findings call for more rational and evidence-based prescribing practices, especially in the elderly, to optimise safety and treatment outcomes.

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