

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20250480>

Original Research Article

Drug-related problems among type 2 diabetes mellitus patients with hypertension: a prospective observational study

Subhajyoti Samanta*, Waseem Hussain Bhat, Jeeva George, Balakeshwa Ramaiah

Department of Pharmacy Practice Karnataka College of Pharmacy Rajiv Gandhi University of Health Sciences, Karnataka, Bengaluru Province, India

Received: 05 December 2024

Accepted: 18 January 2025

*Correspondence:

Dr. Subhajyoti Samanta,

Email: subhajyoti.samanta10@gmail.com

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) and hypertension (HTN) are common comorbid conditions that pose significant management challenges due to drug-related problems (DRPs), which can adversely affect clinical outcomes. This study aimed to evaluate the prevalence and types of DRPs in T2DM and HTN patients, analyse drug utilization patterns and identify factors influencing DRPs.

Methods: A prospective observational study was conducted over six months at a multi-specialty hospital in Bengaluru. Data from 110 adult patients with T2DM and HTN were collected, including demographics, clinical history and medication records. DRPs were identified using the Pharmaceutical Care Network Europe (PCNE) and Hepler-Strand classifications.

Results: The mean age of the participants was 63.45 ± 13.66 years, with a nearly equal gender distribution. Monotherapy (37.27%) and dual therapy (33.63%) were the most common T2DM treatments, while calcium channel blockers (37.27%) and beta blockers (36.36%) were the predominant antihypertensives. DRPs were observed in 36.36% of patients, with untreated indications (14.54%) and drug-drug interactions (13.63%) being most common. Factors such as smoking and alcohol consumption were associated with higher DRP prevalence.

Conclusions: DRPs significantly impact the management of T2DM and HTN, highlighting the need for regular medication reviews and targeted interventions to optimize therapeutic outcomes in these patients.

Keywords: Drug-related problems, Drug utilization, Hypertension, Pharmaceutical care, Polypharmacy, Type 2 diabetes mellitus

INTRODUCTION

Type 2 diabetes mellitus (T2DM) and hypertension (HTN) are among the most prevalent non-communicable diseases worldwide, often termed "silent killers" due to their asymptomatic progression and significant contributions to morbidity and mortality. Diabetes mellitus (DM) is a metabolic disorder characterized by chronic hyperglycemia, which leads to complications affecting the heart, eyes, blood vessels, nerves and kidneys.¹ Globally, approximately 415 million adults are diagnosed with DM, with an additional 318 million experiencing glucose intolerance, a precursor to the disease.² In India, the prevalence of diabetes is estimated at 11.8%, affecting

over 72.96 million adults.³ Several types of DM exist, including T2DM, type 1 diabetes mellitus (T1DM), gestational diabetes, type 3c diabetes and neonatal diabetes, each presenting distinct etiologies and challenges.

T2DM management often involves lifestyle modifications, but many patients require oral hypoglycemics or insulin therapy based on individual clinical parameters. HTN, frequently co-morbid with T2DM, affects more than 60% of diabetic patients.⁴ It is defined as sustained blood pressure levels exceeding 140/90 mmHg and, if untreated, can lead to severe complications.⁵ The complexity of managing these conditions is heightened by

polypharmacy, particularly in older populations, where pharmacokinetic and pharmacodynamic changes increase the risk of drug-related problems (DRPs).⁶ DRPs encompass a range of issues, including medication errors, adverse drug reactions (ADRs), drug-drug interactions and prescription errors, all of which contribute to increased healthcare costs and adverse clinical outcomes. Studies, such as that by Krähenbühl-Melcher et al, have documented an average medication error rate of 5.7% during drug administration, underscoring the significance of addressing DRPs.⁷ Risk factors for DRPs include polypharmacy, advanced age and the use of drugs with narrow therapeutic windows.

Scales such as the Pharmaceutical Care Network Europe (PCNE) classification and Hepler-Strand classification have been developed to identify, categorize and mitigate DRPs effectively. These tools aid healthcare professionals in documenting and addressing DRPs to optimize patient outcomes⁸. Despite their importance, limited studies have explored the burden of DRPs among patients with T2DM and HTN.

Understanding the prevalence, risk factors and types of DRPs in this population is crucial for guiding policymakers and designing interventions that improve patient care while minimizing drug-related harms. This study aims to fill the knowledge gap by evaluating DRPs in patients with T2DM and HTN, offering insights into demographics, drug utilization patterns and influencing factors, thereby contributing to the optimization of therapeutic outcomes.

Objectives

Primary objective

To assess drug-related problems among patients with type II diabetes mellitus and hypertension.

Secondary objectives

To study the demographics, personal history and social habits of the patients. To evaluate the drug utilization patterns in patients with T2DM and hypertension. To identify factors influencing drug-related problems among patients with T2DM and hypertension.

METHODS

Study design

This study was a prospective observational study conducted at a multi-specialty hospital and research center in Bengaluru over six months.

Study population

The study included adult patients aged 30 years and above who were diagnosed with T2DM and hypertension.

Data sources

Data were obtained from patient demographic and clinical records, including medical charts, medication history and laboratory investigations.

Inclusion criteria

Patients diagnosed with T2DM and hypertension. Patients receiving at least one antidiabetic drug (oral antidiabetic drug or insulin) or at least one antihypertensive agent. Adult patients aged 30 years or older.

Exclusion criteria

Patients with missing or incomplete data. Pregnant or lactating women.

Data collection and study procedure

Patients with T2DM and hypertension were identified across various hospital wards and demographic and clinical data, including medical history, social habits (e.g., smoking, alcohol use), risk factors and complications (e.g., neuropathy, nephropathy, retinopathy), were documented using a structured data collection form. Drug-related problems (DRPs), such as drug-drug interactions, adverse effects and medication errors, were analysed using the PCNE classification (V9.0) and hepler-strand classification.

Drug utilization patterns, including modes of therapy (monotherapy, dual therapy or triple therapy), adverse reactions and drug interactions, were recorded. Laboratory readings were examined to categorize glucose and blood pressure levels for the classification of diabetic and hypertensive patients. All collected data were systematically entered into a Microsoft Excel spreadsheet for analysis, with descriptive statistics applied and results visualized through pie charts and bar diagrams.

Ethical considerations

Ethical considerations written informed consent was obtained from all participants, ensuring their voluntary participation. Privacy and confidentiality were maintained throughout the study. Participants were informed they could withdraw at any time without affecting their treatment.

RESULTS

This study included 110 patients with type 2 diabetes mellitus and hypertension. The gender distribution was nearly equal (51% males, 49% females), with a mean age of 63.45 ± 13.66 years. Most patients (27%) belonged to the 71–80 age group. The prevalent comorbidities were ischemic heart disease (21.81%), urinary tract infections (18.18%) and chronic kidney disease (14.54%). The majority were admitted to general medicine (58.18%) or

cardiology (30%) departments. Social history showed 27.27% smokers and 17.27% alcoholics, while over half had unrecorded smoking and alcohol statuses. Glycemic control, as assessed by HbA1C, revealed poor control ($>7.1\%$) in 36.36% of patients, with an overall mean HbA1C of $6.84 \pm 0.50\%$. Diabetic complications were uncommon, with 77.27% showing none. However, hypertension was poorly managed, with 33.63% at Stage 2 Hypertension and an average blood pressure of 148.09 ± 20.57 mmHg, details are depicted in Table 1.

In this study of 110 patients, 37.27% received monotherapy for T2DM, with Human Actrapid being the most common (70.73%). Dual therapy (33.63%) was dominated by Vildagliptin+Metformin (29.72%) and triple therapy (10%) most often involved Metformin+Voglibose+Glimepiride (63.63%). Regarding diabetic medications, 34.54% received only insulin, 28.18% a combination of insulin and oral drugs.

Among antihypertensive classes, calcium channel blockers (37.27%) and beta blockers (36.36%) were prevalent, with Bisoprolol (23.63%) being the most prescribed. Combination antihypertensive therapy was less frequent, with calcium channel blocker and beta blocker

combinations leading (11.81%), details are depicted in Table 2. Out of 110 patients with T2DM and HTN, 40 (36.36%) had at least one drug-related problem (DRP). The Hepler-Strand classification revealed that the most common issues were "Others" (35.45%) and untreated indications (14.54%), while PCNE identified incomplete treatment (14.54%) and inappropriate drug combinations (6.36%) as significant concerns. Issues ranged from adverse drug reactions and wrong dosages to unclear timing and contraindicated drugs, highlighting the complexity of managing comorbid conditions and the critical need for careful medication review and optimization, details are depicted in Table 3.

Drug-related problems (DRPs) were more frequent among younger patients aged 30–50 years (50%), females (50%), smokers (53.33%) and alcohol consumers (57.89%). Conversely, older patients (51+years), non-smokers (33.33%) and non-alcoholics (34.48%) experienced fewer DRPs. This suggests that lifestyle habits like smoking and drinking alcohol, as well as demographic factors such as age and gender, significantly influence the prevalence of DRPs in patients with type 2 diabetes mellitus and hypertension, details are depicted in Table 4.

Table 1: Demographic and clinical characteristics of patients with T2DM and hypertension (N=110).

Parameter	Category/group	Number of patients (%) /Mean $\pm$ SD
Gender distribution	Male/Female	56 (51%)/54 (49%)
Age distribution	30–40 / 41–50 / 51–60 / 61–70 / 71–80 / 81–92	6 (6%)/14 (13%)/22 (20%)/28 (25%)/30 (27%)/10 (9%)
Age	Mean $\pm$ SD	63.45 $\pm$ 13.66 years
Comorbidities	Hyperthyroidism/Dyslipidemia/CHF/IHD/CKD/UTI/LRTI/Others	6 (5.45%)/4 (3.63%)/5 (4.54%)/24 (21.81%)/16 (14.54%)/20 (18.18%)/16 (14.54%)/93 (84.54%)
Department of admission	General medicine/Cardiology/Nephrology/Orthopedic/Surgery	64 (58.18%)/33 (30%)/7 (6.36%)/3 (2.72%)/3 (2.72%)
Smoking status	Smoker/Non-smoker/Not mentioned	30 (27.27%)/18 (16.36%) /62 (56.36%)
Alcoholic status	Alcoholic/Non-alcoholic/Not mentioned	19 (17.27%)/29 (26.36%)/62 (56.36%)
Hba1c levels	$<5.9\%$ / $6.0\text{--}6.5\%$ / $6.6\text{--}7.0\%$ / $>7.1\%$ / Not Mentioned	8 (7.27%)/10 (9.09%)/13 (11.81%)/40 (36.36%)/39 (35.45%)
Hba1c	Mean $\pm$ SD	6.84 $\pm$ 0.50%
Diabetic complications	Retinopathy/Neuropathy/Nephropathy/Foot ulcer / No complications	4 (3.63%)/3 (2.72%)/5 (4.54%)/7 (6.36%)/85 (77.27%)
Blood pressure stages	Normal/Prehypertension/Stage 1 HTN/Stage 2 HTN/Hypertensive crisis	19 (17.27%)/19 (17.27%)/27 (24.54%)/37 (33.63%)/ 8 (7.27%)
Blood pressure	Mean $\pm$ SD	148.09 $\pm$ 20.57 mmHg

Table 2: Drug utilisation pattern in patients with type 2 diabetes mellitus and hypertension.

Parameter	Category/group	Number of patients (%)
No. of drugs prescribed for T2DM	Monotherapy/Dual therapy/Triple therapy	41 (37.27%)/37 (33.63%)/11 (10%)
Type of diabetic medications	Only oral/Only insulin/Oral+Insulin	24 (21.81%)/38 (34.54%)/31 (28.18%)
Monotherapy (Hypoglycemics)	Metformin/Vildagliptin/Linagliptin/Actrapid/Lantus	7 (17.07%)/2 (4.87%)/1 (2.43%)/29 (70.73%)/2 (4.87%)
Dual Therapy (Hypoglycemics)	Vildagliptin+Metformin / Glimepiride+Metformin / Sitagliptin+Metformin / Sitagliptin+Dapagliflozin / Metformin+Actrapid / Metformin+Lantus / Actrapid+Lantus	11 (29.72%)/9 (24.32%)/2 (5.4%)/1 (2.7%)/4 (10.81%)/2 (5.4%)/8 (21.62%)
Triple Therapy (Hypoglycemics)	Metformin+Voglibose+Glimepiride / Glimepiride+Metformin+Vildagliptin	7 (63.63%)/4 (36.37%)
Classes of Antihypertensives	Calcium Channel Blocker / Beta Blocker / ACE Inhibitor / ARB / Diuretics	41 (37.27%)/40 (36.36%)/2 (1.81%)/19 (17.27%)/5 (4.54%)
Different Antihypertensive Medications	Amlodipine / Cilnidipine / Bisoprolol / Carvedilol / Atenolol / Metoprolol / Verapamil / Enalapril / Ramipril / Telmisartan / Losartan / Furosemide	19 (17.27%)/21 (19.09%)/ 26 (23.63%)/ 6 (5.45%)/1 (0.91%)/7 (6.36%)/1 (0.91%)/1 (0.91%)/1 (0.91%)/17 (15.45%)/2 (1.81%)/5 (4.54%)
Combination Therapy for Antihypertensives	ARB+CCB / ARB+Diuretics / CCB+Beta Blocker / Beta Blocker+ACE Inhibitor / Diuretics+Beta Blocker / Diuretics+CCB	8 (7.27%)/3 (2.72%)/13 (11.81%)/1 (0.91%)/1 (0.91%)/1 (0.91%)

Table 3: Summary of drug-related problems in T2DM and HTN patients (n=110).

Category	Subcategory	Frequency (%)
Hepler-strand classification	Drug without indication	2 (1.81)
	Improper drug selection	1 (0.91)
	Drug interactions	15 (13.63)
	Overdose	1 (0.91)
	Adverse drug reaction	5 (4.54)
	Untreated indication	16 (14.54)
	Others	39 (35.45)
PCNE classification	Inappropriate drugs (contraindicated)	5 (4.54)

Continued.

Category	Subcategory	Frequency (%)
	Drugs without indication	1 (0.91)
	Inappropriate drug combinations	7 (6.36)
	No or incomplete treatment despite indications	16 (14.54)
	Too many drugs for the same indication	1 (0.91)
	Inappropriate drug form	1 (0.91)
	Dosage regimen too frequent	2 (1.81)
	Dose timing unclear/wrong	4 (3.63)
	Wrong drug/strength/dosage advised	2 (1.81)
	Inappropriate timing of administration	2 (1.81)

Table 4: Factors influencing DRPs in T2DM and hypertension patients.

Variable	Category	DRPs (%)	Non-DRPs (%)
Age (in years)	30–50	50	50
	51–70	46.93	53.07
	71 years and above	46.34	53.66
Gender	Male	44.64	55.36
	Female	50	50
Smoking	Yes	53.33	46.67
	No	33.33	66.67
Alcohol consumption	Yes	57.89	42.11
	No	34.48	65.52

DISCUSSION

The prospective observational study conducted in a tertiary care hospital in Bangalore evaluated drug-related problems (DRPs) and drug utilization patterns in 110 patients with Type 2 diabetes mellitus (T2DM) and hypertension (HTN). Among the patients, 51% were male and 49% were female, aligning with findings by Huri Hz in Malaysia, where male admissions were higher (52%), though studies like Mendoza et al, in Colombia reported contrasting results with more female admissions (56.3%).^{9,10} The majority of patients were elderly, with 27% aged 71-80 years, similar to the findings by Nzayisenga et al, in Kibuye Referral Hospital but differing from Ayele Y et al, who reported higher admissions among younger populations.^{11,12}

Key comorbidities included ischemic heart disease (21.81%), chronic kidney disease (14.54%) and urinary tract infections (18.18%), comparable to Roy et al's study, which also highlighted significant comorbidity burdens among diabetic patients.¹³ Drug utilization analysis showed that 37.27% of patients were on monotherapy, 33.63% on dual therapy and 10% on triple therapy; the most commonly prescribed drugs included metformin, insulin and combinations of antidiabetic agents, mirroring findings by Sharma et al.¹⁴ Antihypertensive use predominantly featured calcium channel blockers (37.27%), beta blockers (36.36%) and angiotensin receptor blockers (17.27%), consistent with studies like Abdulmalik et al, which reported similar trends.¹⁵ DRPs were observed in 36.36% of patients, with drug-drug interactions (13.63%) and untreated indications (14.54%) being the most common, paralleling findings from studies by Huri HZ and Chung

AYS.¹⁶ Adverse reactions were reported in 4.54% of patients and inappropriate drug prescriptions were seen in 1.81%, aligning with similar observations by Zazuli et al.¹⁷ Smoking and alcohol consumption were associated with higher DRP incidences (53.53% and 57.89%, respectively), reaffirming findings by Nzayisenga et al, who identified smoking as a significant risk factor for DRPs. Notably, DRPs were more prevalent among younger patients (30-50 years) and males (44.64%), contrasting with studies that observed higher DRPs in females, such as Nzayisenga et al, where 72.2% of females had DRPs.¹³ These findings highlight the complex interplay of polypharmacy, patient demographics and lifestyle factors in managing T2DM and HTN.

The study's limitations include its small sample size of 110 patients from a single hospital, potentially restricting the generalizability of the findings. Additionally, incomplete patient records, particularly concerning smoking and alcohol habits, may have introduced bias into the analysis. The six-month duration of the study limited the assessment of long-term outcomes related to medication use and DRP mitigation strategies. Furthermore, the exclusion of pregnant women and patients with missing data may have omitted important subsets of the population, reducing the comprehensiveness of the findings.

CONCLUSION

The study highlights the significant burden of DRPs among patients with T2DM and HTN, influenced by factors such as lifestyle habits, age and gender. Polypharmacy and inappropriate drug combinations were notable challenges,

emphasizing the need for tailored pharmacological interventions. The findings provide crucial insights for healthcare professionals to improve drug utilization practices and patient outcomes. Future research should focus on implementing and evaluating strategies to minimize DRPs in similar populations.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Samanta S, Bhat WH, George J, Ramaiah B. Drug-related problems among type 2 diabetes mellitus patients with hypertension: a prospective observational study. *Int J Basic Clin Pharmacol* 2025;14:213-8.