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Prospective Observational Study on Drug-Related Issues in Patients with Type 2 Diabetes Mellitus and Coexisting Hypertension

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Abstract ***Background:*** *Type 2 Diabetes Mellitus (T2DM) is a prevalent metabolic disorder that often coexists with hypertension, both of which can significantly impact the health outcomes of patients. Drug-related issues (DRIs) in this patient population are increasingly recognized as contributors to poor management of the diseases and adverse health events. However, systematic analyses of DRIs in T2DM patients with concurrent hypertension are limited.*

Aim of the study: *To explore the prevalence, types, and consequences of drug-related issues in patients with T2DM and coexisting hypertension, identifying key patterns and outcomes associated with pharmacotherapy in this cohort.*

Methods: *This study was a prospective observational investigation conducted over a six-month period at a multi-specialty hospital in Bengaluru. Data were collected from 100 adult patients diagnosed with Type 2 Diabetes Mellitus (T2DM) and Hypertension (HTN). The collected data included demographic information, clinical history, and medication records. Drug-related problems (DRPs) were identified and classified using the Pharmaceutical Care Network Europe (PCNE) and Hepler-Strand classifications.*

Result: *The mean age of the participants was 61.85±15.62 years, with a nearly equal gender distribution (51% males, 49% females). Monotherapy (39%) and dual therapy (34%) were the most common treatment regimens for T2DM, with insulin-only (39%) and insulin plus oral hypoglycemics (31%) being the predominant agents. Among antihypertensives, beta blockers (37%) and calcium channel blockers (31%) were most frequently prescribed. Drug-related problems (DRPs) were identified in 36% of patients, with "other" issues (39%), untreated indications (18%), and drug-drug interactions (15%) being the most prevalent. Factors such as smoking (63.33%) and alcohol consumption (67.89%) were significantly associated with a higher occurrence of DRPs, with a higher prevalence observed among females (58%) compared to males (38.64%).*

Conclusion: *Drug-related problems pose a significant challenge in the clinical management of type 2 diabetes mellitus and hypertension, emphasizing the importance of routine medication assessments and individualized interventions to enhance treatment effectiveness and patient outcomes.*

Keywords: *Type 2 Diabetes Mellitus, Hypertension, Drug-related Issues, Pharmacotherapy, Drug Interactions, Patient Adherence, Clinical Outcomes*

Original Research Article

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) and hypertension (HTN) are among the most common chronic non-communicable diseases globally. They frequently coexist and are considered major contributors to cardiovascular morbidity and mortality, especially when left inadequately managed [1]. T2DM is defined by persistent hyperglycemia resulting from insulin resistance and/or impaired insulin secretion, which leads to various complications involving multiple organ systems such as the eyes (retinopathy), kidneys (nephropathy), nerves (neuropathy), and cardiovascular system (atherosclerosis) [2]. HTN, typically defined as sustained blood pressure levels exceeding 140/90 mmHg, is a common comorbid condition in diabetic patients, with an estimated prevalence of 60–80% in individuals diagnosed with T2DM [3-4]. According to the International Diabetes Federation, in 2021, an estimated 537 million adults worldwide had diabetes, and this number is projected to increase to 643 million by 2030, and 783 million by 2045, driven by aging populations, urbanization, and lifestyle changes [5]. Bangladesh, referred to as the growing diabetes capital of the world, accounts for over 78 million

diabetic individuals, with an adult prevalence rate of 6.9% [6]. The coexistence of T2DM and HTN significantly increases the risk of both microvascular and macrovascular complications and makes pharmacological management more challenging due to the requirement of multidrug regimens and close monitoring [7]. The frequent use of multiple medications in managing both conditions often results in polypharmacy, which in turn increases the likelihood of drug-related problems (DRPs). DRPs encompass a wide range of issues, including adverse drug reactions (ADRs), drug-drug interactions (DDIs), inappropriate dosing, medication non-adherence, and untreated or improperly treated indications [8]. These problems are associated with poor clinical outcomes, increased rates of hospitalization, prolonged hospital stays, and rising healthcare costs [9]. Risk factors that predispose patients to DRPs include advanced age, multiple comorbidities, impaired renal or hepatic function, and the use of drugs with narrow therapeutic indices [10]. Several studies have shown that DRPs are both prevalent and preventable, particularly in patients with coexisting chronic diseases like T2DM and HTN. In resource-constrained settings, where patient education and pharmacist-led interventions may be limited, the burden of DRPs is often more pronounced [11]. To address these issues systematically, validated tools such as the Pharmaceutical Care Network Europe (PCNE) classification system and the Hepler-Strand model are used to identify, categorize, and resolve DRPs, improving patient safety and clinical outcomes [12-13]. Despite the rising burden of T2DM and HTN in Bangladesh, there is limited prospective data on the frequency, classification, and risk factors of DRPs in patients suffering from both conditions. Most available studies are retrospective or lack detailed assessments of drug utilization. This study aims to fill that gap by prospectively evaluating DRPs and identifying contributing factors and utilization patterns, thereby supporting improved pharmacotherapeutic practices and clinical decision-making.

MATERIAL AND METHODS

This prospective observational study was conducted at a multi-specialty hospital and research center in Dhaka, Bangladesh over a six month period. The study included a population of 100 participants that was designed to assess the clinical profile, management strategies, and outcomes of patients diagnosed with both Stage 4 chronic kidney disease (CKD) and Type 2 diabetes mellitus (T2DM), with particular emphasis on hypertension and its related complications.

All of the patients were carefully observed to meet the research objectives and provide valuable insights within the specified timeframe.

Inclusion Criteria:

- Age ≥ 30 years
- Diagnosis of T2DM and hypertension
- Diagnosis of CKD Stage 4 based on KDIGO 2021 criteria
- On at least one oral antidiabetic drug or insulin and at least one antihypertensive agent

Exclusion Criteria:

- Patients with acute kidney injury (AKI) or rapidly progressive renal failure
- Pregnant or lactating women
- Patients with incomplete or missing medical records
- Patients with known malignancies or autoimmune renal disorders

Ethical Considerations

Ethical considerations were integral to the study design and execution. The study adhered to ethical principles of confidentiality and privacy, ensuring that all patient data were anonymized and securely stored. Informed consent was obtained where applicable, and the research protocol was reviewed and approved by the relevant institutional ethics committee, ensuring compliance with ethical standards in human subject research.

Data Collection

Patients diagnosed with both Type 2 Diabetes Mellitus (T2DM) and hypertension were recruited from various inpatient departments within the hospital. A standardized data collection tool was used to capture relevant demographic and clinical information, including past medical history, lifestyle behaviors (such as tobacco use and alcohol consumption), associated risk factors, and diabetes-related complications (e.g., nephropathy, retinopathy, and neuropathy). Drug-related problems (DRPs) including drug-drug interactions, adverse drug reactions, and medication errors were evaluated using the Pharmaceutical Care Network Europe (PCNE) classification system version 9.0 and the Hepler-Strand classification framework. Medication usage patterns, such as monotherapy, dual, or triple therapy, were documented along with any reported adverse effects and observed drug interactions. Laboratory investigations were reviewed to assess glycemic control and blood pressure parameters, which were subsequently used to classify the status of diabetes and hypertension in each patient.

Statistical Analysis

The collected data were meticulously organized and recorded in Microsoft Excel, where descriptive statistical methods were employed for analysis. The outcomes were subsequently illustrated using graphical representations such as pie charts and bar graphs.

RESULTS

A total of 100 patients diagnosed with both type 2 diabetes mellitus (T2DM) and hypertension were included in the study. The gender distribution was nearly equal, with 51% males and 49% females. The mean age of the participants was 61.85±15.62 years, with the largest group being in the 71–80-year range (28%), followed by 61–70 years (25%) and 51–60 years (21%) (Table 1). Ischemic heart disease (IHD) was the most prevalent comorbidity (27%), followed by urinary tract infections (UTI) (20%), lower respiratory tract infections (LRTI) (18%), chronic kidney disease (CKD) (16%), and hyperthyroidism (6%). Most patients (60%) were admitted under the Department of General Medicine, with smaller numbers in Cardiology (27%) and Nephrology (7%). Smoking and alcohol use were underreported, with 23% documented smokers and 19% alcohol consumers. Glycemic control was suboptimal, with a mean HbA1c of 8.14±2.50%. A majority (37%) had HbA1c <7.1%, while 39% had missing documentation (Table 1). Regarding diabetes-related complications, 7% had foot ulcers, 4% had nephropathy, 3% had retinopathy, and 2% had neuropathy, with 84% showing no complications. Blood pressure measurements revealed 60% of patients were hypertensive, with 24% in Stage 1, 36% in Stage 2, and 7% in hypertensive crisis (Table 1). In table 2, drug utilization patterns indicated that 39% of patients received monotherapy for T2DM, 34% received dual therapy, and 13% received triple therapy (Table 2). The most common diabetic medications were insulin-only (39%) and oral hypoglycemics with insulin (31%). Metformin was most commonly used in monotherapy (7%), followed by Actrapid (29%). For hypertension, beta blockers (37%) and calcium channel blockers (31%) were the most frequently prescribed classes. In terms of drug-related problems (DRPs), "Others" was the most common issue (39%), followed by untreated indications (18%) and drug interactions (15%). Under the PCNE classification, no or incomplete treatment despite indications was found in 11% of patients (Table 3). The table 4 showed the factors influencing DRPs in T2DM and Hypertension patients. Smoking (63.33%) and alcohol consumption (67.89%) were associated with a higher occurrence of DRPs. Gender differences were also observed, with more females (58%) experiencing DRPs compared to males (38.64%).

Table 1: Demographic and clinical characteristics of patients with T2DM and hypertension (N=100).

Variable	Group/Category	Frequency (n)	Percentage (%)
Gender	Male	51	51
	Female	49	49
Age Distribution	30-40	5	5
	41-50	12	12
	51-60	21	21
	61-70	25	25
	71-80	28	28
	81-92	9	9
Age (Years)	Mean±SD	61.85±15.62	
Comorbidities	Hyperthyroidism	6	6
	Dyslipidemia	4	4
	CHF	3	3
	IHD	27	27
	CKD	16	16
	UTI	20	20
	LRTI	18	18
	Others	88	88
Department of Admission	General Medicine	60	60
	Cardiology	27	27
	Nephrology	7	7
	Orthopedic	3	3
	Surgery	3	3
Smoking Status	Smoker	23	23
	Non-smoker	15	15
	Not Mentioned	62	62
Alcoholic Status	Alcoholic	19	19
	Non-alcoholic	29	29
	Not Mentioned	62	62
Hba1c Levels	<5.9%	5	5

	6-6.5 %	7	7
	6.6-7%	12	12
	<7.1%	37	37
	Not Mentioned	39	39
Hba1c (%)	Mean±SD	8.14±2.50	
Diabetic Complications	Retinopathy	3	3
	Neuropathy	2	2
	Nephrology	4	4
	Foot ulcer	7	7
	No Complications	84	84
Blood Pressure Stages	Normal	14	14
	Prehypertension	19	19
	Stage 1 HTN	24	24
	Stage 2 HTN	36	36
	Hypertensive Crisis	7	7
Blood Pressure (mmHg)	Mean±SD	146.8±22.27	

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

Variable	Group/Category	Frequency (n)	Percentage (%)
No. of Drugs Prescribed for T2DM	Monotherapy	39	39
	Dual Therapy	34	34
	Triple Therapy	13	13
Type of Diabetic Medications	Only Oral	23	23
	Only Insulin	39	39
	Oral+Insulin	31	31
Monotherapy (Hypoglycemics)	Metformin	7	7
	Vildagliptin	4	4
	Linagliptin	5	5
	Actrapid	29	29
	Lantus	6	6
Dual Therapy (Hypoglycemics)	Vildagliptin+Metformin	11	11
	Glimepiride+Metformin	9	9
	Sitagliptin+Metformin	7	7
	Sitagliptin+Dapagliflozin	2	2
	Metformin+Actrapid	4	4
	Metformin+Lantus	2	2
	Actrapid+Lantus	8	8
Triple Therapy (Hypoglycemics)	Metformin+Voglibose+Glimepiride	5	5
	Glimepiride+Metformin+Vildagliptin	9	9
Classes of Antihypertensives	Calcium Channel Blocker	31	31
	Beta Blocker	37	37
	ACE Inhibitor	2	2
	ARB	14	14
	Diuretics	5	5
Different Antihypertensive Medications	Amlodipine	16	16
	Clinidipine	12	12
	Bisoprolol	18	18
	Carvedilol	5	5
	Atenolel	1	1
	Metoprolol	7	7
	Verapamil	1	1
	Enalapril	1	1
	Ramipril	8	8
	Telmisartan	11	11
	Losartan	2	2
	Furosemide	5	5
Combination Therapy for Antihypertensives	ARB+CCB	8	8
	ARB+Diuretics	3	3

	CCB+Beta Blocker	13	13
	Beta Blocker+ACE Inhibitor	4	4
	Diuretics+Beta Blocker	1	1
	Diuretics+CCB	2	2

Table 3: Summary of drug-related problems in T2DM and HTN patients (N=100).

Category	Subcategory	Frequency (n)	Percentage (%)
Helper-strand Classification	Drug Without Indication	2	2
	Improper Drug Selection	1	1
	Drug Interactions	15	15
	Overdose	1	1
	Adverse Drug Reaction	5	5
	Untreated Indication	18	18
	Others	39	39
PCNE Classification	Inappropriate Drugs (Contraindicated)	5	5
	Drug Without Indication	1	1
	Inappropriate Drug Combinations	7	7
	No or Incomplete Treatment Despite Indications	11	11
	Too Many Drugs for the Same Indication	1	1
	Inappropriate Drug Form	2	2
	Dosage Regimen Too Frequent	4	4
	Dose Timing Unclear/Wrong	3	3
	Wrong Drugs/Strength/Dosage Advised	3	3
	Inappropriate Timing of Administration	3	3

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

Variable	Category	DRPs (%)	Non-DRPs (%)
Age (Years)	30-50	50	50
	51-70	45.63	54.37
	71 Years and Above	39.34	60.66
Gender	Male	38.64	61.36
	Female	58	42
Smoking	Yes	63.33	36.67
	No	43.33	56.67
Alcohol Consumption	Yes	67.89	32.11
	No	44.48	55.52

DISCUSSION

This prospective observational study evaluated drug-related problems (DRPs) among patients with type 2 diabetes mellitus (T2DM) and coexisting hypertension, emphasizing demographic patterns, comorbid conditions, drug utilization, and risk factors contributing to DRPs. Our findings reinforce the complexity of managing polypharmacy in patients with multiple chronic conditions, in line with previous evidence indicating a high prevalence of DRPs among such populations. The mean age of our cohort was 61.85 ± 15.62 years, with the majority of patients aged between 61 and 80 years. This age group represents a vulnerable population prone to polypharmacy and pharmacokinetic alterations, predisposing them to adverse drug events and therapeutic inefficacies. A similar age distribution and its impact on polypharmacy have been reported in studies by Abukhalil et al. and Tigabu et al., where elderly patients with T2DM had a significantly higher risk of DRPs due to comorbidities and complex therapeutic regimens [14-15]. Our population had a near-equal gender distribution, yet DRPs were more frequently reported among females (58%) than males (38.64%). This observation aligns with findings from Wasilow-Mueller et al., who reported a higher incidence of DRPs in female patients, possibly due to differences in pharmacodynamics, healthcare-seeking behavior, and adherence patterns [16]. Cardiovascular comorbidities were highly prevalent, with ischemic heart disease (27%) and chronic kidney disease (16%) topping the list. These findings are consistent with other observational studies where IHD and CKD are dominant among patients with T2DM and hypertension, adding to the complexity of therapy management [17-18]. The co-occurrence of urinary and respiratory tract infections in 20% and 18% of patients, respectively, also reflects the immunocompromised state often observed in diabetic individuals. Glycemic control was suboptimal, with a mean HbA1c of 8.14 ± 2.50%. Only 5% of patients had HbA1c <5.9%, while a significant proportion (39%) lacked documented HbA1c values. This is concerning given the ADA-recommended target of <7% for most non-pregnant adults with T2DM [2]. Our findings are consistent with a multicenter study by Davies et al., where a significant proportion of patients failed to meet glycemic targets despite ongoing therapy,

partly attributed to therapeutic inertia and lack of patient follow-up [19]. The antihypertensive regimen was dominated by beta-blockers (37%) and calcium channel blockers (31%), followed by ARBs (14%). Notably, ACE inhibitors were underutilized (2%), which contrasts with guidelines recommending ACEIs or ARBs as first-line agents in diabetic hypertensive patients due to their renoprotective effects [20]. A similar discrepancy was reported in a study by Niriayo et al., indicating suboptimal adherence to hypertension management guidelines in diabetic populations [21]. In terms of antidiabetic regimens, insulin-only therapy was most prevalent (39%), followed by combined oral and insulin regimens (31%). The use of insulin in a substantial number of patients suggests advanced or poorly controlled diabetes, which corresponds with the elevated HbA1c levels. This aligns with findings by Abushanab et al., where insulin use was associated with higher rates of DRPs due to its narrow therapeutic index and administration complexity [22]. Drug-related problems were prevalent in our study, with "untreated indications" (18%), "drug interactions" (15%), and "adverse drug reactions" (5%) being the most common, according to the Helper-Strand classification. Similar patterns were reported by Viktil et al., where untreated indications and interactions were among the leading causes of DRPs in multimorbid patients [8]. The PCNE classification further revealed gaps in therapy, such as "no or incomplete treatment despite indication" (11%) and "inappropriate drug combinations" (7%). Notably, lifestyle factors played a significant role. Smokers and alcohol consumers had markedly higher rates of DRPs (63.33% and 67.89%, respectively), highlighting the need for behavior-modifying interventions as part of chronic disease management. These findings are supported by studies from Cano et al. and Leendertse et al., which demonstrated a strong correlation between unhealthy lifestyle practices and increased DRP incidence [23-24]. Interestingly, younger patients (30–50 years) showed a 50% DRP incidence, while the oldest age group (>70 years) had the lowest (39.34%), contradicting the usual trend of age-associated increase in DRPs. This could reflect closer monitoring of elderly patients or underreporting in this subgroup, as suggested by Hanlon et al. [25]. Overall, the high burden of DRPs observed in this study underscores the urgent need for interdisciplinary approaches, including pharmacist-led medication reviews, integration of clinical decision support systems, and improved documentation practices. Optimizing therapy for T2DM and hypertension demands individualized care, vigilant monitoring, and strict adherence to evidence-based guidelines.

Limitations of the Study: Like most hospital-based investigations, this study is subject to certain limitations. The findings may not be generalizable to broader national or global populations due to the limited sample size and single-center design. The relatively small number of enrolled patients, compared to similar research, may affect the statistical power and the strength of conclusions drawn. The short study duration also posed challenges in assessing long-term complications and mortality outcomes. Furthermore, incomplete documentation in some patient records—particularly regarding lifestyle factors such as smoking and alcohol use—could have introduced bias into the data analysis. The six-month timeframe restricted the evaluation of the sustained impact of medications and the effectiveness of interventions to reduce drug-related problems (DRPs). Additionally, the exclusion of pregnant individuals and patients with incomplete data may have led to the omission of significant subpopulations, potentially limiting the overall scope and representativeness of the results.

CONCLUSION

The study underscores the considerable prevalence of drug-related problems (DRPs) among patients with type 2 diabetes mellitus (T2DM) and hypertension (HTN), highlighting the influence of demographic factors such as age and gender, along with lifestyle behaviors. Key challenges identified include polypharmacy and the use of inappropriate drug combinations, underscoring the importance of individualized pharmacological management. These findings offer valuable guidance for healthcare providers in optimizing medication use and enhancing clinical outcomes. Further research is warranted to develop and assess targeted interventions aimed at reducing the incidence of DRPs in similar patient populations.

Declarations

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Conflict of interest: *None declared*
Ethical approval: *The study was approved by the Institutional Ethics Committee.*

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