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Impact of Drug Therapy Problems on the Management of Diabetes and Hypertension in Geriatric Patients at Sulaymaniyah City, Iraq

Hozan Jaza Hama Salh,[1] Tavga Ahmed Aziz,[2,*] Roshna Shawkat Aziz,[3] and Taha Othman Mahwi[4]

[1] *Department of Clinical Pharmacy, College of Pharmacy, University of Sulaimani, Sulaimani, Kurdistan Region, Iraq.*
[2] *Department of Pharmacology and Toxicology, College of Pharmacy, University of Sulaimani, Sulaimani, Kurdistan Region, Iraq.*
[3] *Department of Basic Medical Sciences, College of Medicine, University of Sulaimani, Sulaimani, Kurdistan Region, Iraq.*
[4] *Department of Clinical Sciences, College of Medicine, University of Sulaimani, Sulaimani, Kurdistan Region, Iraq.*

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ABSTRACT

Background: Drug therapy problems (DTPs) are related to many health outcomes, such as increased morbidity and mortality in geriatric diabetic patients with hypertension.
Objectives: To determine DTPs and the relationship between DTPs, blood pressure, and HbA1c control in elderly type 2 diabetic patients with hypertension.
Materials and methods: A cross-sectional study was carried out for two months at the Diabetes and Endocrine Center in Sulaimani City, Iraq. The participants were 96 elderly type 2 diabetes mellitus (T2DM) patients with hypertension who were taking at least one antidiabetic agent and at least one antihypertensive agent, and who were aged $\geq$ 65 years. Cipolle's method was used to categorize DTPs.
Results: Overall, 356 DTPs were observed among patients. Commonly recorded DTPs were non-compliance (41.85%) and adverse drug reactions (18.82%). A highly significant association between the number of DTPs and uncontrolled HbA1c was observed (P-value = 0.0001). However, there was no statistically significant relation between the number of DTPs and uncontrolled blood pressure (P-value = 0.059).
Conclusion: The prevalence of DTPs was high among elderly patients with T2DM and hypertension, and these DTPs were associated with poor HbA1c control. It is recommended that comprehensive pharmaceutical care service be implemented for all elderly T2DM patients with hypertension.
Keywords: Drug therapy problems; Elderly; HbA1c; Hypertension; Type 2 diabetes mellitus

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) ranks as one of the most prevalent metabolic conditions globally. Its onset is mainly due to a blend of two key causes: impaired insulin release by β-cells of the pancreas and the resistance of insulin-sensitive tissues to react to insulin [1]. The International Diabetes Federation (IDF) predicts that the number of people with diabetes will increase from 425 million individuals globally in 2017 to 629 million by 2045 [2].

Chronic hyperglycemia impairs the microcirculation, adversely affecting the performance of several organs and tissues and promoting long-term complications. These complications arise from micro- and macrovascular damage and primarily present as neuropathy, retinopathy, nephropathy, peripheral arterial disease, and coronary arterial disease [3, 4].

Hypertension (HTN) and diabetes mellitus are the most

* Corresponding author: E-mail: tavga.aziz@univsul.edu.iq

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common chronic medical disorders that often coincide [5]. The prevalence of HTN is twice as common when diabetes is present [5]. Both HTN and T2DM are risk factors for cardiovascular (CV) disease [5–8], stroke, and end-stage kidney disease [7]. The presence of HTN alongside T2DM results in a 7.2-fold surge in mortality risk [8]. Therefore, diabetes and HTN are considered to be unfavorable partners, making the control of blood pressure crucial for patients with diabetes who also have HTN [8].

Drug therapy is essential for treating chronic diseases such as HTN and T2DM, and it significantly enhances the quality of life for affected patients [9]. Drug therapy problems (DTPs) refer to situations or conditions related to drug therapy that are believed to adversely affect desired health outcomes [10]. DTPs can result from ineffective communication between healthcare providers; thus, enhanced collaboration between general practitioners and pharmacists is necessary to enhance pharmaceutical care [11]. In every stage of the treatment course, DTPs can happen, including prescribing, transcribing, dispensing, and administering medication. As a result, DTPs represent a significant concern in healthcare delivery, basically due to their link to longer hospital stays, higher costs, and an increased economic burden, along with a rise in morbidity and mortality that nearly doubles the risk of death [9].

T2DM patients often take various pharmacotherapeutic agents, which places them at an elevated risk of experiencing DTPs. These issues can negatively impact patient outcomes and may lead to increased healthcare costs [12]. In addition, nearly two-thirds of patients with T2DM and HTN were unable to reach their target levels of blood sugar and blood pressure, primarily because of the evolution of DTPs [13]. Elderly patients with T2DM experience a greater occurrence of DTPs, averaging four DTPs for each patient [14]. The geriatric population is particularly vulnerable to DTPs for several reasons. Firstly, physiological changes that occur with ageing can significantly impact the pharmacokinetic and pharmacodynamic properties of a drug. Secondly, many elderly patients have co-morbidities, which often lead to challenges in medication adherence and an increased risk of polypharmacy, where multiple medications are prescribed [14].

In Iraq, there have been several pharmaceutical studies done in patients with T2DM [15, 16]. However, there is no study regarding the prevalence of DTPs in elderly diabetic patients with HTN. Accordingly, the present study was undertaken to identify DTPs and the relation between DTPs, blood pressure control, and HbA1c control in elderly diabetic patients who are also hypertensive.

MATERIALS AND METHODS

A cross-sectional study involving individuals diagnosed with both T2DM and HTN was carried out from October to December 2024 at the Diabetes and Endocrine Center in Sulaimani City, Iraq. Informed consent has been obtained from each patient before being involved in the study. Approval of the study protocol was obtained by the Local Research Ethics Committee of the University of Sulaimani, College of Medicine, with registration number 22 on September 25, 2024.

The required sample size was calculated based on the formula for comparing two proportions:

$$N = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \times [p_1(1-p_1) + p_2(1-p_2)]}{(p_1 - p_2)^2}$$

where: $Z_{\alpha/2} = 1.96$ for a 95% confidence level, $Z_{\beta} = 0.84$ for 80% power, P1 = Expected proportion of uncontrolled HbA1c in patients without DTPs, P2 = Expected proportion of patients with DTPs.

Assuming P1 = 0.40 and P2 = 0.70, the calculated sample size was approximately 80 patients (40 per group). To improve precision and account for potential data loss, a total of 96 patients were recruited.

The inclusion criteria included patients who had been diagnosed with T2DM and HTN and were receiving at least one antidiabetic agent and at least one antihypertensive agent, and who were aged $\geq$ 65 years. Patients who were not willing to participate and those with psychiatric comorbidities were excluded. Each patient was interviewed by a clinical pharmacist to collect data face-to-face, including sociodemographic and clinical data (sex, duration of diabetes, duration of HTN, comorbidities, diabetic complications, and prescribed medications). A mercury sphygmomanometer was used to assess the patient's blood pressure before the collection of blood samples. Five milliliters of venous blood samples were obtained from each individual to measure HbA1c. HbA1c was determined by the Cobas c111, according to the method of turbidimetric inhibition immune assay. HTN is considered controlled based on the Eighth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC8) standards if the blood pressure of the patient is less than 150/90 in patients older than 60 years old [17]. Diabetes is considered controlled when HBA1c is below 7% according to the American Diabetes Association guidelines [18].

Cipolle's method of identification and classification was used to report and evaluate DTPs. DTPs are classified into 7 categories, which include the following: unnecessary drug therapy, necessity for additional drug therapy, ineffectual drug therapy, subtherapeutic dose, overdose, adverse drug reaction, and non-compliance [19]. The DTPs were identified based on reviewing patients' electronic medical and medication records, resulting from laboratory tests and interviewing patients regarding the medications they use. The first two categories were associated with the indication. The third and fourth categories are with effectiveness, the fifth and sixth categories are with safety, and the seventh with compliance. The JNC8 recommendation for HTN and the American Diabetes clinical guidelines for the treatment of T2DM were used to determine the appropriate and effectiveness of treatment. The safety of drugs was assessed by identifying specific information regarding medications, such as contraindications, drug interactions, undesirable effects, incorrect administration, and wrong dose [20]. During reporting, each frequency was recorded as the prevalence of specific causes of DTPs categories and then converted to a percentage.

Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences) for Windows version 22 (IBM Corp, Armonk, NY, USA). Continuous variables are expressed as mean ± standard deviation (SD), and discrete variables are expressed as numbers (N) and percentages (%). The Chi-square test/Fisher exact test, and the Mann-Whitney U test were used to compare qualitative variables and continuous data, respectively. P-value < 0.05 is considered a statistically significant difference.

RESULTS

A total of 96 patients participated throughout the data collection period. Table 1 shows that 65 (67.7%) of them were male (P-value = 0.001). More than half of the patients have lived with diabetes for more than 10 years (P-value = 0.0001). The majority of patients had comorbidities conditions other than HTN (P-value = 0.0001). The most common comorbidities, other than HTN, starting with the highest percentages to lowest, were dyslipidemia (P-value = 0.0001), ischemic heart disease (P-value = 0.0001), and stroke (P-value = 0.0001). Furthermore, most of the patients had developed diabetes complications (P-value = 0.0001). Only 31 patients had controlled HBA1c (P-value = 0.001). However, most patients had controlled HTN, with a mean value of 125 ± 12/75 ± 7 mm Hg (P-value = 0.0001).

Patients received an average of 5.59 ± 1.75 medications per patient. The most commonly received antidiabetics in monotherapy was metformin, and the most commonly prescribed antidiabetics in dual therapy, triple therapy, and quadruple therapy were metformin plus sulfonylurea, metformin + sulfonylurea + DPP4i, and metformin+ sulfonylurea + DPP4i + SGLT2i, respectively. Regarding HTN medications, more than half of the patients used antihypertensive in monotherapy. The angiotensin receptor blockers (ARBs) were the most frequently used drugs, followed by angiotensin-converting enzyme inhibitors (ACEIs). Furthermore, statins and aspirin were commonly prescribed drugs (Table 2).

A total of 356 DTPs were recorded in 94 patients, with a mean of 3.71 ± 2.0 DTPs per patient. Patients were classified as less than 3, 3-4, and more than 4 DTPs (Table 3).

The most commonly observed DTPs was non-compliance (41.85%). While, the least (1.69%) common DTPs were unnecessary drug therapy (Figure 1).

The results in Figure 2 indicate that the mean number of DTPs (4.2) in individuals with uncontrolled HbA1c was greater than in individuals with controlled HbA1c. Additionally, there was a significant association between the number of DTPs and uncontrolled HbA1c (P-value = 0.0001).

Table 4 demonstrates the exact causes of DTPs categories that significantly impact HbA1c control. Three causes of DTPs categories were significantly associated with poor HbA1c control, which included synergistic or potentiating (P-value = 0.004), condition refractory to drugs (P-value = 0.001), and drug interaction (P-value = 0.005).

The mean number of DTPs was higher in individuals with uncontrolled blood pressure (4.4) was greater than in individuals with controlled blood pressure (3.4). However, there was no statistically significant (P-value = 0.059) difference between the number of DTPs and uncontrolled blood pressure (Figure 3).

Table 5 displays exactly which causes in DTP categories significantly impact blood pressure control. Two causes of the DTP categories were significantly associated with poorly controlled blood pressure, which included synergistic or potentiating (P-value = 0.0001) and ineffective dose (P-value = 0.004).

Table 1. Demographic and clinical characteristics of elderly type 2 diabetic patients with hypertension (N= 96)[†].

Parameters	N (%)	P-value
Sex		
Male	65 (67.7%)	0.001
Female	31 (32.3%)	
Duration of diabetes		
< 5	9 (9.4%)	
5–10	28 (29.2%)	0.0001
> 10	59 (61.5%)	
Duration of hypertension		
< 5	11 (11.6%)	
5–10	34 (35.4%)	0.0001
> 10	51 (53.1%)	
History of comorbidities condition other than hypertension		
Yes	86 (88.7%)	0.0001
No	10 (10.3%)	
Ischemic heart disease		
Yes	26 (27.1%)	0.0001
No	70 (72.9%)	
Stroke		
Yes	15 (15.6%)	0.0001
No	81 (84.4%)	
Dyslipidemia		
Yes	75 (78.1%)	0.0001
No	21 (21.9%)	
Other diseases*		
Yes	31 (32.3%)	0.0001
No	65 (67.7%)	
Diabetic complication		
Yes	83 (85.6%)	0.0001
No	13 (13.4%)	
Control of blood sugar		
Controlled	31 (32.3%)	0.001
Uncontrolled	65 (67.7%)	
Control of hypertension		
Controlled	71 (74.0%)	0.0001
Uncontrolled	25 (26.0%)	
Parameters	Mean ± SD	P-value
HBA1c		
Controlled	6.4 ± 0.4	0.0001
Uncontrolled	8.8 ± 1.6	
Blood pressure (systolic/diastolic) mmHg		
Controlled	125±12/75±7	0.0001
Uncontrolled	156±7/88±7	

[†] N: number; *Asthma, osteoarthritis, renal failure, etc. SD = Standard deviation.

DISCUSSION

DTPs are considered serious, costly, and burdensome to the healthcare system. They commonly affect individuals with chronic illnesses, such as diabetes. If left unresolved, these problems can lead to significant clinical consequences [21]. The study revealed that the vast majority of patients (97.9%) had at least one or more DTPs, which is consistent with the findings of other studies [10, 22]. However, in this study, the prevalence of DTPs is greater than Kefale et al. (62.4%) [13] and Yimama et al. (80%) [23] studies. This difference could be due to the dissimilar study participants conducted among patients aged equal to or greater than 18 years old, while the current study targeted elderly patients aged equal to or greater than 65 years old. Additionally, the mean of DTPs per patient in the current study was 3.71 ±

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Table 2. Prescribing pattern of medications used by elderly type 2 diabetes mellitus (T2DM) patients with hypertension (HTN)[†].

Treatment	N (%)
T2DM medications	
Metformin	17(17.7%)
Sulfonylurea	1(1.0%)
DPP4i	1(1.0%)
Metformin + Sulfonylurea	20(20.8%)
Metformin + DPP4i	15(15.6%)
Metformin + insulin	6(6.3%)
Metformin+ SGLT2i	2(2.1%)
Metformin+ Sulfonylurea + DPP4i	15(15.6%)
Metformin+ Sulfonylurea + Insulin	1(1.0%)
Metformin + DPP4i + Insulin	9(9.4%)
Metformin + DPP4i + SGLT2i	1(1.0%)
Metformin+ Sulfonylurea + DPP4i + SGLT2i	4(4.2%)
Metformin+ Sulfonylurea + DPP4i + Insulin	3(3.1%)
Metformin+ Sulfonylurea + SGLT2i + Insulin	1(1.0%)
HTN medications	
ARBs	27(28.1%)
ACEIs	19(19.8%)
CCBs	8(8.3%)
B-blockers	3(3.1%)
Combined antihypertensive classes	39(40.6%)
Lipid-lowering agents	
Statins	69(71.9%)
Fibrates	2(2.1%)
Antiplatelet	
Aspirin	26(27.1%)
Clopidogrel	9(9.4%)
PPIs	
Omeprazole	16(16.7%)
Esomeprazole	4(4.2%)
Others	25 (26.04%)
Number of medications per patient	
Mean ± SD	5.59±1.75

[†] N: number; DPP4i: Dipeptidyl peptidase-4 inhibitors; SGLT2i: Sodium-glucose cotransporter 2 inhibitors; ARBs: Angiotensin receptor blockers; ACEIs: Angiotensin-converting enzyme inhibitors; CCBs: Calcium channel blockers; PPIs: Proton-pump inhibitors; SD = Standard deviation.

Table 3. Number of drug therapy problems (DTPs) in the patients[†].

Total number of reported DTPs	356
Number of DTPs per patient, mean ± SD	3.71±2.0
Total number of patients with DTPs, N (%)	94(97.9%)
Number of DTPs	N (%)
< 3 DTPs	27(28.7%)
3–4 DTPS	39(41.5%)
> 4 DTPs	30(31.9%)

[†] N: Number; SD = Standard deviation.

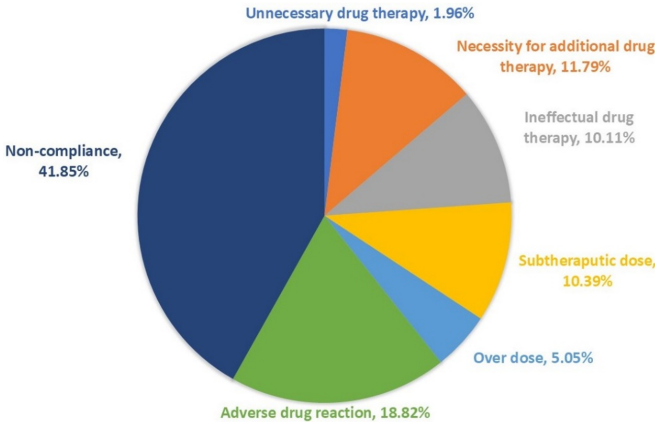

Figure 1. Categories of drug therapy problems identified among elderly diabetic patients with hypertension.

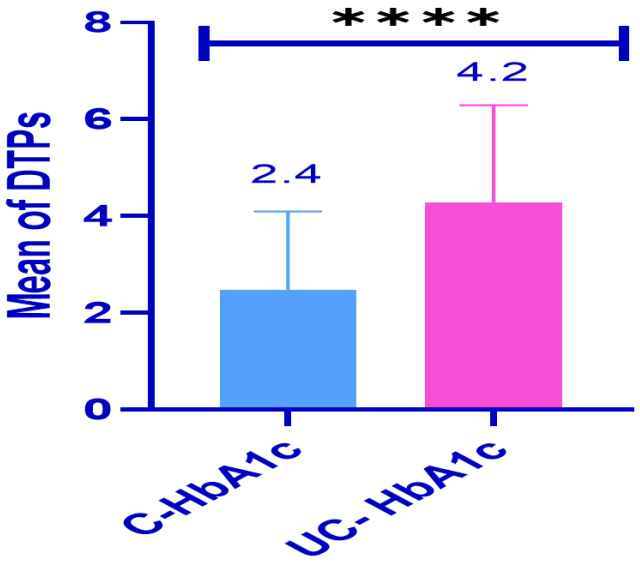

Figure 2. Mean differences of drug therapy problems among respondents with controlled HbA1c (C-HbA1c) and uncontrolled HbA1c (UC-HbA1c). P-value **** = 0.0001.

2.0 which is in line with the findings of a study by Sola KF et al. conducted among elderly nursing home residents [24]. However, it was higher than in previous studies [22, 23]. The discrepancy between our results with the product of the previous studies may be due to, dissimilarities in study sample size, participants' characteristics, and the DTPs classification used (Pharmaceutical Care Network of Europe (PCNE) criteria) in the later studies, and using high number of medications, by our patients which is the mean number of DTPs per patient was 5.59 ± 1.75. Polypharmacy, or the use of multiple pharmaceuticals, is frequently linked to toxicities associated with medications, adverse drug responses, and drug-drug interactions [13].

In the current study, the most frequently observed DTPs were noncompliance (41.85%) and adverse drug reactions (18.82%). These findings are consistent with those of Ogbonna et al., who also reported noncompliance and adverse drug reactions as the two most common types of DTPs [25].

Table 4. Causes of drug therapy problems categories according to controlled and uncontrolled HBA1c[†].

Drug therapy problem categories	HBA1c control		P-value
	Controlled (31)	Uncontrolled (65)	
Duplicate therapy (yes, N (%))	2 (6.5%)	5 (7.7%)	1.000
Prevention or prophylactic (yes, N (%))	4 (12.9%)	8 (12.3%)	1.000
Untreated condition (yes, N (%))	0	2 (3.1%)	1.000
Synergistic or potentiating (yes, N (%))	3 (9.7%)	25 (38.5%)	0.004
More effective drug available (yes, N (%))	6 (19.4%)	12 (18.5%)	1.000
Condition refractory to drugs (yes, N (%))	0	18 (18.8%)	0.001
Ineffective dose (yes, N (%))	3 (9.7%)	18 (18.8)	0.064
Frequency inappropriate (yes, N (%))	2 (2.1%)	10 (10.4%)	0.326
Drug interaction (yes, N (%))	0	4 (6.2%)	0.301
Undesirable effect (yes, N (%))	4 (12.9%)	12 (18.8%)	0.596
Unsafe drug for the patient (yes, N (%))	7 (22.6%)	19 (29.2%)	0.625
Drug interaction (yes, N (%))	2 (6.5%)	21 (32.3%)	0.005
Contraindication present (yes, N (%))	0	2 (3.1%)	1.000
Dose too high (yes, N (%))	6 (19.4%)	9 (14.1%)	0.555
Frequency too short (yes, N (%))	1 (3.2%)	0	0.323
Incorrect administration (yes, N (%))	0	2 (3.1%)	1.000
Does not understand instruction (yes, N (%))	3 (9.7%)	18 (27.7%)	0.064
Cannot afford drug product (yes, N (%))	10 (32.3%)	24 (36.9%)	0.820
Patient prefers not to take (yes, N (%))	10 (32.3%)	22 (33.8%)	1.000
Patient forgets to take (yes, N (%))	9 (29%)	30 (46.2%)	0.125
Drug product not available (yes, N (%))	2 (6.5%)	8 (12.3%)	0.492
Cannot swallow/ administer drug (yes, N (%))	3 (9.7%)	10 (15.4%)	0.538

[†] N: Number.

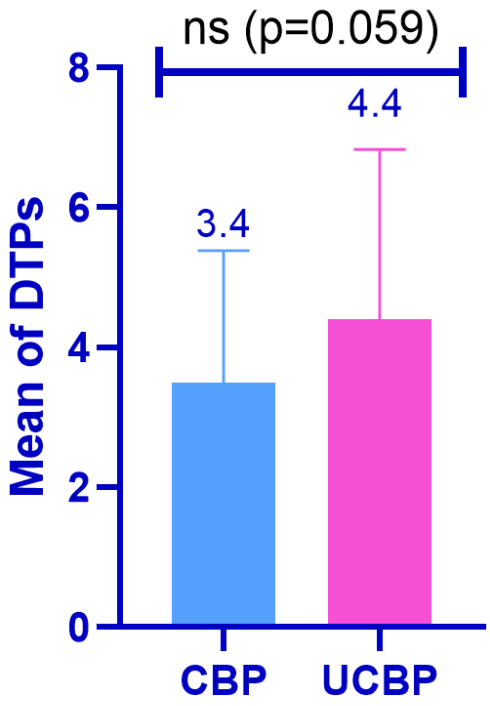

Figure 3. Mean differences of drug therapy problems among respondents with controlled blood pressure (CBP) and uncontrolled blood pressure (UCBP). P-value = 0.059).

However, an Ethiopian study reported that noncompliance and the necessity for added drug therapy were the most frequently identified DTPs [13]. Furthermore, the study by Sola et al. found that very low dosages and adverse drug reactions were the most frequent DTPs [24]. In addition, Eze et al. targeted elderly medical patients and observed that unnecessary DTPs and adverse drug reactions were the recurrently identified DTPs [26]. According to the findings of this study, the mean number of DTPs in patients who had uncontrolled HbA1c was (4.2) significantly higher compared to those with (2.4) controlled HbA1c. Furthermore, there was a significantly higher percentage of the reasons for DTPs, which included 38.5% needing synergistic or potentiating drugs, 18.8%) condition refractory to drugs, and 32.3% drug interaction, than controlled HbA1c. Currently, a study shows a significant association between inadequate dose and hyperglycaemia [27], and a significant association between non-adherence to anti-diabetic medication and uncontrolled blood glucose in T2DM patients has been reported [28].

The mean number of DTPs in patients with (4.4) uncontrolled blood pressure was higher than in patients (3.4) with controlled blood pressure, but the difference was not statistically significant. Although the study demonstrates a notable correlation between the number of DTPs and blood pressure control in individuals with HTN [29]. This variation may be attributed to the difference in study sample size and target blood pressure control in our study, which was less than 150/90 mm Hg for elderly patients. However, in previous studies was less than 140/90 mm Hg [29]. Our results showed that the percentage of reasons for DTPs, which included 64% needing synergistic or potentiating drugs and 44% ineffective doses, was significantly greater in individuals with uncontrolled blood pressure than controlled blood

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Table 5. Causes of drug therapy problems categories according to controlled and uncontrolled hypertension[†].

Drug therapy problems categories	Hypertension control		P-value
	Controlled (71)	Uncontrolled (25)	
Duplicate therapy (yes, N (%))	6 (8.5%)	1 (4.0%)	0.672
Prevention or prophylactic (yes, N (%))	9 (12.7%)	3 (12.0%)	1.000
Untreated condition (yes, N (%))	1 (1.4%)	1 (4.0 %)	0.455
Synergistic or potentiating (yes, N (%))	12 (16.9%)	16 (64.0%)	0.0001
More effective drug available (yes, N (%))	11 (15.5%)	7 (28.0%)	0.232
Condition refractory to drugs (yes, N (%))	12 (16.9%)	6 (24.0%)	0.552
Ineffective dose (yes, N (%))	10 (14.1%)	11 (44.0%)	0.004
Frequency inappropriate (yes, N (%))	10 (14.1%)	2(8%)	0.726
Drug interaction (yes, N (%))	2 (2.8%)	2 (8.0%)	0.277
Undesirable effect (yes, N (%))	13 (18.6%)	3 (12.0%)	0548
Unsafe drug for patient (yes, N (%))	19 (26.8%)	7 (28.0%)	1.000
Drug interaction (yes, N (%))	17 (23.9%)	6 (24%)	1.000
Contraindication present (yes, N (%))	1 (1.4%)	1 (4.0%)	0.455
Dose too high (yes, N (%))	13 (18.3%)	2 (8.3%)	0.341
Frequency too short (yes, N (%))	1 (1.4%)	0	1.000
Incorrect administration (yes, N (%))	2 (2.8%)	0	1.000
Does not understand instruction (yes, N (%))	13 (18.3%)	8 (32.0%)	0.169
Cannot afford drug product (yes, N (%))	25 (35.2%)	9 (36.0%)	1.000
Patient prefers not to take (yes, N (%))	22 (31.0%)	10 (40.0%)	0.463
Patient forgets to take (yes, N (%))	28 (39.4%)	11 (44.0%)	0.813
Drug product not available (yes, N (%))	6 (8.5%)	4 (16%)	0.281
Cannot swallow/ administer drug (yes, N (%))	9 (12.7%)	4 (16%)	0.737

[†] N: Number.

pressure. DTPs are an essential issue in the management of chronic diseases such as diabetes and HTN, particularly in elderly patients, which leads to poor control of HbA1c and blood pressure. Pharmacists have an important role in identifying DTPs and improving therapy. Interventional studies showed that patients receiving pharmaceutical care intervention significantly reduced HbA1c [15, 16]. Furthermore, the study by De Souza et al. demonstrated that blood pressure was significantly reduced in patients who received pharmaceutical care [30].

The limitations of this study include its single-center design, which may limit the generalizability of the findings to the broader population. Additionally, as a cross-sectional study conducted over a short period, it did not assess the impact of individual DTPs on medical costs. Furthermore, the study did not provide specific recommendations for addressing the identified DTPs. Therefore, further studies are recommended to evaluate the impact of pharmacist interventions on the outcomes of DTPs in elderly patients with T2DM and HTN.

CONCLUSION

The prevalence of DTPs among elderly patients with T2DM and HTN is high. These DTPs were associated with poor glycemic control, as indicated by elevated HbA1c levels. Effective integration and collaboration among healthcare professionals, particularly physicians and pharmacists, are essential to reduce the occurrence of DTPs and enhance pharmaceutical care services. Such efforts are crucial to achieving optimal therapeutic outcomes in this patient population.

ETHICAL DECLARATIONS

Acknowledgments

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Ethics Approval and Consent to Participate

Approval of the study protocol was obtained by the Local Research Ethics Committee of the University of Sulaimani, College of Medicine, with registration number 22 on September 25, 2024. This study complies with the Declaration of Helsinki. Informed consent was obtained from all participants before participation in the study.

Consent for Publication

Not applicable. This manuscript does not contain any person's data in any form (including individual details, images, or videos).

Availability of Data and Material

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Competing Interests

The authors declare that there is no conflict of interest.

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Authors' Contributions

Salh HJH collected the data and wrote a manuscript. Aziz TA and Mahwi developed the research design and analysed the data. Aziz RS analysed the data and completed the final version. All the authors reviewed and confirmed the final version of the manuscript.

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