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Original Research

Pharmacist interventions in the management of drug-related problems among renal dialysis patients: A cross-sectional observational study

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INTRODUCTION

Chronic kidney disease (CKD) is a global health problem with an increasing worldwide prevalence and burden in the 21st century. It has been associated with high risks of morbidity, mortality, and poor quality of life (QoL).[1] Renal replacement therapy (RRT) refers to treatment methods used to replace the normal kidney's waste-filtering function and includes hemodialysis (HD), peritoneal dialysis (PD), and Kidney transplants from living and deceased donors. In 2020, a total of 28,769 patients were on RRT, with 19,715 patients on hemodialysis, 1,781 on peritoneal dialysis, and 7,273 patients undergoing follow-up after kidney transplantation in Saudi Arabia (KSA). The combined prevalence of patients on dialysis in KSA was estimated at 621 per million population.[2]

Patients with CKD and end-stage renal disease (ESRD) often suffer from comorbidities and complications such as hypertension, diabetes mellitus, fluid overload, infection, anemia, and hyperphosphatemia that can negatively impact the patient's QoL if not treated appropriately.[1] The confluence of CKD and comorbidity leads to multiple medication use, which increases overall health costs, drug-related problems (DRPs), and hospital length of stay, affects clinical outcomes, and reduces patient QoL.[3] Polypharmacy, the concomitant use of five or more medications, is a common and significant problem among HD patients.[4] On average, 10 to 12 medications were prescribed per day for HD patients.[5,6] because there are some drugs to continue during dialysis such as antibiotics to treat patients with sepsis, anticoagulants, antihyperglycemics, immunosuppressants, and analgesics.[6]

The pharmacokinetics of many drugs are altered in patients with renal failure receiving continuous renal replacement therapy (RRT).[7] In general, RRT enhances drug clearance, but the magnitude of drug removal is affected by the modality used and its frequency, drug's physicochemical properties, and timing of drug administration.[7] Therefore, designing rational dosage regimens which optimize therapeutic outcomes is challenging and continuous drug monitoring is crucial for appropriate dosage titration.[8]

DRP is defined as "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes", according to the Pharmaceutical Care Network Europe Classification for Drug-Related Problems V9.1.[9] The PCNE categorized the main causes of DRPs into inappropriate drug selection, inappropriate doses, and patient-related causes. Drug-related problems in CKD and renal dialysis patients, such as inappropriate drug selection, indications without treatment, and drug-drug interactions, have been frequently reported.[10,11]quantitative evidence comparing the effect of performing multidimensional interventions is scarce. The present paper reviews data from previous randomized controlled trials (RCTs The incidence of DRPs is usually increased in patients receiving multiple drugs, patients with poor medication adherence.[12] and patients with comorbidities such as cardiovascular therapy, antithrombotics, and drugs for peptic ulcers.[13] Therefore, the role of pharmacists to lower the risk of DRPs and improve health outcomes is unique.

Pharmacists are well-trained to identify DRPs, prioritize high-risk patients for medication management through a structured medication review and communication with physicians to

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propose therapeutic alternatives.[14] Several decades ago, pharmacist-led interventions in detecting DRPs and improving medication safety among renal disease patients were proposed at the physician, drug, and patient levels.[10,15] These interventions have been associated with reduced patient harm, shortened length of hospitalization, and improved clinical outcomes.[16] Therefore, pharmacy interventions are highly significant in all chronic illnesses, particularly in critically-ill hospitalized patients who are more vulnerable to drug-related complications.[17]

Rational and evidence-based prescribing is essential to ensure safe, effective, and economic use of medications and adherence to therapy. Pharmacist-physician collaboration is vital to minimize DRPs, improve patient's QoL and clinical outcomes of drug therapy. No data about DRPs and pharmacists' interventions in therapeutic monitoring of patients receiving RRT are available in Tabuk region. Therefore, the primary aim of this study was to quantify the pharmacists' interventions in detecting and managing drug-related problems in renal dialysis patients at a tertiary care hospital in Tabuk city. The study aimed also to identify and characterize types, frequencies, and factors associated with drug-related problems in these patients.

METHODS

Study Design and Site

This study was a prospective observational documentation of pharmacists' interventions in reviewing the medical records, identifying and managing DRPs for patients receiving renal dialysis. The Institutional Review Board, Health Affairs at Tabuk approved this study (reference number TU-077/023/183, Jan 31, 2023). Because the data collection involved the patient's medical records and medication charts with no further therapeutic or diagnostic interventions, informed consent from participants was not necessary. We obtained a waiver of consent because of no determined risk.

The study was conducted over four months between February and May 2023 at a tertiary care hospital belonging to the Ministry of Health in Tabuk city, Saudi Arabia.

The renal dialysis unit within the Nephrology Department consisted of 23 chairs for both men and women. The medication orders were provided through a comprehensive computerized physician order entry and unit dose distribution system. The routine pharmaceutical care activities provided by pharmacists in the renal dialysis unit included medication reconciliation, therapeutic drug monitoring service, medication safety services, drug educational services and lifestyle modification recommendations.

Study Population and Data Collection

All adult patients diagnosed with ESRD and receiving dialysis in the renal dialysis unit were included. The sample size was estimated using the Raosoft Sample Size Calculator (http://www.raosoft.com/samplesize.html) based on a margin of error of 5%, a confidence level of 95%, a population size of Tabuk province 886,036 according to the General Authority for statistics, and a prevalence of renal replacement therapy of 621 per million populations [2]. The calculated sample size was 384. This study included all accessible patients in the dialysis unit who fulfilled the inclusion criteria.

This study documented the daily routine practice of pharmacists while providing patient care. Two pharmacists who had experience of five years in dialysis unit and three pharmacy interns (authors) carefully reviewed patients' medication records and relevant clinical data. They extracted patient demographic data, comorbid diseases, laboratory investigations, past medication history, all newly prescribed medications during the dialysis, and discharge medications.

The pharmacists assessed patients' drug charts and identified any potential prescribing, administration, and monitoring DRPs using the Pharmaceutical Care Network Europe Association.[9] This updated form classifies the types and possible causes of DRPs and the types of proposed interventions or recommendations to manage the identified DRPs. The pharmacists proposed their therapy recommendations for each potential drug problem to the physicians. The outcomes of this study were the frequency of DRPs in renal dialysis patients and the number of pharmacists' interventions provided to resolve the encountered DRPs. A panel of a consultant nephrologist, two academic pharmacy practice professors (authors), two working pharmacists at the Department of Nephrology, and three pharmacy interns reviewed the identified DRPs using daily online messages and regular weekly meetings.

The severity of the DRPs' consequences was rated using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index[18] for classifying medication errors. In this study, the severity of DRPs was divided into four main categories; (1) MEs resulted in "no harm" to patients (subcategories B and C); (2) MEs resulted in "temporary harm" to patients (subcategories D, E and F); (3) MEs resulted in "permanent harm" to patients (subcategories G and H); and (4) MEs resulted in "patient's death" (sub-category I). For each identified DRP, the panel discussed the severity outcome given by the working pharmacists and assigned a consistent decision based on the potential or actual degree of clinical harm to the patients.

Statistical Analyses

All the statistical analyses were performed using the SPSS version 22 (SPSS Inc., Chicago, IL, USA). The significance level was set at a p-value <0.05.

Standard descriptive analysis was executed and reported for patients' demographics, disease-related baseline characteristics (such as age, sex, years of dialysis, comorbid diseases, number of prescribed drugs, and laboratory investigations) and causes of DRPs.

Categorical variables were reported as frequencies and percentages, while continuous variables were reported as mean and standard deviation (SD). Multivariate binary regression analysis was used to predict potential factors associated with the occurrence of the DRPs. Post estimation Hosmer-

Lemeshow and Pearson Chi square tests were performed to check the model goodness of fit.

RESULTS

Participants' Baseline Characteristics

A total of 124 Saudi adult patients received RRT at the renal dialysis unit during the study period, of whom 62 (50%) were males and 78 (63%) were above 40 years of age (Table 1). Most patients received HD (97, 78.2%) and 53 (42.7%) started dialysis for 5-9 years. The most frequently reported comorbidity among patients was hypertension (91, 73.3%) followed by diabetes (20, 16.1%).

The pharmacists reviewed a total of 733 medication orders for the admitted patients. The median number of prescribed medications per patient was six (range 3-11 drugs), with 95 (76.6%) patients were prescribed five or more drugs. The top prescribed drugs were folic acid, calcium carbonate, proton pump inhibitors (PPIs) and antihypertensive drugs (Figure 1).

Drug related problems

During the daily routine work, pharmacists detected 72 potential DRPs for 60 patients, and all DRPs were reviewed and analyzed by the authors, yielding a medication error rate of 9.8% (Table 2). According to the PCNE Classification V9.1, the main causes of DRPs were related to the selection of drugs (19, 27.1%), such as no or incomplete drug treatment for certain indications that required the initiation of drug therapy. The common conditions with no prescribed treatments were high cholesterol, triglyceride levels, and hypocalcemia. Another drug-selection problem was inappropriate drug combinations, such as co-prescribing of clopidogrel and omeprazole or unnecessary duplication of antihypertensive drugs (nifedipine, amlodipine, and ARBs). Some drugs, such as hydralazine and cinacalcet, were found with no more valid indications. A similar proportion of DRPs were related to dose selection (19, 27.1%), particularly lower prescribed drug doses (12, 17.1%) to produce the desired responses which resulted in high serum phosphorus and low calcium levels. Patients' nonadherence to the prescribed drug regimens, notably the underuse of drugs (24.3%), was among the patient-related causes of DRPs. The nonadherence behavior was related to either patient/caregivers misunderstanding the physician's instructions, patient-reported frustration/disbelief about the drug effect, or the complex drug regimen (polypharmacy).

Pharmacist Interventions and Severity of DRPs

The pharmacists proposed a total of 92 interventions to manage the identified DRPs before causing severe patient harm (Table 2). Drug-related interventions were the common pharmacist interventions (64, 69.6%), such as consulting the prescribers for dosage adjustments (19.6%), stopping drugs with no more valid indications (13%), and starting new drugs (10.9%) for undertreated conditions. Many drug-related patient counseling sessions were provided to alleviate the negative patient behavior toward drug administration or clarify the written physician instructions.

Figure 2 illustrates the severity of the observed DRPs that was determined using the NCC MERP Index for Categorizing Medication Errors. Some DRPs caused no patient harm (categories A, B, and C) because the errors were observed and corrected either before patients administered the drugs or errors reached the patients and caused no clinical harm. About one-half (34, 49%) of DRPs occurred and caused temporary patient harm (categories E and F). Examples of the DRPs' severity and the proposed pharmacists' interventions to solve it are described in Table 3. The physicians accepted 87% of the pharmacists' interventions.

Table 1. Patients baseline demographic and clinical characteristics

Item	Number of patients n= 124 (%)
Gender	
Male	62 (50)
Female	62 (50)
Age (years)	
18-25	11 (8.9)
26-40	35 (28.2)
41-60	47 (37.9)
61-75	31 (7.5)
Type of dialysis	
Haemodialysis	97 (78.2)
Peritoneal dialysis	27 (21.8)
Duration of dialysis (years)	
1-4	39 (31.5)
5-9	53 (42.7)
10-14	32 (25.8)

Comorbidities	
Hypertension	91(73.3)
Diabetes mellitus	20 (16.1)
Ischemic heart diseases (IHD)	11 (8.9)
Epilepsy	2 (1.6)
Polypharmacy	
< 5 dugs	29 (23.4)
≥ 5 drugs	95 (76.6)
Laboratory investigations (serum)	**Mean (SD)**
Creatinine (µmol/L)	755.2 (313.8)
Blood glucose (mmol/L)	7.3 (4.3)
AST (U/L)	16.9 (9.9)
ALT (U/L)	18.9 (17.9)
Alkaline phosphatase	192.7 (161)
Albumin (g/dl)	32.5 (9.6)
Bilirubin (µmol/L)	6.6 (3.9)
Protein urea (g/L)	22.4 (15.3)
Uric acid (µmol/L)	344.3 (94.9)
Cholesterol (mmol/L	4.2 (3.2)
TG (mmol/L)	2.1 (0.4)
Calcium (mmol/L)	2.1 (0.26)
Phosphorus (mmol/L)	1.6 (0.68)
Potassium (mmol/L)	4.5 (0.84)

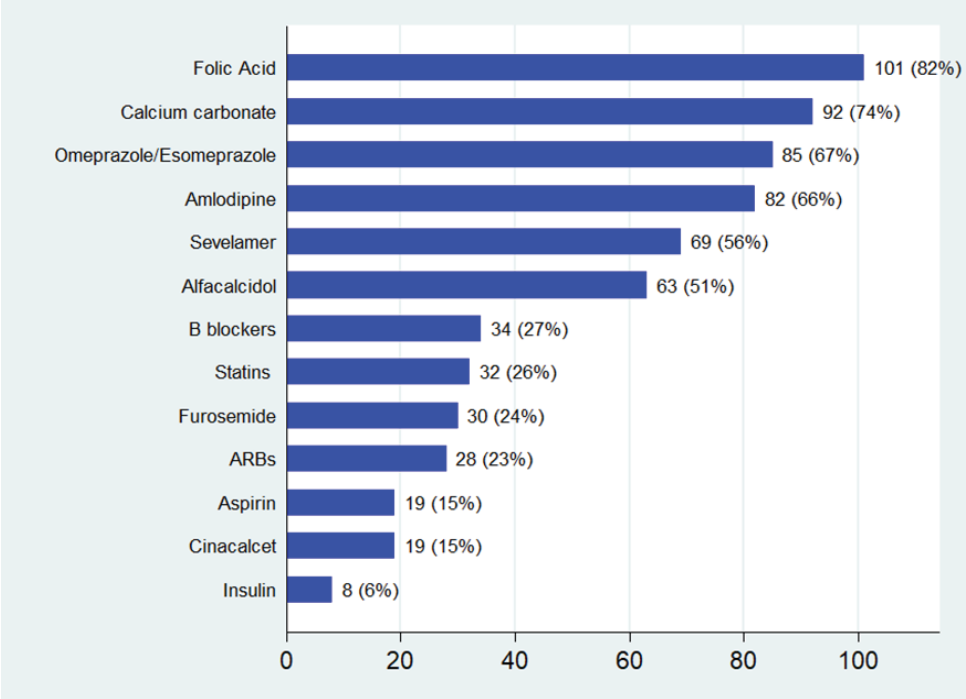

Figure 1. Frequency and percentages of top prescribed medications to renal dialysis patients

Table 2. Causes of observed drug-related problems and the proposed pharmacist interventions according to the PCNE Classification ver. 9.1

Causes of DRP	**PCNE Code**	**Descriptions**	**n=72 (%)**
Drug selection	C1.1	Inappropriate drug according to guidelines/formulary	3 (4.3)
	C1.2	No indication for drug	5 (7.1)
	C1.3	Inappropriate combination of drugs	4 (5.7)
	C1.4	Inappropriate duplication of therapeutic group	2 (1.4)
	C1.5	No or incomplete drug treatment	6 (8.6)
Dose selection	C3.1	Drug dose too low	12 (17.1)
	C3.2	Drug dose of a single active ingredient too high	2 (2.9)
	C3.3	Dosage regimen not frequent enough	1 (1.4)
	C3.4	Dosage regimen too frequent	3 (4.3)
	C3.5	Dose timing instructions wrong	1 (1.4)
Patient related	C7.1	Patient intentionally uses/takes less drug than prescribed	17 (24.3)
	C7.2	Patient uses/takes more drug than prescribed	1 (1.4)
	C7.5	Patient takes food that interacts	2 (2.9)
Other	C9.1	No or inappropriate outcome monitoring	9 (12.9)
		Adverse effects from drugs	3 (4.3)
Pharmacist intervention	**PCNE Code**	**Descriptions**	**N=92 (%)**
At prescriber level	11.1	Prescriber informed only	30 (32.6)
	11.2	Prescriber asked for information	9 (9.8)
	11.3	Intervention proposed to prescriber	40 (43.5)
	11.4	Intervention discussed with prescriber	13 (14.1)
At patient level	12.1	Patient (drug) counselling	23 (25)
	12.3	Patient referred to prescriber	2 (2.2)
	12.4	Spoken to family member/caregiver	3 (3.3)
At drug level	13.1	Drug changed	7 (7.6)
	13.2	Dosage changed	18 (19.6)
	13.3	Instructions for use changed	8 (8.7)
	13.4	Drug paused or stopped	12 (13)
	13.5	Drug started	10 (10.9)
Other intervention	14.1	Drug monitoring	9 (9.8)
Acceptance of the intervention			
	A1	Intervention accepted	80 (87)
	A2	Intervention not accepted	12 (13)
Status of the DRP	O0.1	Problem status unknown	2 (2.8)
	O1.1	Problem totally solved	49 (68.1)
	O2.1	Problem partially solved	18 (25)
	O3.1	Problem not solved, lack of cooperation of patient	3 (4.2)

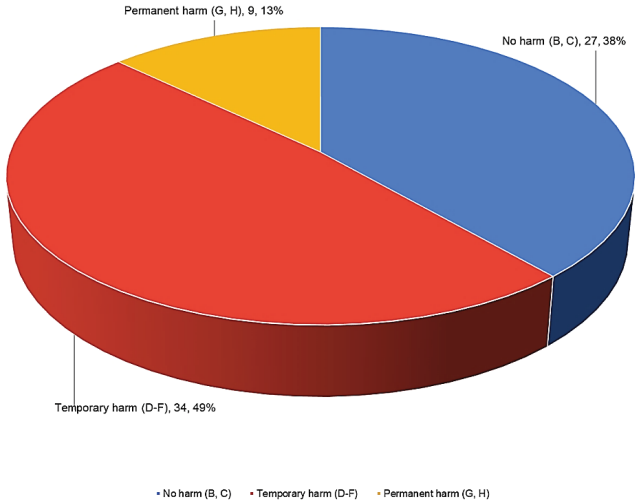

Figure 2. The severity of the observed drug-related problems according to the NCC-MERP-Index

Table 3. Examples of DRPs and the proposed pharmacist interventions		
Severity of DRPs	Examples	Proposed pharmacist interventions
No harm		
Category C and D	Slight elevation of K^{+} and P^{++}	Monitor electrolyte level and counsel patient to avoid K^{+} rich foods
	Drug interaction between clopidogrel and omeprazole	Change omeprazole with pantoprazole
Temporary harm		
Category E	Hypotension due to too frequency of amlodipine BID	Lower the daily frequency to once daily
	High serum phosphorus level due to lower prescribed doses of sevelamer	Increase the prescribed daily doses of sevelamer
	Low serum Ca^{++} level	Start calcium supplements
	High serum cholesterol and TG level	Increase atorvastatin dose and life-style counseling
	High blood pressure due to nonadherence to drugs	Counsel patient about the importance of drug adherence
	Adverse effect occurred from cinacalcet	The drug was changed to IV zimplar
	Gastric upset due to underuse of PPI	Counsel patient about the proper use of PPI
	Constipation due to calcium carbonate	Add lactulose to the drug regimen
Severe harm		
Category F	Diabetic foot due to nonadherence to insulin	Refer to physician and counsel patient about the correct insulin regimen
Category H	Patients admitted to the emergency department because of arrhythmia	Monitor K+ level and counsel patient to adhere to drug therapy
	Hypoglycemia due to insulin	The patient was referred to physician to correct insulin dose
	Epitaxies because of aspirin	Stop or lower aspirin doses

Factors associated with DRPs

Multivariate logistic regression analysis revealed that none of the tested factors was identified as a predictor of the incidence of DRPs (Table 4). Age above 40 years had an odds ratio of 1.36 and polypharmacy and comorbid hypertension disease had an odds ratio of 1.3; however, they were not statistically significant at p = 0.05.

Table 4. Multivariate regression analysis of potential factors associated with the incidence of DRPs in renal dialysis patients		
Variable (reference)	Odds ratio (95% CI)	P value
age (age<40 years)	1.36 (0.61 - 3.04)	0.450
Sex (female)	0.77 (0.36 -1.64)	0.492
Polypharmacy (<5 drugs)	1.29 (0.52 -3.24)	0.583
Years of dialysis (1-4 years)	2.36 (0.81 - 6.97)	0.117
Hypertension (none)	1.32 (0.54 -3.21)	0.536

p values of Hosmer-Lemeshow test = 0.899 and Pearson Chi-square test=0.060

DISCUSSION

This study revealed that polypharmacy and DRPs were common in patients with ESRD receiving renal dialysis and the pharmacist-led interventions helped to resolve many DRPs and reduce the risk of patient harm. Many of the study population (63%) were above 40 years old because the prevalence of chronic kidney disease and ESRD increases with age.[19] Our finding showed that most patients (73%) had hypertension as a comorbidity, followed by diabetes mellitus. Uncontrolled hypertension and diabetes mellitus are among the leading causes of CKD, together accounting for >70% of ESRD.[20,21] Previous studies evaluating DRPs reported frequent comorbidities such as hypertension and diabetes in patients with CKD and renal dialysis.[6,11,22].

Polypharmacy was highly prevalent among patients in this study (76.6%), with a varied number of prescribed drugs for individual patients (3–11 drugs) because of the associated complications of renal failure such as secondary hyperparathyroidism, hyperphosphatemia, hypocalcemia, anemia, and infection. Some patients were also admitted to the dialysis unit with chronic comorbidities that required additional drug therapy, such as hypertension and diabetes. The polypharmacy finding in this study was consistent with previous studies on CKD and HD patients, which reported a prevalence of polypharmacy ranging from 89.2% up to 97.2%.[5,6,11,22] Polypharmacy has been associated with several DRPs, such as drug-drug interactions and adverse drug reactions, and it may increase the risk of morbidity and mortality and patients' quality of life in hemodialysis patients.[23]

In this study, we observed an overall 72 DRPs with an error percentage of 9.8 % out of all prescribed medication orders. This percentage is lower than a previously reported prevalence of DRPs in HD studies. Daifi et al., documented 1,403 DRPs in 157 HD patients, with an average of 8.96 DRPs per patient.[12] Alshamrani et al. documented 280 DRPs for 83 HD patients who were prescribed a mean of 14 (SD 4.6) with an error rate of about 23%.[6] Garedow *et al*., identified a rate of 30.95% DPRs out of all medication orders in CKD patients [24]. A pooled analysis of seven studies calculated 1,593 DRPs in 395 HD patients.[25] This study's lower percentage of DRPs may be explained by the lower median number of prescribed medications (6 drugs) per patient.

In this study, the most commonly identified DRPs were related to drug selection (27%), followed by inappropriately prescribed doses (27%). Generally, the causes of DRPs in previous studies were related to seven types of DRPs, including unnecessary drug therapy; incomplete or omitted drug therapy, subtherapeutic doses, drug-drug interactions, adverse drug reactions (ADRs), overdosing, and nonadherence with varied proportions depending on the study population, country, and the received care. For example, Peri et al. 2022 found that inappropriate combination of drugs was the most commonly (37%) experienced cause of DRPs.[26] Medication nonadherence was the most common medication-related problem (31%) reported by Daifi et al.[12] Drug interactions were the most frequently reported DRPs (59.94%), followed by improper frequency (11.57%) and indication without drug (11.28%) in a study conducted by Subeesh et al.[11]reported, and categorized as per the Pharmaceutical Care Network Europe classification V 5.01. The association between categorical variables was analyzed using the Chi-square test. The predictors of DRPs were identified using binary logistic regression analysis. Results: The mean age of the study population was 50.08 ± 15.32 years with male predominance (71% Alshamrani et al. found that drug use without indication was the most frequently identified (36%) DRP, followed by subtherapeutic dosing (23%), and overdosing (15%).[6]

None of the examined factors was a potential determinant of the increased likelihood of DRPs. This is because most of our study population had multiple drugs (polypharmacy) and hypertension and the length of dialysis did affect the complex drug therapy regimen for the existing comorbidities. Previous studies suggested some underlying risk factors, such as polypharmacy, number of comorbidities, and length of hospital stay, were significant predictors associated with increased DRPs.[6, 22] These risk factors may apply to the care of admitted patients because of the severity of the disease and the complex drug regimen.

In this study, the pharmacists suggested 92 interventions for the reviewed and identified DRPs, such as patient drug counseling, and the physicians accepted 87% of the proposed interventions. Generally, more than 75% of pharmacists' interventions and therapy recommendations were accepted by physicians in previous studies. Patient counseling and education about drugs and nutrition were particularly important interventions for our study population because many patients were frustrated and had negative attitudes toward drug efficacy. Therefore, they suffered from multiple disease complications, such as uncontrolled hypertension, hypocalcemia or hyperphosphatemia. A recent meta-analysis reported that optimum adherence to the prescribed drugs in patients with renal failure remains a changeling practice despite educational interventions delivered by pharmacists about goals of therapy, lifestyle changes, and nutrition.[10] However, the author concluded from subgroup analyses of 33 studies that pharmacist-led interventions improved some healthcare outcomes, such as uncontrolled blood pressure, risk of cardiovascular diseases and renal complications, and medication adherence behavior, in both ESRD patients receiving hemodialysis and predialysis patients.[10] The underlying causes of medication nonadherence are multifactorial and include, but are not limited to illiteracy, misunderstanding of treatment instructions, complexity of medication regimen, cost, fear of treatment failures, adverse drug reactions, health condition severity, and poor communication with healthcare providers.[27]

The pharmacotherapy of renal dialysis patients is complex and highly variable. Therefore, pharmacist-led medication reviews and frequent drug monitoring are crucial to ensure optimal pharmacotherapy, lower the risk of polypharmacy, adverse drug reactions, and control of comorbidities and other disease complications. There is a growing global prevalence of kidney failure patients and the economic burden of dialysis

is significant, especially in low-income and middle-income countries. Inappropriate pharmacotherapy may increase the burden of dialysis because it leads to negative health outcomes. Multicenter studies are warranted to emphasize the substantial role of pharmacists in providing patient-centered pharmaceutical care and saving the cost of therapeutic failures.

Strengths and weaknesses

This study emphasized the substantial role of pharmacist intervention to manage DRPs in renal dialysis patients in Tabuk City. The study was cross-sectional in design and conducted over a short duration of time in a single healthcare center which may affect the drawn conclusion about routine and long-term pharmacist intervention in other healthcare settings. Residual bias is possible because pharmacists and pharmacy interns carried out the study, and there was no control group to compare the pharmacist care because pharmacists routinely examined the medication records of all patients. Therefore, a panel of experts addressed the severity and clinical outcomes assigned by the pharmacists. In this context, this study did not include objective measurement of the impact of pharmacist-led interventions in improving clinical outcomes, drug adherence, or patient quality of life. However, all drug-related interventions for the identified DRPs were proposed in situ to the treating physicians, and the majority were approved and implemented. Fewer potential determinants of factors affecting the occurrence of DRPs were examined, which did not allow causal relationships to be determined.

CONCLUSIONS

The current study demonstrated that polypharmacy and DRPs were common in renal dialysis patients. One-half of the DRPs were of moderate severity. The results suggested that pharmacists' medication review and drug counseling interventions could have positive effects, feasibly preventing the severity of DRPs and improving health outcomes and patient's adherence to their drug and dietary regimens.

AUTHOR CONTRIBUTIONS

Conceptualization, M.A.; methodology, M.A., R.A., A.L., M.K, K.A; software, R.A.; validation, M.A., H.A., and R.A; formal analysis, M.A.; investigation, R.A., A.L., M.K, K.A; resources, R.A.; data curation, R.A., M.A.; writing—original draft preparation, M.A.; writing—review and editing, H.A.; visualization, M.A., H.A.; supervision, M.A.

All authors have read and agreed to the published version of the manuscript.

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CONFLICTS OF INTEREST: The authors declare there is no conflict of interest

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