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Evaluation of clinical pharmacist interventions on drug-related problems in the gastroenterology ward

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ABSTRACT: Integrating clinical pharmacists in a multidisciplinary patient care team improves the treatment process by identifying and resolving drug-related problems (DRPs). The aim of the study was to determine the effect of clinical pharmacist intervention for DRPs in the gastroenterology service. The first period of the study was conducted between 15.06.2018 and 15.02.2019. Eighty patients admitted to the gastroenterology ward, who used at least one medication, were included in 'the study group'. The clinical pharmacist participated in ward rounds and made interventions to solve identified DRPs. In the second period of the study, the control group consisted of 80 patients admitted to the same ward between 01.03.2019 and 06.06.2019. DRPs were determined only from the data obtained from the hospital system in the control group. DRPs were classified according to the European Pharmaceutical Care Network (PCNE V9.1). A total of 136 and 46 with an average of 1.7 and 0.57 DRPs per patient ($p \leq 0.01$) were identified in the study and control groups, respectively. Of the DRPs in the study group, 59 were related to treatment effectiveness, while 61 were related to treatment safety. Likewise, 21 DRPs were related to treatment effectiveness in the control group, while 12 were related to treatment ($p \leq 0.01$). 65% of the interventions were made at the physician level and 49% at the drug level. 97% (n=133) of the total interventions were accepted. The number of DRPs was significantly reduced in the control group within the time frame after the clinical pharmacist intervention period. In conclusion, clinical pharmacists' importance in detecting and preventing DRPs in the gastroenterology ward has been demonstrated.

KEYWORDS: Clinical pharmacist; drug-related problems; gastroenterology; medication review.

1. INTRODUCTION

According to the Pharmaceutical Care Network Europe (PCNE), a drug-related problem (DRP) is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes. DRPs are associated with increased health care costs and hospital admissions, prolonged hospital stays, lower quality of life, and increased mortality. According to the PCNE, DRPs consist of three parts: treatment efficacy, safety, and other problems. The causes of these problems, interventions addressing these problems, and acceptance of these interventions are classified according to the PCNE classification system. These problems are related to drug selection, dose selection, adverse drug reactions, drug interactions, failure to monitor drug effects/toxicity, and adherence issues. DRPs include both existing and potential problems. An actual problem can result in clinical signs and treatment failure. A potential problem does not manifest, but it may cause drug-related harm to the patient if it is not resolved. For this reason, the most appropriate pharmacotherapy should be chosen with the main aim of preventing drug-related morbidity [1-4].

DRPs can occur at all stages in the hospital setting, from admission to discharge. Certain conditions, drugs in specific therapeutic groups, and variability of pharmacological knowledge among health care professionals may also be associated with DRPs [5,6]. Clinical pharmacist practices include reviewing medications and relevant clinical data to optimize the efficacy and safety of treatments. The inclusion of pharmacists in multidisciplinary teams has been shown to increase the detection rates of DRPs. The

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interventions described in studies focusing on DRPs are diverse and cover a wide range of aspects, including adherence, dose modification, and treatment management [7-11].

According to a two-year study conducted by Babelghaith et al., the most common cause of DRPs was serious potential drug–drug interactions (49%). Throughout the study, the incidence of most DRPs decreased. While 241 DRPs were detected in the first year, this number decreased to 128 in the second year. [12].

Hailu et al. evaluated clinical pharmacist interventions for DRPs. They reported that at least one DRP was detected in approximately 82% of patients, and there were 1.9 DRPs detected per patient on average. The physician acceptance rate for clinical pharmacist interventions was 91.7% [13].

According to a review of clinical pharmacist interventions in Turkey, studies were conducted in oncology (33.3%), geriatrics (20%), pulmonary diseases (13.3%), psychiatry (6.7%), cardiology (6.7%), and infectious diseases (6.7%) clinics. When the results of the studies were examined, most of the interventions were conducted at the prescriber level, followed by the drug and patient levels [14]. However, no study in Turkey has examined a clinical pharmacist intervention for DRPs in the gastroenterology ward. Indeed, studies on the detection and resolution of DRPs in gastroenterology are limited. It is striking that the extant studies are generally aimed at DRPs in a few wards, including gastroenterology wards.

The aim of the current study is to identify drug-related problems in the gastroenterology ward, to plan the interventions for these problems, and to evaluate the role of the clinical pharmacist in the gastroenterology ward, considering the acceptance/rejection of the interventions.

2. RESULTS

A total of 160 patients, n=80 for each; control group and the study group, were included. The study group consisted of 38 male (47.5%) and 42 female (52.5%) patients and the control group consisted of 40 male (50%) and 40 female (50%) patients (p>0.05). While the median age of the patients in the study group was 57.5 (51-66), the median age of the patients in the control group was 54.5 (45-62) (p>0.05). The median value of body mass indexes (BMI) of both groups was 23 (22-25); (p>0.05). Details are given in Table 1.

Tablo 1. Patient demographic characteristics

	Study Group (n=80) Median, Inter Quartile Range (IQR)	**Control Group (n=80) Median, Inter Quartile Range (IQR)**	**P**
Age, median	57.5 (51-66)	54.5 (45-62)	p>0.05
Gender			p>0.05
Male n (%)	38 (47.5)	40 (50)	
Female n (%)	42 (52.5)	40 (50)	
Body Mass Index, median	23 (22-25)	24 (22-25)	p>0.05

When the medication distributions in the study and control groups were examined according to the diagnoses, the highest median value in the study group was observed in patients with acute pancreatitis (n=9.5), and the highest median value in the control group was observed in patients with liver cirrhosis (n=8.5). While the lowest median value in the control group was observed in gastritis (n=2) patients, the lowest median value in the study group was observed in patients diagnosed with cholelithiasis, GIS bleeding, and ulcerative colitis (n=3). The distribution of the number of medications according to the diagnoses in the study and control groups is explained in detail in Table 2.

Tablo 2. Distribution of the number of medications according to the diagnosis in the study and control groups

Diagnosis	Study Group	Control Group	P
	Number of Medications median (IQR)	Number of Medications median (IQR)	
Liver Cirrhosis	8 (6-11)	8.5 (4.75-10)	p>0.05
Acute Pancreatitis	9.5 (8-10)	7 (4-9)	p>0.05
Choledocholithiasis	9 (7-10)	7.5 (4-8.25)	p>0.05
Cholelithiasis	6 (6-6)	4 (4-4)	p>0.05
Cholecystitis	7 (9-12)	7 (4-8)	p>0.05
Portal Hypertension	7 (7-7)	-	-
Hepatitis	11 (10-12)	3.5 (1.75-5.5)	p=0.04*
Gastrointestinal System Cancers	8 (6.5-12)	4 (3.5-6)	p>0.05
Gastritis	7.5 (6-9)	2 (4-7)	p=0.03*
Ulcerative Colitis	6 (5-7)	4 (2-6.5)	p>0.05
Gastrointestinal System Bleeding	6 (3.5-8)	3 (2-7)	p>0.05
Cholangitis	8.5 (7-8,5)	3 (6-6)	p=0.04*
Other	9 (7-9.5)	7 (6.25-8)	p>0.05

*p<0.05 statistically significant.

Potential drug-drug interactions of the patients were determined from the Medscape Drug Interactions Checker Module. While the rate of interaction monitoring closely was 65% in the study group, this rate was 64% in the control group. In the study group, 1% of interactions were contraindicated. The distribution of potential drug-drug interactions of the patients according to the groups is shown in Table 3.

Tablo 3. The distribution of potential drug-drug interactions

Interaction Level	Study Group n (%)	Control Group n (%)	*p*
Contraindicated	5 (1)	0 (0)	-
Serious (Use alternative)	58 (12)	4 (4)	**p≤0.01***
Monitor closely	316 (65)	64 (67)	**p≤0.01***
Minor	110 (22)	27 (28)	**p≤0.01***

*p<0.05 statistically significant.

There were 136 DRPs in the study group and 46 in the control group. While there were 1.7 DRPs per patient in the study group, this rate was 0.57 in the control group. The distribution of DRPs by groups is explained in Table 4. When the study and control groups are considered together, polypharmacy creates a 3.26-fold risk for DRPs. The risk factors calculated for DRPs are given in Table 4.

Tablo 4. Number of DRPs and risk factors

DRPs	Study Group (n=80)	Control Group (n=80)	p
Total number of DRPs	136	46	**p≤0.01***
Number of DRPs per patient	1.7	0.57	
DRPs, median (IQR)	2 (0-4)	0 (0-1)	
	Odds Ratio (Confidence Interval)		
Polypharmacy	3.26 (2.06-5.31)		**p≤0.01****
Gender	-		p>0.05
e-GFR	-		p>0.05
Child-Pug Score	-		p>0.05

*p<0.05 statistically significant.

In the study group, 136 DRPs were identified. Problems with the effectiveness of treatment, 59 of them; 61 are problems related to the safety of the treatment. In the control group, 46 DRPs were detected. Twenty-one of these are problems related to the safety of the treatment; 12 of them cause problems related to treatment safety (p≤0.01). Details are given in Table 5.

Tablo 5. Distribution of DRPs

DRPs	Study Group n (%)	Control Group n (%)	p
P1. Treatment effectiveness	59 (43)	21 (45)	**p≤0.01***
P1.1. No effect of drug treatment despite correct use	23 (16)	7(15)	**p=0.02***
P1.2. Effect of drug treatment not optimal	30 (21)	12 ()	**p=0.01***
P1.3. Untreated symptoms or indication	6 (4)	2 (3)	**p>0.05**
P2. Treatment safety	61 (44)	12 (26)	**p≤0.01***
P3. Other	16 (12)	13 (28)	**p>0.05**
P3.2. Unclear problem/complaint. Further	16(12)	13 (28)	
clarification necessary	0 (0)	0 (0)	

*p<0.05 statistically significant.

When the reasons behind DRPs were analyzed in both study and control groups, 106 of the 177 causes in the study group, and 32 of the 59 causes in the control group were related to drug selection (N1) (p≤0.01). Another statistical significance between both groups is because the treatment results were not followed up or were followed inappropriately (p≤0.01). The distribution of DRPs in the study and control groups according to the reasons behind is shown in Table 6.

Tablo 6. Distribution of DRPs in the study and control groups according to the causes

DRPs Causes	**Study Group n (%)**	**Control Group n (%)**	**p**
C1 Drug selection	106 (60)	32 (54)	**p≤0.01***
C1.1 Inappropriate drug according to guidelines/formulary	5 (2)	0 (0)	
C1.2 No indication for drug	12 (6)	2 (3)	
C1.3 Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements	68 (38)	17 (28)	
C1.4 Inappropriate duplication of therapeutic group or active ingredient	3 (1)	0 (0)	
C1.5 No or incomplete drug treatment in spite of existing indication	15 (8)	2 (3)	
C1.6 Too many different drugs/active ingredients prescribed for indication	3 (1)	11 (18)	
C2 Drug form	0 (0)	0 (0)	-
C3 Dose selection	21 (11)	16 (27)	p>0.05
C3.1 Drug dose too low	10 (6)	9 (15)	
C3.2 Drug dose of a single active ingredient too high	9 (5)	7 (11)	
C3.5. Dose timing instructions wrong, unclear or missing	2 (1)	0 (0)	
C4 Treatment duration	0 (0)	0 (0)	-
C5 Dispensing	2 (1)	0 (0)	-
C5.2. Necessary information not provided or incorrect advice provided	2 (1)	0 (0)	
C6 Drug use process	0 (0)	0 (0)	-
C7 Patient related	4 (2)	1 (1)	**p>0.05**
C7.1. Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason	3 (1)	1 (1)	
C7.6. Patient stores drug inappropriately	1 (0,5)	0 (0)	
C8 Patient transfer related	0 (0)	0 (0)	-

C9 Other	44 (24)	10 (16)	**p≤0.01***
C9.1. No or inappropriate outcome monitoring (including therapeutic drug monitoring)	44 (24)	9 (15)	
C9.3 No obvious cause	0 (0)	1(1)	

*p<0.05 statistically significant.

The control group data were taken from the system, and the clinical pharmacist did not make any intervention in the control group; interventions were made in the study group. Of the 202 interventions, 65% were performed at the prescriber level (n=132), while 49% were performed at the drug level (n=24). The distribution of planned interventions made for DRPs in the study group is shown in Table 7.

Tablo 7. Distribution of the planned interventions made for DRPs in the study group

Intervention	**n (%)**
I1. At prescriber level	132 (65)
I1.1. Prescriber informed only	26 (12)
I1.2. Prescriber asked for information	1 (0.04)
I1.3 Intervention proposed to prescriber	104 (51)
G1.4. Intervention discussed with prescriber	1 (0.04)
I2 At patient level	3 (1)
I2.3. Patient referred to prescriber	1 (0.04)
I2.4. Spoken to family member/caregiver	2 (1)
I3 At drug level	49 (24)
I3.1. Drug changed to …	11 (5)
I3.2. Dose changed to …	8 (3)
I3.5. Drug paused or stopped	18 (8)
I3.6. Drug started	12 (5)
I4 Other intervention or activity	18 (8)
I4.1. Other intervention (specify)	13 (6)
I4.2. Side effect reported to authorities	5 (2)

Of the 136 interventions made in the study group, 97% (n=133) were accepted. The acceptance status of the interventions proposals is given in Table 8. In the study group, 133 of 136 DRPs were resolved. It was determined that only three problems were not resolved. The status of the DRP is shown in Table 8.

Tablo 8. The acceptance status of the interventions proposals

Implementation	**n (%)**
A1 Intervention accepted (by prescriber or patient)	133 (97)
A1.1. Intervention accepted and fully implemented	125
A1.2. Intervention accepted, partially implemented	6
A1.3. Intervention accepted but not implemented	2
A2 Intervention not accepted (by prescriber or patient)	3
A2.1. Intervention not accepted: not feasible	1

A2.2. Intervention not accepted: no agreement	2
Outcome of intervention	**n (%)**
O1 Problem totally solved	123 (90)
O2. Problem partially solved	10 (7)
O3 Not solved	3 (2)
O3.1 Problem not solved, lack of cooperation of patient	1
O3.2 Problem not solved, lack of cooperation of prescriber	1
O3.3 Problem not solved; intervention not effective	1
O3.4 No need or possibility to solve problem	

3. DISCUSSION

DRPs can cause significant morbidity and mortality, and are statistically associated with patients' clinical outcomes, health care costs and quality of life [16]. DRPs were detected in both control and study groups of our study. Interventions were planned DRPs for the study group. Most DRPs in the study group were resolved (97%).

In the study group, the clinical pharmacist performed a medication review and attended the visits with the physician. The patients' information was only accessed from the hospital patient registry system in the control group. It was observed that the medications used by the patients at home mainly were not recorded in the patient system. This is likely the reason for the low number of medications used by the patients in the control group. 136 DRPs were detected in the study group and 46 in the control group in this study. The number of DRPs per patient in the study group was 1.7. In a similar study conducted in Turkey, the number of DRPs per patient was 1.63 [17]. In a prospective observational study of 189 patients in India, the rate was 2.2 [18]. According to a study conducted in the nephrology, urology, gastroenterology, and metabolic disease wards in Germany, most of the DRPs in the gastroenterology ward occurred during hospitalization. The study also found that the most common cause of DRPs in the gastroenterology ward was drug selection [18].

In a very large two-year prospective cohort study conducted in Brazil, including patients in the gastroenterology ward, treatment ineffectiveness (11.5%) and treatment costs (5.90%) were the most common. The duration of medication use (18.4%) and duration of treatment (31.0%) were among the main causes of DRPs [19]. In the study, the most common DRPs were related to the effectiveness of the treatment (43% in the study group, 45% in the control group). In both studies, parallelism was observed when DRPs were compared.

The most common cause of DRPs in the study and control groups was drug selection (60% and 54%, respectively). The most common cause of problems related to drug selection was the inappropriate combination of drugs with other drugs or herbal supplements (38% and 28%). This was followed by non-monitoring or inappropriate monitoring of the treatment outcome (24% and 16%, respectively). In a prospective observational study conducted in Jordan involving 3112 patients in five hospitals, the most common cause of DRPs was that patients were not followed up frequently (48%) [20]. In a prospective observational study of 173 patients in the gastroenterology ward in India, the most common causes of DRPs were drug selection (21%), dose modifications (17%), inappropriate combinations (15%), and the use of inappropriate pharmaceutical forms (15%) [21].

A total of 125 (97%) of the 133 interventions planned in the study group were fully accepted and implemented. Six (4%) interventions were accepted and partially implemented, while three (2%) were not accepted. In studies conducted in China and Israel outside the gastroenterology ward, the interventions by clinical pharmacists were accepted and implemented at a rate of 76.31% and 70%, respectively [22,23]. Examining the studies in Turkey, most of the interventions by clinical pharmacists are planned at the physician level, followed by the drug and patient levels. It has been observed that drug-related problems in Turkey are resolved by clinical pharmacists between 54.2–93.2% [14].

Polypharmacy was detected in 118 (74%) of the 160 patients who participated in the study. DRPs were detected in 90% of the patients with polypharmacy. When the odds ratio for DRPs was calculated, it was observed that polypharmacy increased the risk of DRPs by 3.26 times ($p<0.05$). Another prospective study reported that polypharmacy increased the risk of DRPs by 4.35 times [13]. In a study on patients with decompensated cirrhosis (n=57) examining the prevention and determination of DRPs, the number of DRPs per patient was found to be six, with adherence (31.5%) and indication problems (29.1%) among the most common causes of DRPs. As the Child–Pugh score increased, high-risk DRPs also increased in patients. A total

of 221 DRPs (58.9%) were resolved after pharmacist intervention [24]. In our study, the Child–Pugh score was not among the risk factors affecting the occurrence of DRPs ($p>0.05$). This may be due to the low number of patients with liver cirrhosis in the study group.

In the study, the control groups data were collected after the date of the study group. Accordingly, some recommendations made to physicians are accepted, and they are constantly put into practice. This may be one of the reasons for the low number of DRPs in the control group compared to the study group. The use of ceftriaxone and calcium acetate, which are contraindicated in concomitant use, was observed in five patients in the study group. No contraindicated interactions were observed in the control group, which indicates that clinical pharmacist recommendations were applied consistently.

This study has few limitations. First, it was conducted in a single center with a limited number of patients. For a better understanding of the effect of clinical pharmacists on drug-related problems, multicenter studies with larger samples are needed across the country. In addition, the control groups data were obtained from the hospital system. The clinical pharmacists could not take the responsibility and could not have an active role regarding the control group. Hence, some DRPs may have not been detected.

4. CONCLUSION

At least one DRP was detected in most patients in the study and control groups. The most frequently identified DRPs are due to reasons related to drug selection. Polypharmacy is a risk factor for DRPs. Clinical pharmacists, gastroenterologists, and other healthcare professionals should work collaboratively during the delivery of pharmaceutical care to minimize DRPs. Increasing pharmaceutical care programs that integrate the clinical pharmacist into the multidisciplinary patient care team will increase therapeutic success and reduce health-related expenditures. This research has taken its place among the limited studies conducted by the clinical pharmacist in the world literature on the identification, resolution, and prevention of DRPs in the gastroenterology ward.

5. MATERIALS AND METHODS

5.1. Data collection

The research was carried out in the gastroenterology ward of Necmettin Erbakan University Meram Medical Faculty Hospital. The total number of beds in the hospital is 1330, and the total number of beds in the gastroenterology ward is 30. Ethics committee approval numbered 10840098-604.01.01-E.2623 was obtained from Istanbul Medipol University Non-Interventional Clinical Research Ethics Committee Presidency.

In the first period of the study, 80 patients who were hospitalized in the gastroenterology service between 15.06.2018 and 15.02.2019, used at least one medication and agreed to participate in the study were included in the study group. The clinical pharmacist participated in the visits of the study group and identified DRPs and interventions for their solutions. In the second period, 80 patients hospitalized between 01.03.2019 and 06.06.2019 were selected as the control group, and only DRPs were detected from the data obtained from the hospital system.

The sample size was calculated using the G Power program according to effect size 0.5, type I error 0.05, and power 0.90. In the light of these data, the study was conducted with a total of 160 patients.

Inclusion criteria for the study were determined as receiving inpatient treatment at the gastroenterology ward, being over 18 years old, signing the consent form by agreeing to participate in the study, and using at least one medication. Exclusion criteria were determined as leaving the study voluntarily and transferring to another service or hospital.

Polypharmacy is defined as using five or more medications [25].

UpToDate® recommendations, Medscape® recommendations, and medication guidelines were reviewed for medication information. Possible drug-drug interactions were checked with the Medscape® drug interactions checker system. According to Medscape, the interaction levels are classified as follows; contraindicated, serious, monitor closely, and minor interactions.

DRPs are classified according to the PCNE V9.1 [1]. DRPs were detected in the study group; Interventions were made for the identified DRPs. The intervention's acceptance/rejection status was recorded. In the control group, only DRPs were detected.

5.2. Statistical analyses

SPSS 22.0 (Statistical Package for the Social Sciences) program was used for statistical analysis. Categorical data were analyzed with the chi-square test and the non-parametric Mann-Whitney U test for those that did not fit the normal distribution for continuous variable data. Clinical risk factors were analyzed by logistic regression testing. The results were evaluated as significant as $p<0.05$ at a 95% confidence interval.

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