



Research Article

Pharmacist Intervention to Address Drug Related Problems in Patients with Decompensated Liver Cirrhosis

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ABSTRACT

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Background: Patients with decompensated cirrhosis are often given therapeutic and prophylactic drugs. Polypharmacy raises both the likelihood of prescription errors and the complications associated with drugs. Clinical pharmacists are excellent at recognizing, addressing, and preventing clinically significant drug-related problems.

Objectives: Identification types of pharmacist interventions to address drug-related problems in patients with decompensated cirrhosis and assess the acceptance/implementation of these recommendations. And identify patient factors associated with accepting pharmacist recommendations.

Subjects and Methods: Prospective, interventional, clinical study for 80 hospitalized decompensated cirrhosis patients was conducted at Baghdad Teaching Hospital and lasted for four months, from the first of December 2021 until the last of March 2022. The study involved two phases, the first one was observational to identify drug-related problems and classify them according to the Pharmaceutical Care Network Europe classification version 9.1, and the second phase was interventional to increase the awareness of patients and health care providers about those problems and to propose a proper solution for each one.

Results: The most frequent pharmacist intervention was proposed to the prescriber (54.7%), followed by speaking to the caregiver (37.7%). Acceptance and full implementation were highly observed in 71.1% of the intervention. There is a significant association between occurring ascites and bleeding in patients and accepting/implementing pharmacist recommendations.

Conclusions: Patients with decompensated liver cirrhosis have a significant prevalence of drug-related problems. Clinical pharmacists are excellent at recognizing drug-related problems and reducing their incidence, and their interventions were well accepted.

Introduction

Patients with cirrhosis, a late stage of progressive fibrosis with liver vascular and architectural changes, have the highest risk of morbidity and mortality. Clinically, cirrhosis is classified as compensated, a latency period with median survival durations of more than 12 years, or decompensated, a rapidly advancing phase characterized by portal hypertension or liver insufficiency with median survival times of less than 2 years (1). Cirrhosis and other chronic liver diseases contribute significantly to worldwide morbidity and mortality. Cirrhosis accounted for 2.4% of global deaths in 2017, up from 1.9% in 1990. In 2017, there were also 106 million cases of decompensated cirrhosis and 112 million cases of compensated cirrhosis globally (2). Cirrhosis becomes a systemic illness if decompensation occurs, resulting in multi-organ/system dysfunction (3). Drug-Related Problems (DRPs) are drug-related events or circumstances that interfere with or have the potential to interfere with desirable health outcomes. Pharmaceutical Care Network Europe (PCNE) created a classification scheme for DRPs in 1999, and it has been regularly updated since then. The most recent version (9.1) was published in February 2020, and it includes problems, causes, and interventions (4). Clinical pharmacists are effective at identifying, resolving, and preventing clinically relevant drug-related problems. A proactive rather than reactive approach appears desirable to maximize the benefit of interventions. This involves pharmacist participation in multidisciplinary team talks – during the ordering and prescribing process – during which all drug-related issues, including possible problems, should be discussed (5). Cirrhosis patients who have decompensated are frequently offered a complex prescription of therapeutic and prophylactic drugs. Polypharmacy raises the likelihood of medication errors and medication-related complications. Patients who have decompensated cirrhosis are more likely to have DRPs. Nearly 60% of drug-related problems were recognized and resolved as a direct result of the pharmacist intervention (6). This study aimed to identify the types of pharmacist interventions used to address drug-related problems in patients with liver cirrhosis, determine the acceptance/implementation of these recommendations, and identify patient factors associated with accepting/implementing pharmacist recommendations.

Subjects and Methods

A prospective, interventional, clinical study was conducted at Baghdad Teaching Hospital. The research consisted of two phases: observational and interventional (behavioral). The primary purpose of the first phase (observation) was to determine the prevalence of DRP in patients with decompensated liver cirrhosis. Using version 9.1 of the PCNE Classification for Drug-Related Problems(4), the researcher recognized and classified any drug-related problems throughout the observation phase. During the second phase, the researcher's pharmacist conducted interventions with patients and their caregivers regarding issues related to the improper use of their medication regimen, as well as interventions with hospital gastroenterologists regarding DRPs related to physicians e.g., (improper drug dose, incorrect dosage frequency, contraindication). The collecting of data lasted four months, from the first of December

2021 to the last of March 2022. Eighty patients with decompensated liver cirrhosis were enrolled in the study.

Inclusion criteria

Hospitalized patients with decompensated liver cirrhosis, patients older than 18 years old, and patients who provide their agreement to participate in the study were included.

Exclusion criteria

Patients who refuse to participate in the study were excluded from the study.

Data collection/ observational phase

The researcher prepared a specific data collection sheet in accordance with the aims of the study. The demographic data, comorbidities, laboratory investigations, numbers, and relevant medications of patients were acquired via their case sheets and by participating in daily morning rounds with physicians and clinical pharmacists. All data was confirmed with patients, caregivers, or physicians.

Interventional phase

During this interventional phase, appropriate clinical pharmacological interventions were provided at both the patient and physician levels. then determining the level of agreement regarding these interventions. The majority of patients were severely ill and unable to talk, thus the researcher conducted interviews with members of the patient's family or caretakers. The majority of drug-related problems at the patient level were due to the improper use of their medication regimen or using their medication in low doses that did not match their prescribed dose which led to the nonoptimal effect of their treatment. The interventions at the patient level included speaking to the patients or their caregivers and providing them with verbal and in-writing information regarding the proper use of their medication regimen. In accordance with American Association for the Study of Liver Diseases (AASLD) Guidelines (7), the researcher indicated a suitable clinical intervention at the physician level. The intervention centered on ensuring that physicians prescribe the medicines that decompensated liver cirrhosis patients require for their therapeutic and prophylactic regimens at the correct dose, and frequency, and that their choice of medication conforms to the guidelines. These physician interventions were supplemented by information from the references (AASLD Guidelines) to convince the physicians to implement the researcher-proposed alteration. Using Medscape, all prescribed medications were checked for potential drug interactions.

Ethical consideration

A research proposal was approved by the Scientific Committee of the College of the Pharmacy/ University of Baghdad before it was submitted and officially approved. In addition, the study was approved by the hospitals, and a verbal agreement was gained from the patients. regarding critically ill patients' agreement was gained from their family members.

Statistical analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) software version 25. Descriptive statistics (means, standard deviation, frequencies, and percentages) were conducted for all study items. Binary logistic regression analysis was used to measure the associations between 11 patient factors (independent variables) and the acceptance/implementation of pharmacist recommendations (outcome variable). A P-value of less than 0.05 was considered statistically significant.

Results

In this study, the mean age of the decompensated liver cirrhosis patients was 52.46 ± 16.43 . More than two-thirds of the patients in the study sample were Male 58 (72.5%). The average Child-Pugh Score for Cirrhosis Mortality was 9.3 ± 1.6 which reflects moderately severe liver disease while the MELD-Na Score has a mean of 21.74 ± 7.70 and Alcoholic liver cirrhosis was the most common etiology in study group 35(43.8%). Type 2 Diabetes Mellites (DM) was the most frequent comorbidities in decompensated liver cirrhosis patients 23(28.7%) followed by hypertension 13 (16.3 %). regarding complication of liver cirrhosis ascites was found in 41(51.2%) of the patients, also 11 of the study sample presented to the hospital with two complications, whereas the rest presented with a single complication, as shown in Table (1).

There were 16 causes (30.2%) of DRPs related to the Drug dose of a single active ingredient being too high, while the Patient unintentionally administering/using the drug in a wrong way was responsible for 12 causes (22.6%) of DRPs. Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements, Duration of treatment too short, Patient uses/taking more drugs than prescribed had the least causes one for each (1.9%) as shown in Table (2).

The most common medication related to DRPs was omeprazole, followed by lactulose. Norfloxacin, Metronidazole, Octreotide, Gaviscon, Prednisolone, and Simal (Curcuma rhizomes, Milk thistle, Artichoke, and Liquorice roots extract) had the least DRPs as shown in Table (3).

The intervention proposed to the prescriber was the most common frequent intervention proposed by pharmacists 29(54.7 %), followed by speaking to a family member or caregiver 20 (37.7 %). Prescriber informed only and Instructions for use changed to was the least frequent with 2(3.8%) interventions for each one as shown in the figure (1).

Acceptance and full implementation were observed in 38(71.1%) of the intervention while no agreement on intervention was seen in 8(15.1%) as shown in figure (2).

The binary logistic regression analysis showed a significant ($P < 0.05$) positive correlation between the occurrence of ascites and bleeding on one side and the acceptance/implementation of pharmacist recommendations on the other. In other words, physicians accepted and implemented pharmacist recommendations for ascites and bleeding patients as shown in table (4).

Table 1: Demographic data and clinical characteristics of the study sample

Parameter	value		
Age(years) mean \pm SD	52.46 \pm 16.43		
BMI(kg/m ²)	28.04 \pm 4.12		
Child-Pugh Score	9.31 \pm 1.62		
MELD- Na Score	21.74 \pm 7.70		
Number of medications	6.89 \pm 2.44		
Total Bilirubin(mg/dl)	9.12 \pm 10.67		
Albumin(g/dl)	2.90 \pm 0.71		
Gender	Male N (%)	58 (72.5)	
	Female N (%)	22 (27.5)	
Etiology	Cryptogenic	20 (25)	
	Alcoholic	35 (43.8)	
	HBV	9 (11.3)	
	HCV	8 (10.0)	
	AIH	6 (7.5)	
	Wilson disease	1 (1.2)	
	NAFLD	1 (1.2)	
	Comorbidities of patients	hypertension	13 (16.3)
Number of complications of liver cirrhosis for each patient	DM	23 (28.7)	
	Acute myeloid leukemia	1 (1.3)	
	Parkinson disease	1 (1.3)	
	Osteoarthritis	1 (1.3)	
	chronic kidney disease	1 (1.3)	
	Benign prostate hypertrophy	1 (1.3)	
	One complication		69 (86.3)
		Two complications	11 (13.7)
	Complication of decompensated cirrhosis	Ascites	41 (51.2)
		Bleeding	22 (27.5)
Hepatic encephalopathy		18 (22.5)	
Jaundice		10 (12.5)	

HBV; Hepatitis B Virus, HCV; Hepatitis C virus, AIH; Auto-Immune Hepatitis, NAFLD; Non-Alcoholic Fatty Liver Disease.

Table 2: Types and causes of identified drug-related problems

Causes of drug-related problems	N	%
Drug dose of single active ingredient too high	16	30.2
Patient unintentionally administers/uses the drug in a wrong way	12	22.6
Prescribed drug not available	7	13.2
Drug dose too low	6	11.3
Dosage Regimen is not frequent enough	3	5.7
Inappropriate drug according to guidelines/formulary	2	3.8
No or incomplete drug treatment in spite of existing indication	2	3.8
Necessary information not provided or incorrect advice provided	2	3.8
Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements	1	1.9
Duration of treatment too short	1	1.9
Patient uses/takes more drug than prescribed	1	1.9
Total	53	100.0

Table 3: Frequency of medicines associated with DRPs

Medications	N (%)
Omeprazole	16(30.2)
Lactulose	9(16.9)
Rifaximin	4(7.7)
Ciprofloxacin	3(5.6)
Cefotaxime	3(5.6)
Lasix	3(5.6)
Albumin	3(5.6)
spironolactone	2(3.8)
Urso	2(3.8)
Paracetamol	2(3.8)
Norfloxacin	1(1.9)
Metronidazole	1(1.9)
Octreotide	1(1.9)
Gaviscon	1(1.9)
Prednisolone	1(1.9)
Simal	1(1.9)
total	53(100)

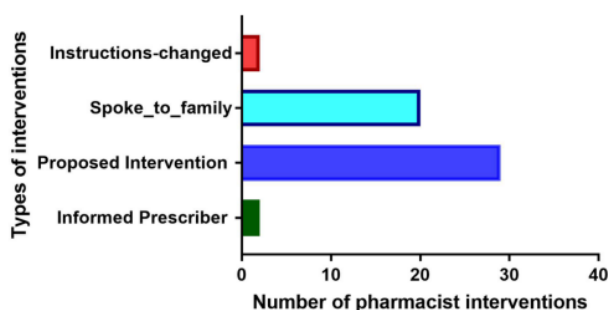


Figure 1: The types and number of pharmacist interventions to address drug-related problems

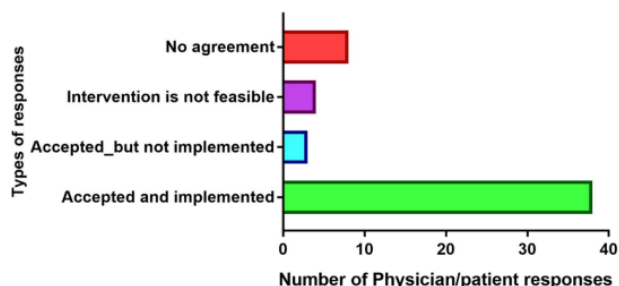


Figure 2: Clinical pharmacist's interventions acceptance

Table 4: Patient Factors associated with the acceptance/implementation of pharmacist recommendations

Variable	β	S.E.	P-value	Exp(β) (OR)
AGE (Y)	-0.003	0.034	0.928	1.00
BMI	0.289	0.152	0.058	1.34
Gender	1.574	1.401	0.261	4.82
Alcoholic	0.160	1.202	0.894	1.17
HBV	0.684	1.722	0.691	1.98
HCV	-0.684	1.500	0.649	0.51
Ascites	6.539	3.268	0.045*	691.32
Bleeding	6.411	3.212	0.046*	608.35
MELD_NA_score	-0.040	0.085	0.639	0.96
Total bilirubin mg/dl	0.077	0.090	0.388	1.08
Encephalopathy-grade	1.924	1.228	0.117	6.85

*Significant (P-value<0.05) according to binary logistic regression. Outcome variable is the acceptance/implementation pharmacist recommendation

Discussion

The majority of the research participants were male (72.5%). Gender disparities exist in outcomes among patients with cirrhosis and the male gender is more likely to experience hepatic decompensated events than the female (8). The means of the Child-Pugh Score is 9.31 ± 1.62 while the MELD- Na Score has a mean of 21.74 ± 7.70 . our result is nearly comparable to the result of Fayad et al (9) in Brazil who studied the effectiveness of prognostic models as mortality predictors in 123 patients with acute decompensation of cirrhosis and found that 52% of patients had a Child-Pugh C and MELD-Na score mean was 19.12 ± 7.38 . Type 2 Diabetes Mellites (DM) was the most frequent comorbidity in decompensated liver cirrhosis patients 23(28.7%) followed by hypertension 13 (16.3 %). this result was in contrast with the result of a retrospective cohort study done by Vaz et al (10) in Sweden and founded in 598 liver cirrhosis patient's hypertension 196 (33%) followed by type 2 diabetes mellites 171 (29%) was the most common frequent comorbidities. Liver cirrhosis is commonly associated with type 2 diabetes mellitus, a disease of glucose metabolism characterized by hyperglycemia and insulin resistance. More than 80% of individuals with liver cirrhosis exhibit glucose intolerance, and about 30% have type 2 diabetes(11). Alcoholic liver cirrhosis was the most common etiology in study group 35(43.8%).our result is comparable to the result of Goncalves et al (12) in Brazil who reported of total 1516 liver cirrhosis patients chronic alcoholism was responsible for 602(39.7%) cases of liver cirrhosis. Regarding complication of decompensated cirrhosis ascites was found in 41(51.2%) of the patients. Apica et al (13) in Uganda who study Admissions in a large urban hospital due to decompensated cirrhosis reported that of the total of 85 patients with decompensated cirrhosis 81(95.3%) of them suffer from ascites. Pharmaceutical Intervention refers to the process of recognizing DRPs and then providing a recommendation to either prevent or solve the problem. Pharmacotherapy monitoring is a practice in which the pharmacist is accountable for the patient's needs to medicine. This is often accomplished by identifying DRP, avoiding and treating problems that are related to medication, and addressing the adverse effects of medications. In our study, the intervention proposed to the prescriber was the most common frequent intervention proposed by pharmacists 29(54.7 %) followed by speaking to a family member or caregiver20 (37.7 %). Ceylan et al (14) in Turkey reported in their study for Evaluation of clinical pharmacist interventions on medication-related problems in the gastroenterology ward by using PCNE classification, of total of 202 interventions made in the study group 104(51%) of them were interventions proposed to the prescriber followed by Prescriber informed only 26 (12%). Aghili and Kasturirangan (15) in India Using PCNE classification, they identify 394 drug-related problems in critically ill patients with decompensated liver cirrhosis. for each problem detected interventions proposed by clinical pharmacist to consulting physicians was made and recommendation was offer to solve the problems. The clinical pharmacist's pharmaceutical management can impact the patient's outcome positively. The clinical pharmacist's review of the patient's drug therapy will optimize drug therapy. The positive nature of the pharmacist's reactive intervention and health care professionals' passive interventions demonstrates that pharmacists play a significant role in the health care team through the appropriate use of medications(16). The interventions in this study were accepted and fully implemented in 71.7%. of DRPs This greater acceptance rate was also found by

Párraga et al. (17), who reported that over 70% of the pharmacist intervention on one-third of the prescriptions for patients with hepatic insufficiency who are candidates for pharmacist intervention was accepted. In addition, Aghili and Kasturirangan (15) reported that 73.3 % of pharmacist interventions were accepted and fully implemented. While Talib and Anwer (18) in Iraq who study DRPs in hemodialysis patients using PCNE classification reported that 34.3 % of recommendations were accepted and implemented completely. The medical community accepts and values pharmacists' intervention; they play a vital role in establishing the safe use of medications(19). In this study, the acceptance of pharmacist recommendations was substantially associated with the incidence of ascites and bleeding in patients with decompensated liver cirrhosis. Al-Jumaili et al (20) in Iraq reported in their study for Physician Acceptance of Pharmacist Recommendations Regarding Medication Prescribing Errors that physician specialty, pharmacist gender(male), and patient gender were significantly associated with the acceptance of pharmacist interventions. While Zaal et al (21) in the Netherlands found that acceptance was significantly associated with the number of prescribed drugs.it is obvious from the studies above that the factors that influences the acceptance of pharmacist recommendation where different in each study And the occurrence of ascites and bleeding in our patients may have been a motivating factor for the acceptance of pharmacist recommendations, as these patients will be severely ill and their therapeutic and prophylactic medication regimens will be complex, thus also enhancing the role of the clinical pharmacist in the adjustment of their medication regimens. The most important limitation was patients were extremely exhausted and lacked the incentive to share information, necessitating the use of family members to acquire information, while some patients were left alone in hospitals, which made the mission more challenging. In addition, the sample size was small and the study was conducted in one center.

Conclusion

Patients with decompensated liver cirrhosis have a significant prevalence of drug-related problems. Clinical pharmacists are excellent in recognizing drug related problems and reducing their incidence, and the intervention that they provided was very well accepted.

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This research did not receive any specific fund.

Conflict of Interest

No conflict of interest

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