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Original Research Article

Impact of clinical pharmacist intervention on therapy-related problems and costs in a cardiovascular unit of a tertiary healthcare facility in Amman, Jordan

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Abstract

Purpose: *To evaluate the impact of clinical pharmacist intervention on patients' treatment-related problems (TRPs) in patients admitted to the cardiology unit of a university-affiliated hospital; to assess physician acceptance of clinical pharmacist suggestions; and to determine the impact on costs to patients.*
Methods: *To determine the impact of clinical pharmacist intervention on the care of patients with cardiovascular disease (CVD), a prospective design was applied to compare a standard care group with a clinical pharmacist care group using 100 CVD patients per group over a 5-month period. The pharmacist responsible for patient counseling reviewed the patient records, collected demographic data, clinical data as well as medical history, diagnosis and medication plan. All the interventions made by the clinical pharmacist were analyzed in terms of potential cost savings for the patient.*
Results: *Of the clinical pharmacist's recommendations, 70 % were accepted by the treating physician. The most frequent TRPs detected were: efficacy (more effective drugs were available), the need for combination therapy, indication (specifically untreated conditions), inappropriate knowledge, adherence, and safety. Approximately 52 % of the TRPs were resolved and 35 % experienced improvement.*
Conclusion: *A clinical pharmacist intervention has a significant impact on the cost of drug therapy and patient outcomes. The results support the usefulness of pharmaceutical care services for all hospitalized CVD patients.*

Keywords: *Clinical pharmacy, Treatment-related problems (TRPs), Cost saving, Cardiovascular disease (CVDs), Pharmacist-intervention*

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INTRODUCTION

Cardiovascular disease (CVD) continues to be a leading cause of early death throughout the world [1]. CVD is a major public health issue that has created growing concern in developing countries, including Jordan [2]. Recently, polypharmacy has increased with increased need to treat rising comorbidities in CVD patients. Polypharmacy and the disproportionate use of medications, combined with age-related and disease-related pharmacokinetic and

pharmacodynamic changes, increases the risk of treatment-related problems (TRPs), with reported incidents in up to 68 % of CVD patients [3]. Mortality, morbidity, and economic costs are the most frequent consequences of TRPs.

Clinical pharmacists can play an important role in treating CVD patients by intervening and correcting TRPs [4]. The involvement of a clinical pharmacist has been shown to decrease drug–related costs, prevent the development of TRPs, improve overall clinical health, raise patient quality of life, decrease the incidence of re-hospitalization, and reduce morbidity [5]. Previously published reports have shown that clinical pharmacist intervention improve outcomes for CVD patients in both inpatient and outpatient settings [6-13]. Our study evaluates the impact of clinical pharmacist intervention and physician acceptance of pharmaceutical care services in hospitalized CVD patients. We also wish to identify and quantify the outcomes of clinical pharmacist interventions and the potential economic impact.

METHODS

Study design, setting and subjects

We performed a prospective single-blinded randomized controlled interventional study conducted in the cardiology ward of the University of Jordan Hospital over five months (August 2014 through January 2015). Patients provided written consent agreeing to be monitored over a period of three months after their baseline assessment. Follow-up conversations were conducted by phone and at subsequent physician visits.

This study was conducted following the guidelines outlined in the Declaration of Helsinki [14], and Good Clinical Practice guideline [15]. Institutional review board committee approval was obtained from The University of Jordan Hospital human ethics committee (JU/EA no. 7-2014).

A pilot study of 30 patients determined the necessary sample size based on the number of TRPs identified per patient. With a standard deviation (SD) for this primary outcome of 2.56, the minimum required sample size needed to estimate the average number of TRPs within an accuracy of 0.5 was determined to be 100 patients per group. Inclusion criteria for the study stipulated that patients be older than 18 years of age, a current patient in the cardiology department, and taking at least two cardiac medications. Exclusion criteria for the study rejected any patients with a history of dysphasia, psychiatry, or Alzheimer's disease, or patients with life-threatening conditions. Recruited CVD patients were randomized into two groups, the intervention group or control group, using the website www.randomization.com. Neither physicians nor nurses were informed about the group assignment of the patients, though they were aware of the study.

Study protocol

The clinical pharmacist interviewed and thoroughly reviewed all subjects' medical records to collect demographic characteristics and clinical data including medical history, drug profile and patient knowledge of medications. Subjects completed the medication adherence questionnaire and self-care activity assessment sheet. The patients' data were assessed daily to identify any potential or current TRPs utilizing a systematic evidence-based approach as previously described [16,17]. Patient treatment and dosing regimens were assessed with the most recent therapeutic strategies recommended in the evidence-based guidelines. Any potential adverse drug reactions (ADRs) or drug-drug interactions were evaluated using Lexicomp Drug Information®.

Interventions initiated by the clinical pharmacist included: patient counseling, medication initiation, medication adjustment, clarification of drug dosage and frequency, identification of contra-indication and incorrect indications, discovery of harmful drug interactions, patient education, and patient counseling for lifestyle modifications. The clinical pharmacist discussed the patients' cases with the treating physician and verbally provided therapeutic recommendations to optimize the therapy. Moreover, the clinical pharmacist submitted a written pharmaceutical care plan including all recommendations to the treating cardiologist. The acceptance of the recommended intervention by the treating physician for each intervention was also recorded as either accepted or not accepted. Drug compliance in the intervention group was assessed and analyzed using the medication adherence questionnaire. The clinical pharmacist delivered a variety of compliance aids to help patient adherence, including providing pillboxes, telephone follow-up reminders, encouraging patients to have a treatment diary or calendar on their mobile phones, providing patients with drug information leaflets, and one-on-one counseling on the indications of medications including possible ADRs.

Outcomes measured

The clinical pharmacist conducted a post-intervention follow-up after three months for both groups by telephone call or hospital visit for medication refill. The post-intervention assessed changes in treatment, number of TRPs, changes in adherence, and changes in lifestyle. The post-intervention follow-up documented outcomes of TRPs and overall success of pharmacists' interventions. The overall outcomes of TRPs were classified into four categories [18]: (A) the therapeutic outcome was achieved or improved, (B) future morbidity was prevented by avoidance of ADRs, (C) the therapeutic outcome was not improved or changed, or (D) the therapeutic outcome worsened.

CVD-specific clinical outcomes

CVD-specific outcomes were assessed using four parameters: (A) change from baseline in the number of patients receiving appropriate progression-modifying therapy and achieving their goals for hypertension, dyslipidemia, and diabetes, (B) change in the number of patients receiving appropriate management and prophylaxis of common complications including heart failure, stroke, sudden cardiac death, or CVD progression, (C) Clinical pharmacy intervention (e.g. safety of medication, lack of indication, errors, drug interactions and inappropriate doses in case of kidney disease), and (D) change in the level of adherence.

Cost evaluation

An independent clinical panel assessed the impact of clinical pharmacist intervention on patient cost savings [19]. Clinical pharmacists assessed all interventions that were accepted or changed by the treating physician for any impact on: probability of re-admission, length of hospital stay, changes in patient statistics that required laboratory monitoring, and other necessary medical procedures. Cost saving was designated when the cost of therapy was reduced after the intervention. For calculating cost savings (C), Eq 1 was used [20].

$$C = T\{(AV + (AH*CV*VH*CH*DH)\} \quad (1)$$

where T is the no. of TRPs, AH is avoided care visits (%), CV is average cost/visit, VH is avoided hospitalization, CH is average cost per hospitalization/day, and DH is no. of days of hospitalization)}.

The potential cost savings calculated did not include cost saving due to initial primary care contacts or indirect societal cost savings (e.g. sick leave costs). Cost savings did not include the salary of pharmacist, primary care physician, or consultant. The average cost of treatment was calculated according to the University of Jordan Hospital's average cost per day.

Statistical methods

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) for Windows, version 20 (SPSS Inc, Chicago, Illinois). Continuous data obtained before and after the study for each participant were analyzed using the two-sided paired t-test. Continuous data between the two groups were analyzed by the 2-sample t-test. $P < 0.05$ was considered statistically significant

RESULTS

A total of 560 patients were admitted to the cardiology department between August 2014 and January 2015. The total number of patients recruited was 100 randomly selected patients representing 17.85 % of admissions. The demographic details and clinical characteristic of all patients are summarized in Table 1.

During the study period, the total number of identified TRPs was 760 incidents [51.18 % for the intervention group and 48.82 % for the control group]. The average number of TRPs was 7.6 ± 26.01. The average number of TRPs in the intervention group was 8 ± 3.86 at their baseline measurement and 2 ± 2.16 at discharge ($p < 0.05$). For the control group, the number of TRPs at admission was found to be 8 ± 3.4 and at discharge 3 ± 2.07, both with significant P-values. The types of TRPs are summarized in Table 2.

The TRPs identified during the study were categorized as previously described [19]. The significance level of TRPs was minor when the TRPs required only small adjustments to optimize therapy. Moderate TRPs required adjustments to enhance the effectiveness of drug therapy. Major TRPs required intervention to prevent the development of DRP [4]. Approximately 453 (56.6 %) of TRPs [275 (60.71 %) in the intervention group and 178 (39.29 %) of the control group] were classified as major. Approximately 237 (31.18 %) of the intervention group and 143 (60.34 %) of the control group were classified as moderate. The remaining 9.21 % of TRPs [20 (28.57 %) of the intervention, and 50 (71.43 %) of the control] were considered minor.

Table 1: Demographic and clinical characteristics of the patients

Variable		N (%) or mean ± SD	Intervention	Control
Age (years, mean ± SD)		63 ± 11.47	63 ± 11.84	62 ± 11.19
Gender	Male (%)	54%	29%	25 %
	Female (%)	46%	21%	25 %
No. of acute and chronic medical problems, mean ± SD		6 ± 4.1	3 ± 2.5	3 ± 2.1
No. of acute medical problems, mean ± SD		2 ± 1.93	1 ± 0.97	1 ± 0.85
No. of chronic medical problems, mean ± SD		4 ± 2.18	2 ± 0.8	2 ± 1.4
No. of pre-admission medications, mean ± SD		6 ± 3.22	4 ± 2.5	2 ± 1.5
No. of current medications, mean ± SD		10 ± 5.44	4 ± 2.9	6 ± 3.5
No. of discharge medications, mean ± SD		9 ± 3.69	5 ± 2.1	4 ± 3.2
	Hypertension	87 (87 %)	50 (100 %)	37 (74 %)
	Diabetes mellitus	63 (63 %)	39 (78 %)	23(46 %)
	Stable angina	49 (49 %)	22 (44 %)	27(54 %)
Chronic conditions	Heart failure	30 (30 %)	14 (28 %)	16 (32 %)
	Dyslipidemia	26 (26 %)	16 (32 %)	10 (20 %)
	Chronic kidney disease	20 (20 %)	6 (12 %)	14 (28 %)
	Chest pain	30 (30 %)	16 (30 %)	14 (28 %)
Admission reasons	Shortness of breath	26 (26 %)	13 (26 %)	13 (26 %)
	Unstable angina	24 (24 %)	9 (18 %)	14 (28 %)
	Decompensated heart failure	17 (17 %)	9 (18 %)	8 (16 %)
	Salicylic Acid	93 (93 %)	50 (100 %)	43 (86 %)
Most commonly used drugs	Furosemide	85 (85 %)	40 (80 %)	45 (90 %)
	Enoxaparin	84 (84 %)	48 (96 %)	36 (72 %)
	Enalapril	80 (80 %)	35 (70 %)	45 (90 %)
	Isosorbide dinitrate 5 mg	75 (75 %	40 (80 %)	35 (70 %)

N = number of observations = 100, SD = standard deviation

Table 2: Treatment-related problems (TRPs) at baseline*

TRPs	Frequency of TRPs N=760 (%)	Intervention group N=389 (%)	Control group N=371 (%)
Indication	157 (20.7)	89 (22.9 %)	68 (18.3 %)
Efficacy	193 (25.4)	101 (26 %)	92 (24.8 %)
Safety	94 (12.37)	45 (11.6 %)	49 (13.2 %)
Inappropriate knowledge	106 (13.9)	54 (13.9 %)	52 (14 %)
Inappropriate adherence	25 (3.29)	11 (2.8 %)	14 (3.8 %)
Miscellaneous	149 (19.61)	77 (19.8 %)	68 (18.3 %)
Additional diagnostic test	66 (8.68)	30 (7.7 %)	36 (9.7 %)
Need for consultation	13 (1.71)	9 (2.3 %)	4 (1.1 %)
Drug not cost-effectiveness	66 (8.68)	38 (9.8 %)	28 (7.5 %)
Discharge TRPs	36 (4.74)	12 (3.1 %)	24 (6.5 %)

(%) Percentage is within the total number of TRPs

During the clinical rounds, approximately 4.1 % of TRPs were diagnosed. Physicians accepted and implemented 275 (71 %) clinical pharmacist recommendations, and made modifications on 47 (12 %) recommendations. Physicians also accepted, but did not implement, 40 (10 %) recommendations. Physicians rejected 11 (3 %) recommendations.

All patients received routine follow-ups until discharged. Significantly more TRPs, 360 (92.55 %), were resolved or improved in the intervention group compared to the 303 (79.85 %) in the control group. Additionally, 9 (2.4 %) TRPs worsened in the control group compared with 6 (1.5 %) in the intervention group. The outcomes of the remaining TRPs were not significantly changed between the two groups.

Clinical results

Physician visits

Number of emergency room (ER), general practitioner (GP), and specialist visits were compared for each patient three months before and after the study. The average number of visits decreased by more than half in the intervention group. The drop-in visits were significant Table 3.

Table 3: Average number of ER or GP visits 3 months before and after the study in the control and intervention group

Variable		Mean (SD)	Difference by t-test	P-value*	P-value** Intervention versus Control
Intervention	ER or GP visits before 3 M	2.12 (1)	1.34 ± 1	0.000	
	ER GP after 3 M	0.78 (.76)			
Control	ER or GP visits before 3 M	3 (2)	1 ± 1.56	0.007	0.007 ± 0.720
	ER GP after 3 M after 3 M	2 (.8)			

*S = standard deviation; *p-value between number of visits 3 months before and after the beginning of the study within each group; **p-value comparison between the difference in the number of ER and GP visits 3 months before and after the beginning of the study between groups by independent t-test*

Table 4: Mean for initial and follow-up adherence scale in each study group

Item		Mean (SD)M	*P*-value**P*-value**P*	Mean**	*P*-value***P*-
Intervention	Admission	14.22 (4.95)	< 0.05		
	Follow-up	6.24 (3.89)			
Control	Admission	10.42 (5.63)	< 0.05		
	Follow-up	9.00 (5.14)		0.65	0.00

*SD = standard deviation; *P-value using paired t-test between initial and follow-up adherence scale within each group*

Table 5: Mean number of initial and follow-up self-care scale in both groups

Item		Mean (SD)	*P*-value*	Mean**	*P*-value***
Intervention	Initial evaluation for self-activity scale at admission	27.62 (6.72)	0.000		
	Evaluation for self-activity scale at follow-up	34.26 (7.02)		-7.80	0.00
Control	Initial evaluation for self-activity scale at admission	28.62 (7.73)	0.140		
	Evaluation for self-activity scale at follow-up	27.4 (7.99)			

*SD = standard deviation; *P-value according paired t-test between initial and follow-up self-care scale within each group*

Length of hospitalization

When comparing the average number of hospitalized days in each group, the mean hospitalization length was (5.00 ± 1.33 versus 4.00 ± 2.36 days) (p = 0.001) and (4.00 ± 2.06 versus 6.00 ± 3.94) (p = 0.004) for the intervention group and control respectively. The length of hospitalization was significantly shorter than expected in the intervention group, while it was longer than the expected in the control group. The difference between the two study groups was significant.

Adherence and self-care activity

When comparing the adherence score during admission and at follow-up, the score was decreased by half in the intervention group, with almost no change in the control group Table 4. Although the difference between outcomes for the adherence scale was significant for both study groups, this change was more pronounced in the intervention group. The main non-adherence reasons were that the physician did not have enough time to explain the proper use of the medication (79 %), patients were taking too many medications at the same time (56 %), patients could not afford expensive medications (40 %), patients did not have suitable time to take their medications (10 %), patients forgot their medications (30 %), patients did not like taking their medications (42 %), and patients stopped taking their medications because of unpleasant side effects (31 %).

Self-care activities were improved in the intervention group, while slightly worsened in the control group. Table 5 shows the average number of self-care activities. Analysis showed equal means between the two groups, meaning there was no significant difference in the change of self-care activity scores between for the intervention group and control respectively.

Cost outcomes

Hospitalization cost

The actual hospitalization cost was less than expected because of the impact of clinical pharmacist in the intervention group Table 6.

Table 6: Mean of expected and actual hospitalization cost in each study

Item		Mean (SD)	*P*-value
Intervention	Expected hospitalization cost	319.84 JD ± 219.04	0.006
	Actual hospitalization cost	260.77 JD ± 259.21	
Control	Expected hospitalization cost	256.50 JD ± 187.51	0.002
	Actual hospitalization cost	333.30 JD ± 269.98	

P-value by paired t-test; between expected and actual hospitalization cost within group

Direct drug cost

The potential financial impacts that result from implementation of counseling pharmacist provided in the intervention group in the cardiac unit was also determined. Direct savings in drug cost arising from clinical pharmacist intervention were because of the discontinuation of medications due to inappropriate use (e.g. lack of indication, drug-drug interactions, etc.). The monthly costs of drugs prior to admission and at discharge were estimated. When calculating the average cost of medications per month, it was found that within the intervention group, the average cost were $235.37 ± 194.99 in personal treatment allowance (PTA) before admission versus $245.51 ± 236.12 after discharge (p < 0.002). The control group (PTA) before admission were $232.13 ± 170.03 and after discharge were $229.33 ± 203.03 ($p$ = 0.000).

The costs increased in both groups; however, this does not mean that the clinical pharmacists did not lower cost effectively. If the cost saving extrapolated to the whole year, the observed increase in the direct cost is paralleled by a decrease in indirect costs, (e.g. re-hospitalization, the need more emergency care, and increased GP visits). There is financial impact of the pharmacist interventions on the cost of drug therapy as the total net cost savings over the study period. Further research is needed to validate our finding that the provision of clinical pharmacy services in an the hospital provides value for money to the healthcare system.

Laboratory data monitoring:

We examined the probability that a clinical pharmacist can positively influence other outcomes, such as improvement of levels of markers for drug use (e.g. Optimization of lipid levels, blood pressure and glycated haemoglobin test. Active participation of clinical pharmacists greatly improved the laboratory data readings as shown in Table 7.

Table 7: Laboratory data comparison at baseline and at follow-up

Category	Intervention N=50 Mean ± SD	Control N=50 Mean ± SD
HbA1c baseline	10.38 ± 1.68	9.98 ± 1.54
HbA1c at follow-up	7.7 ± 1.68	9.7 ± 1.36
Systolic BP baseline	137 ± 18	120 ± 14
Systolic BP follow-up	128 ± 5.7	128 ± 5.7
Total cholesterol baseline	116 ± 5.7	120 ± 8.2
Total cholesterol follow-up	96.32 ± 8.6	106 ± 8.8
LDL baseline	85 ± 8.7	86 ± 8.7
LDL follow-up	71.5 ± 5.7	77 ± 11.6

DISCUSSION

Clinical pharmacy is an important part of creating an effective healthcare team that best utilizes medicine. Collaboration between physicians and clinical pharmacists can effectively minimize TRPs and morbidity and mortality rates, and improve overall quality of life [24]. Team-based care increases quality through optimization of drug use, avoidance of adverse drug events and transitional care activities focusing on medication reconciliation and patient education. This is the first study conducted in Jordan with the aim of evaluating the potential utility of clinical pharmacy services for hospitalized CVD patients.

Patients with CVD are at significant risk for adverse drug events and medication errors due to polypharmacy. CVD patients often have concomitant diseases and more frequently use high risk medications.

The propensity for error in cardiovascular medications can be partially attributed to the rising number and complexity of options [22]. Cardiovascular hospitalized patients are at particularly high risk for developing TRPs. TRPs preclude many patients from the full benefit of pharmacological treatment [23], resulting in unnecessary suffering for patients and higher healthcare costs for society [12]. CVD can progress rapidly from patient non-adherence to regular outpatient visits. This requires special

efforts during hospitalization and more clinical attention to modify medication regimen and lifestyle to minimize disease progression.

Most patients had multiple TRPs, which were largely of major significance. Issues with efficacy and indication problems most frequently caused TRPs [3]. Not following physician's orders, in addition to discomfort from multiple TRPs, causes avoidable re-hospitalization as well as higher costs to patients and society [4]. Systematically implementing clinical pharmacist services can decrease TRPs and related negative consequences [5]. Better management of blood pressure and other laboratory monitored outcomes such as lipids profile and HbA1c resulted from follow-up with the clinical pharmacists. Utilizing clinical pharmacists leads to lower incidences of TRPs, improves patient functional capacity and compliance to treatment, all of which improve overall quality of life [3,4,5].

Non-pharmacological interventions are cost effective by changing CVD patients' lifestyle choices (e.g. reducing salt intake, starting exercise classes, or even walking). These cost effective changes decrease re-hospitalization rates and disease progression [25]. The cardiovascular benefit resulting from reducing salt intake to 1 gram per day is analogous to using medications to lower blood pressure in adults with hypertension [26]. Including pharmaceutical care in the treatment of patients with CVD will result in significant reductions in the risk of hospitalizations when paired with improvements in lifestyle choices [25]. Those improvements reflect drug adherence, especially to diuretics or ACEI (e.g. enalapril) and were also observed in our intervention group.

The amount of time spent with the physician was not adequate to explain all the necessary information about prescribed drugs and overall disease state. Clinical pharmacist's time with patient improved patients' use of medications, as demonstrated by decreased safety and drug-drug interaction issues which increased drug efficacy. Better therapeutic outcomes were achieved with the implementation of the clinical pharmacist's recommendations and the positive influence on patient education and adherence.

The number of hospitalization days decreased, adherence and self-care activities improved, and the number of emergency visits also decreased. These results support previous findings in the literature in which clinical pharmacist services had a positive impact on decreasing the number of TRPs and achieving treatment goals [6, 7, 18 and 20]. Studies that proved the cost benefit of clinical pharmacy services and its effect on hospitalization length, re-hospitalization rates, and long-term cost support our study's results [21,22]. While Wallerstedt [24] concluded that clinical services had no cost benefit for patients or effect on re-hospitalization rate, our studies and others disagree.

Other studies concluded like ours that clinical pharmacist services increase the direct cost, while the long-term costs decrease through lower indirect costs [11]. When we compared a three-month period pre-study GP, specialist, and emergency visits versus post-discharge the total cost was lower. The intervention group cost saving from the clinical pharmacist's interventions was an average of $219 per year [24]. Decreased hospitalization length lowered cost, as seen in reductions in the cost of intervention group. The direct cost for the patient, as determined by comparing the monthly drug cost drugs pre- and post-study, was not reduced in either group. Because government hospitals are subsidized, this recommendation may initially increase the financial burden on the government and the hospital. However, only two clinical pharmacists in the cardiac department could manage all patients and alleviate the long-term financial burden.

Limitations of the study

The study has some limitations. No statistical data seem to be available from previous studies to compare. Longer term cost-effect analyses are outside the scope of this study. We were restricted to medications available within the hospital and patient insurance. Community pharmacies may have more alternatives available than the clinical pharmacist had.

CONCLUSION

Therapy-related problems are common in the cardiovascular unit in Jordanian hospital. Clinical pharmacist's role in a hospital setting positively impacts the quality of patient care by reviewing the drug therapy for identification and resolution of drug related problems which helps in achieving better therapeutic outcomes and improved patient care. Thus, the clinical pharmacist practice is a crucial part of a health care team to improve the level of patients' care by increasing the quality of therapy with the least expense for cardiovascular units in hospitals. Therefore, pharmaceutical care services should

be implemented for hospitalized CVD patients since their presence has been proved to be very helpful.

DECLARATIONS

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Conflict of interest

No conflict of interest is associated with this work.

Contribution of authors

We declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by them. Dr. Refae conceived of and designed the study and collected and analyzed the data. Dr. Sawsan wrote the manuscript. Both authors read and approved the manuscript for publication.

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