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A Clinical Trial to Investigate the role of Clinical Pharmacist in Resolving/Preventing Drug Related Problems in ICU Patients Who Receive Anti-infective Therapy

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ABSTRACT

To highlight the role of the clinical pharmacist in resolving/preventing drug related problems and to measure the acceptance of the pharmaceutical care plan for patients who receive anti-infective therapy in the intensive care unit. Two groups of patients were randomly selected from general intensive care unit ward of the King Hussein Medical Center, Royal Medical Services, Amman, Jordan ; Intervention group, n=52 and control group, n=50. The intervention group received complete pharmaceutical care services. Consult notes were written to identify drug related problems according to a pharmacy care plan. Clinical pharmacist's recommendations for the intervention group were submitted to and discussed with physicians. Acceptance rate of the recommendations was then measured. A total of 251drug related problem were identified for both groups. For the intervention group, the physicians' acceptance rate of the submitted recommendations was very high (around 98%). Clinical pharmacist plays a key role as member of multidisciplinary team as he is able to assess the patient's medication treatment from different aspects during intensive care unit stay; consequently, physicians are increasingly accepting the clinical pharmacist recommendations regarding drug related problems for patients in intensive care unit.

Keywords: Clinical pharmacist, Drug related problem.

INTRODUCTION

Errors are common in most health care systems and are reported to be the seventh most common cause of death overall[1]. A recent systematic review demonstrated that adverse effects occurred in approximately 9% of patients admitted to hospitals and lead to a lethal outcome in 7% of cases; A large portion of these events were operations or drug related problems(DRPs); moreover, most of these events were preventable[2].

DRPs may result in reduced quality of life and increased morbidity and mortality. At least one DRP was found in about four fifth of patients in general hospitals [3, 4]. DRPs have several classifications; AbuRuz, et al[5] (2006) carefully examined these classifications and then determined that DRPs can be pooled under six main categories; Indication, Effectiveness, Safety, Knowledge, Adherence, Miscellaneous.

There is an imperative for hospital-based clinical pharmacists to become involved in the management of patients through the process of pharmaceutical care provision. Pharmaceutical care has been defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life[6].

In the intensive care unit (ICU), Patients are prescribed medications under stressful, complex and changing environment and under the stewardship of multiple providers [7]. It is important to remember that critically ill patients have fewer defenses against adverse events than other patients do. Moreover, they have

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limited ability to participate in their medical care.

This study is an attempt to highlight the role of the clinical pharmacist in resolving/preventing drug related problems and to measure the acceptance of the pharmaceutical care plan for patients who receive anti-infective therapy in the ICU.

Methods

Two groups were selected randomly; control (n=50) and intervention group (n=52). Randomization was done according to computer generated randomization table (www.randomization.com). The study was carried out at the general ICU ward of the King Hussein Medical Center at the Royal Medical Services (RMS), Amman, Jordan, from October, 2009 till April, 2010. This ICU has 37 beds. Average of 35 patients were admitted every week from internal medicine, surgery and traumatic patients (for example, road traffic accidents). Five ICU physicians working in the ward were involved in the study (two intensivists and three attending physicians).

It should be mentioned that the approval from the ethics committee in the RMS was granted to conduct this study.

Each new ICU admission was reviewed by the clinical pharmacist for inclusion into the study. Subjects were recruited daily from Saturday to Thursday (except Friday) between 8.00 AM and 2 PM. The clinical pharmacist recruited and followed up 4-5 patients per week (inclusion criteria are mentioned below). Written consents for participation were obtained from all patients or their health guards, i.e. the person who was taking care of the patient if he was unconscious (mostly, father, brother, son, etc.)

Patients eligible for inclusion in the study should be over 14 years (in DRMS, patient under 14 years is considered as child and should be referred to Queen Rania Hospital for children) and receiving antimicrobial treatment in the ICU. All patients included in the study were followed up until they were transferred from the ICU to other wards or died. Patients who had life-threatening drug-related problems were excluded from the study due to ethical reasons.

The intervention group received complete Pharmaceutical Care service including five steps:

1- Collecting patient database.

A. The database was collected from patients' medical files for demographics, medical characteristics, lab and other diagnostic tests.

B. All conscious and oriented patients (if otherwise, their legal guardians) were interviewed to obtain any information missing from patients' medical files.

C. The clinical pharmacist participated in the clinical rounds and discussed the cases with physicians who were taking care of ICU patients to obtain new information, or to clarify missing or incomplete data.

2- Patient's database was analyzed to identify DRPs.

3- A pharmacy care plan (PCP) was designed to address each DRP.

4- Consult notes were written to address the identified DRPs according to the pharmacy care plan and submitted to the responsible physician (attending or consultant).

5- Patients were followed up to ensure implementation of recommendations and to measure the desired outcomes.

The control group received only the first three steps of Pharmaceutical Care service without submitting consult notes to the physician. DRPs were identified without any intervention. However, all identified DRPs were documented in the form of PCPs and the outcomes of the drug related problems were monitored and recorded.

DRPs classification used in this study was designed by AbuRuz, et al, 2006. One clinical pharmacist, holding MSc degree in clinical pharmacy, was recruited to review, follow up the patients and submit consult notes to the physician.

Results*:*

The demographic characteristics of the study sample are shown in Table 1. The mean age for the intervention and control groups was 54.7, and 52 years respectively, with no statistical difference between groups.

Table 1: Demographic characteristics of the study samples

Parameter	Control group	Intervention group	Total population	P value*
Age, mean (SD)	52 (19.1)	54.7 (18.9)	53.4 (18.9)	0.48
Gender, male N (%)	29 (58)	25 (48.1)	54 (52.9)	0.32
Weight (kg), mean (SD)	76.5 (9.9)	75.2 (10.1)	75.8 (10)	0.54

* Independent t-test and Chi-square were used as appropriate

There were no statistical differences between the intervention and control groups regarding frequency of medical conditions and the number of current medications received (Tables 2).

Table 2: Clinical characteristics of the study sample*

Parameter	Control group	Intervention group	Total population	P value**
Number of chronic medical conditions	1.42 (1.43)	1.69 (1.65)	1.56 (1.55)	0.375
Number of current medications	6.3 (2.53)	6.92 (2.84)	6.62 (2.7)	0.245

*Parameter described as mean (standard deviation) unless otherwise stated

** Independent t-test

In general, a total number of 251 DRPs were identified during the study period for both groups (Table 3); 109 DRPs in the control group and 142 DRPs in the intervention group. The mean number of DRPs was 2.5±1.5 (i.e. two-to- three DRPs for each patient). There was no statistical difference in the number of identified DRPs between the intervention and control groups (2.7±1.7 and 2.2±1.1, respectively, P>0.05; CI -1.1 to 0.05) before the intervention. The most common types of DRPs identified were the need for additional therapy (29.9%) and safety dosage regimen (21.1%).

Table 3: DRPs identified during the stay in the ICU

Type of DRP	Number of DRPs in control group (% from 109 DRPs)	Number of DRPs in intervention group (% from 142 DRPs)	Number of DRPs in total population (% from 251 DRPs)
The patient requires additional therapy	37 (34)	38 (26.8)	75 (29.9)
Efficacy dosage regimen issues	28 (25.7)	16 (11.3)	44 (17.5)
More effective drug is available	4 (3.7)	14 (9.9)	18 (7.2)
Untreated condition	2 (1.8)	3 (2.1)	5 (2)
Safety dosage regimen issue	19 (17.4)	34 (23.9)	53 (21.1)
A current drug is contraindicated/unsafe	0	2 (1.4)	2 (0.8)
Allergic reaction or an undesirable effects	0	1 (0.7)	1 (0.4)
Duplication of therapy	12 (11)	15 (10.6)	27 (10.8)
Drug use without an indication	2 (1.8)	16 (11.3)	18 (7.2)
Other dosage regimen issues	5 (4.6)	3 (2.1)	8 (3.2)

Table 4 shows the outcomes of clinical pharmacist's interventions for the patients in the ICU. For example, an action was made to correct 93 DRPs in the intervention group, although the outcome was not measured throughout the study period; the therapeutic outcome was achieved after intervention in 31 DRPs and other 14 DRPs were prevented.

Table 4: Outcomes of the clinical pharmacist interventions during ICU stay

Outcome	Control group N (%)	Intervention group N (%)	Total population N (%)	P value
DRPs resolved/corrected *	6 (5.5)	93 (65.5)	99 (39.4)	<0.0001
DRPs resolved/improved **	0	31 (21.8)	31 (12.4)	<0.0001
DRPs were prevented	0	14 (9.9)	14 (5.6)	0.023
No change	89 (81.7)	4 (2.8)	93 (37)	<0.0001
Worsened	14 (12.8)	0	14 (5.6)	0.001

*Resolved indicates that an action was made to solve/correct the DRP

** Resolved indicates that therapeutic outcome was achieved

The most common drug classes associated with the identified DRPs were antibiotics (42.2%), followed by H 2 blocker/ Proton Pump Inhibitors (17.9%) then insulin (12.4%). Data is shown in table 5.

Table 5. Drug classes associated most frequently with DRPs

Drug class N of DRPs (% from total DRPs)	The most important DRPs	Frequency
Antibiotics 106 (42.2)	Duplication	25
	Safety dosage regimen issues	20
	Drug use without an indication	16
	Patient requires additional therapy	14
	Efficacy dosage regimen issues	13
	More effective drug is available	11
H 2 blocker/ Proton pump inhibitors 45 (17.9)	Safety dosage regimen issues	27
	Efficacy dosage regimen issues	10
	Patient requires additional therapy	7
Regular insulin 31 (12.4)	Efficacy dosage regimen issues	13
	Patient requires additional therapy	10

A total of 251 consult notes were written for both groups. Only the recommendations in the intervention group were submitted to and discussed with physicians. The acceptance rate by physicians was very high (97.9%; Table 6). Only 6 DRPs in the control group were identified and corrected by physicians by their own.

Table 6: Physician's acceptance of pharmaceutical care recommendations

Parameter	Control group N (%)	Intervention group N (%)
Number of recommendations in ICU	109	142
Number of submitted recommendations	0	142 (100)
Number of agreed (accepted) recommendations	0	139 (97.9)
Number of treatment related problems corrected by physicians without pharmacists intervention	6 (5.5)	0

Discussion

In this study every patient had at least one DRP with a mean of 2.5 problems. "The need for additional therapy" (30%), "Safety dosage regimen issues" (21%) and "Efficacy dosage regimen issues"(18%) were the most common DRPs in the current study; also being comparable to previous studies. Kassam et al[8] (2001), Gurwitz and Rochon[9] (2002) and Viktil et al[10] (2006) found that the "Need for additional therapy" was the most common DRPs (35%), while Paulino et al[11] (2004) and Benkirane et al[12] (2009) found safety (23%) and efficacy (12%) dosage regimen issues to be the most common DRPs among ICU patients.

The high prevalence of "The need for additional therapy" and "The efficacy dosage regimen issues" may indicate that disease management by the medical team was not always based on the management guidelines and/or the follow-up of the pharmacotherapy outcomes was improper.

Safety dosage regimen issues could reflect that the medical team, on many occasions, failed to prescribe the correct dose based on patient's renal function, the adverse effects were improperly monitored, and/or frequency/duration of drug administration was inappropriate.

Eighteen percent of the identified DRPs were "Duplication of drug therapy" plus "More effective drug is available" suggests that the medical team did not have had enough pharmacological information about the classes of medications, was not using disease treatment guidelines systematically, and/or there was no collaboration between the medical team and the inpatient pharmacy in terms of the availability of the medications. This emphasizes the role of clinical pharmacists who are uniquely trained in therapeutics and provide comprehensive drug management to patients and drug information to members of medical care team.

In this study "Untreated condition" comprised only 2% of the identified DRPs, but many of these conditions were chronic; diabetes mellitus is an example. Medical teams are usually not aware or less cautious about medical conditions that are not related to their specialty. Again, this emphasizes the role of a clinical pharmacist who can follow up and assess the patient treatment from every aspect.

A very important finding was that about 98% of the submitted recommendations were accepted by the physicians. This indicates the high quality of submitted recommendations; in addition, this reflects that physicians started to trust the role of the clinical pharmacist and accept his recommendations. On the other hand, it should be mentioned that lower acceptance and implementation rates were presented in previous studies conducted in hospital setting; for example, Rhoads et al[13] (2003) found that 89% of the recommendations were implemented and Triller et al[14] (2003) found that only 65% of the recommendations were implemented.

The clinical pharmacist interventions were significant; 65.5% of the DRPs in the intervention group were resolved and corrected, 21.8% were resolved and improved and no cases were worsened.

Conclusions

Drug choices, dosage regimen and patient monitoring should be given the highest priority in the ICU department as they are associated with the most significant and sometimes lethal DRPs. The involvement of a clinical pharmacist in the care of critically ill patients is associated with improved patient clinical outcomes.

Significantly, more DRPs were resolved/prevented among the patients who received Pharmaceutical Care services compared to those patients having only standard medical care.

Clinical pharmacist plays a key role as member of multidisciplinary team since he is able to assess the patient's medication treatment from different aspects during ICU stay; consequently, physicians are increasingly accepting the clinical pharmacist recommendations regarding drug related problems for patients in the ICU.

The current study provided additional evidence supporting the role of a Clinical pharmacist in the health care system and can serve as a model for optimizing management of DRPs in ICU departments.

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تجربة سريرية للتحقيق في دور الصيدلي السريري في حل / منع المشكلات المتعلقة بالعلاجات للمرضى الذين يتلقون مضادات العدوى في قسم العناية المركزة

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ملخـص

إبراز دور الصيدلي السريري في حل/منع المشكلات المتعلقة بالعلاجات وقياس نسبة قبول خطة الرعاية الصيدلانية للمرضى الذين يتلقون مضادات العدوى في قسم العناية المركز. تم اختيار مجموعتين من المرضى عشوائيا في قسم العناية المركزة في مستشفى الحسين، الخدمات الطبية الملكية، عمان، الأردن، مجموعة التدخل (52 مريضا) و المجموعة الضابطة (50 مريضا)، حيث تلقت مجموعة التدخل كامل خدمات خطة الرعاية الصيدلانية. تم كتابة مذكرات للتشاور و تحديد المشكلات المتعلقة بالعلاجات وفقا لخطة الرعاية الصيدلانية. وقدمت توصيات الصيدلي السريري العائده إلى مجموعة التدخل لمناقشتها مع الأطباء. ثم تم قياس معدل قبول التوصيات. تم تحديد ما مجموعه 251 مشكلة متعلقة بالعلاجات لكلا المجموعتين. كان معدل قبول الأطباء للتوصيات المقدمة لمجموعة التدخل عالية جدا (حوالي 98٪). الصيدلي السريري يلعب دورا رئيسا بوصفه عضوا في فريق متعدد التخصصات، لأنه قادر على تقييم العلاجات الدوائيه للمريض من جوانب مختلفة خلال إقامته في العناية المركزة ، ومن ثم، فإن الأطباء يقبلون بشكل متزايد توصيات الصيدلي السريري بشأن المشكلات المتعلقة بالعلاجات للمرضى في وحدة الرعاية المركزة.

الكلمـات الدالـة: المشكلات المتعلقة بالعلاجات، الصيدلي السريري، مضادات العدوى.

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