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The potential role of clinical pharmacist in the practice of heart transplantation

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Abstract:

Due to the complexity of heart transplant procedure and risk of organ rejection, most heart transplant patients receive multiple medications such as antibiotics, antifungals, and immunosuppressants. Since some medications have narrow therapeutic indexes, more attention is needed by the clinical pharmacists to solve and reduce medication-related problems. Pharmacists can play an essential role in assisting patients and physicians in receiving better treatment with the lowest risk of medication errors.

The purpose of this study was to investigate the types and quality of clinical pharmacist recommendations, the recommendations acceptance rate, and the outcomes related to clinical pharmacist interventions in heart transplant patients. The study was conducted at National Research Institute of Tuberculosis and Lung Diseases (NRITLD), Dr.Masih Daneshvari Hospital, a university affiliated hospital, Tehran, Iran. Main outcome measures included determination of the quality of clinical pharmacist recommendations, physician acceptance rate and the effects of recommendations on patients' clinical outcomes. Clinical pharmacist recommendations were divided into ten categories, and physicians' acceptance rate for each recommendation was recorded. The quality of pharmacist recommendations was also classified into six categories.

The total number of recommendations that were recorded for 46 patients was 344, about 7.47 recommendations per patient. Dose adjustment recommendations were the most recommendations that were made (n=100, 29.06 %). However, this type of recommendation had the lowest physician acceptance rate (62%). Antibiotics had the least acceptance rate in dose adjustment recommendations (40%). Clinical pharmacist recommendations in the drug interaction category prevented 265 moderate and 28 severe interactions, respectively. Clinical pharmacist made 27 (7.84%) extreme significant recommendations and 88 (25.58%) significant recommendations.

Clinical pharmacists could have a critical role in optimizing medication regimens and minimizing drug interactions as well as adverse reactions in transplant patient care and their treatment programs.

Keywords: Pharmacists; Heart Transplantation; Patient Care; Drug-Related Problems

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1. Introduction

Heart transplantation (HT) is still considered a life-saving and definite gold-standard surgical procedure in treating end-stage heart failure. Heart transplantation enhances the quality of life and the survival rates of recipients [1]. The HT patients undergo a long and complicated

pharmacotherapy program, and this program consists of a variety of medications, including immunosuppressants, corticosteroids, and blood pressure and lipid regulating drugs with varied patient adherence [2]. Due to the narrow therapeutic window, close and direct monitoring in the pharmacotherapy process seems to be vital [3]. Drug-induced complication from chronic immunosuppression is one of the serious challenges in heart transplant patients, contributing to patient morbidity and mortality [4]. The incidence of adverse drug reactions and relevant concerns lead to non-adherence, causing heart transplant rejection [5]. A study reported that 40% of hospital admissions after HT are drug-related, and 58% of these cases are preventable [6].

A clinical pharmacy specialist plays a significant role before, after, and during the transplantation process. Part of their role is helping the physicians with pharmacotherapy consultations and also aiding patients with their education and drug compliance [7,8]. Several studies had confirmed the value of clinical pharmacist contribution and interventions in transplantation [9,10]. Targeted drug blood levels are more likely to be reached in patients with a clinical pharmacist in their transplant team [11]. Moreover, clinical pharmacist services decrease the costs of health care by reducing patients' hospital length of stay [12,13]. For instance, a study reported that clinical transplant pharmacy interventions decrease the inpatient length of stay of kidney transplant patients [14].

To optimize the quality of heart transplant recipients' services and improve the overall survival rates, adding a clinical pharmacist to the transplant team will be of great importance. The previous evidence showed that clinical pharmacists play a key role in preventing medical errors and irrational medication consumption [15,16], enhancing ADR reporting [17], improving quality of life [18], reducing medication costs [19], controlling the complications and achieving the treatment goals [20], and promoting patients treatment satisfaction and adherence [21]. Therefore, there is an unmet need for clinical pharmacy services in transplant teams, especially in developing countries [22].

Current study is a retrospective study using the clinical records of all heart transplant surgery patients from May 2015 to May 2017. Since there were no similar studies in heart transplant patients, our study aimed to assess the types and quality of clinical pharmacist recommendations, the recommendations acceptance rate, and the outcomes in heart transplant patients.

2. Materials & Methods

2.1. Settings

The study was conducted at National Research Institute of Tuberculosis and Lung Diseases (NRITLD), Dr.Masih Daneshvari Hospital, a university affiliated hospital, Tehran, Iran.

2.2. Data Collection Form Design

A form was designed by five clinical pharmacy specialists based on the comprehensive review of resources, including previous studies [20].

The form included the following information: name, case number, age, sex, date of transplantation, date of discharge, duration of admission, cause of death, frequency of readmission, and the reason for the patient's readmission.

In addition to the mentioned information, a special form was developed for each patient, including the classification of prescribed drugs, the type of pharmacotherapy recommendation, the physicians' acceptance rate in each recommendation, the incidence of post-transplant infection, and the laboratory data before and after the recommendations.

2.3. Study Implementation

In this study, a list of heart transplant patients with at least one pharmacotherapy consultation completed form was prepared. Patients who did not survive within 24 hours after transplant surgery were excluded from the analysis. These consisted of patients who died in the operating room or within several hours of leaving the operating room, presumably as a result of non-drug-related complications.

All patients' information was recorded according to pre-designed forms. Subsequently, a full review of the patients' history before, after, and during the transplantation was done. Pharmacotherapy consultations were recorded on a case by case basis and with the date of consultation in the relevant form.

Pharmacotherapy consultation process was as follows: each patient was visited by a clinical pharmacist on the basis of receiving written consultation request from the physician in charge or as a verbal request during the clinical rounds.

Patients' medication histories and medical charts were carefully reviewed to identify drug-related problems. Relevant laboratory data (e.g. liver function test and serum creatinine) as well as vital signs (e.g. blood pressure and pulse rate) were all recorded to support the appropriateness of the interventions. A pharmacotherapy sheet or the consultation form consisting of one or more recommendations was then left in the patients` chart for the physician's approval. Any approved recommendation was finally reordered in physician's order section of the medical chart by the responsible physician. Interventions were categorized into ten categories (Table 1).

In order to document physicians' orders, patients' files were used. The physician acceptance of clinical pharmacist recommendations was also evaluated.

The incidence of infection and its cause, the causes of death, the causes of initial hospitalization, and the duration of admission were documented. Also, in cases of patient readmission, the frequency and causes of readmissions were recorded.

In terms of the types of recommendations, clinical pharmacist recommendations were divided into ten categories, and physicians' acceptance rate for each category was recorded. The quality of pharmacist recommendations was also classified into six categories based on criteria determined in previous studies (23–25) (Table 1 and 2). Moreover, the dose adjustment recommendations were classified based on the drug class consisting of antibiotics, immunosuppressants, corticosteroids, antifungals, and gastrointestinal agents (Table 3). Antiviral for cytomegalovirus prophylaxis was used post-transplantation as well, but there was no related dose adjustment recommendation for the studied patients.

Drug interactions were categorized into three categories - weak, moderate, and severe- using the related databases (drugs.com and uptodate.com).

Considering laboratory data, as response to intervention for lipid profile management needs longer period, we assessed the levels of cholesterol and triglyceride up to 2 months, while other laboratory data, including fasting blood glucose, liver function tests, renal function (serum creatinine) and blood pressure have been assessed up to 2 weeks. These factors were categorized before and after the clinical pharmacist recommendations to three categories: improved, maintained, or regressive.

2.4. Statistical analysis

In this study, SPSS (Statistical Package for the Social Sciences) version 23.0 was used to analyze the descriptive data. The results were provided by mean± SD or median if necessary.

Table 1. Type of recommendations and acceptance rate.

Type of consultation	Dose adjustment	Drug interaction	Pre-surgery recommendations	appropriate pharmaceutical dosage form	Nutritional recommendations	Drug discontinuation	Recommendations based on lab results	Recommendations regarding drug-drug and food-drug intervals	Best choice based on patient's condition	ADR	Total
No. of consultation	100	12	39	34	22	40	31	18	40	8	344
%	29.06	3.48	11.33	9.88	6.39	11.62	9.01	5.23	11.62	2.32	100
Accepted recommendations	50	12	35	34	22	25	31	15	27	8	259
Acceptance rate (%)	50	100	89	100	100	62.5	100	75	67.5	100	75.29

Table 2. Clinical pharmacist recommendations' quality categories.

Quality of Clinical Pharmacist Intervention	
Adverse significant	The recommendation resulted in adverse outcomes
Slightly significant	The recommendation is helpful in increasing awareness but its absence won't affect the treatment
Significant	The recommendation leads to general improvement in patient's treatment.
Much significant	The recommendation will protect the organ and decrease the risk of rejection
Extreme significant	The recommendation will lead to elimination of a life threatening factor
Not significant	The recommendation is neutral or lacks clinical significance

3. Results and Discussion

Among 46 heart transplant patients, 344 recommendations were documented, approximately 7.47 recommendations per patient. The study population consisted of 36 (%76.26) males and 10 (%21.73) females. The most two common age groups in our study were 30-40 years (n=17, %36.9) and 50-60 years (n=16, %34.78), and only one patient was under 20 years old. To assess the quality of clinical pharmacist interventions, the recommendations were classified into 6 different categories based on their quality and impact (Table 1). The pharmacotherapy recommendations were categorized into 10 categories. Dose adjustments recommendations (n=100, %26.6) were the most made ones. Equally, two categories came second; recommendations on drug discontinuation (n=40, %11.62) and adding a new drug (n=40, %11.62). The adverse drug reactions category had the fewest number of recommendations. Out of 344 recommendations, 259 (%75.29) were accepted by the physicians. Five categories had a %100 acceptance rate, while the lowest acceptance rate belonged to dose adjustment recommendations (50%) (Table 2). In the dose adjustment recommendations category, antibiotics accounted for the lowest acceptance rate (40%), whereas gastrointestinal medications had the highest rate of acceptance (100%) (Table 3).

Analyzing the severity of medication interactions ,that were prevented, showed a notable number of moderate interactions (n=265, %83.59). However, major interactions had a smaller percentage (n=28, 8.83%), while the minor category accounts for 7.5% (n=24) of all interactions.

Considering the quality of recommendations, only 7.26% (n=25) of clinical pharmacist recommendations were not significant. The majority of recommendations were classified as slight significant (n=122, %35.46). Moreover, the proportions of those recommendations categorized as significant and much significant were quite similar, at %25.58 (n=122) and 23.83% (n=82) respectively. Extreme significant recommendations, made by clinical pharmacists, represent 7.84% [27] of all suggested interventions. Finally, none of the recommendations were classified as adverse significant.

Most patients' outcomes after recommendations were improved (n=37, %80.43), and only two cases had regressive outcomes (n=2, %4.34) (Table 4).

Regarding hospital readmissions, seventeen cases were recorded, and among them, the most common cause was pneumonia (n=5, 10.86%). Also, twelve severe infections were documented. From 9 deaths in transplant patients, only one was due to severe organ rejection.

Out of 344 recommendations, the mean number of clinical pharmacist services for each patient was 7.47. Clinical pharmacists mainly gave dose adjustment recommendations. However, adverse drug reactions had the smallest number of recommendations. In 92.42% of the cases, the drug interactions that were prevented were classified as moderate and major interactions. Regarding the quality of clinical pharmacist recommendations (Table 1), 31.67% of the cases were determined as much and extreme significant. Also, %75.29 of the recommendations were accepted by physicians.

Table 3. Dose adjusment recommendations and their acceptance rate according to drug class.

Drug class	Antibiotics	Immunosuppressants	Corticostreoids	Antifungals	gastrointestinal agents	Total
No. of recommendations	55	15	10	15	5	100
No. of accepted recommendations	22	8	6	9	5	50
Acceptance rate (%)	%40	%53.33	%60	%60	%100	%50

Table 4. Patients' outcomes, 2 weeks after transplantation and clinical pharmacist interventions.

	Improved	Maintained	Regressive	Total
Fasting blood glucose	9	3	1	13
Serum creatinine	14	2	1	17
LFT	8	2	0	10
Blood pressure	15	2	1	18
Patients' lipid profile outcomes, 2 months after transplantation and clinical pharmacist interventions				
Cholesterol / triglyceride	6	0	0	6
Total	37	7	2	46
%	80.43	15.21	4.34	100

For each patient 7.47 recommendations were recorded compared to 1.48 recommendations per patient in Wang et al., a similar study in kidney transplant patients, [23]. Comparing the number of recommendations, a heavy workload of a clinical pharmacist providing services on the care of transplant patients could be assumed in our center. On the other hand, the high number of recommendations might be a result of various drug-related problems in physicians' orders. It seems that physicians need to enhance their practice by more adhering to standard guidelines so that the clinical pharmacist can redirect their focus to more critical issues.
Dosage adjustment represents the highest percentage of clinical pharmacist recommendations (29.06%). A similar study conducted on kidney transplant patients in 2008 found that dose adjustment recommendations were only 14.5% [23]. One of the reasons for our higher rate could be physicians' non-compliance with treatment guidelines, especially for antibiotics and antifungals. Considering the importance of the right dose for medications with narrow therapeutic windows, the presence of clinical pharmacists seems to be necessary in such cases. A study conducted in Tehran from 2008 to 2009 reported a 70.8% adherence rate of physicians to guidelines in antibiotics therapy [26]. With regard to antibiotic therapy, the differences in physicians' adherence rate to guidelines among centers may stem from the differences in the antimicrobial resistance and the patterns of antibiotic use. Also, the differences in physician specialties may be another reason for this variability.
Physicians accepted 259 recommendations, with an overall acceptance rate of 75.29%. A mean number of 5.63 recommendations per patient were accepted. Although dose adjustment recommendations were the most common ones, physicians only accepted half of them. In fact, lower compliance in the categories with the highest number of recommendations was observed. Wang et al. reported the mean acceptance rates based on the drug class and type of recommendations that were 96.0% and 97.1%, respectively [23]. Even if our study acceptance rate considered acceptable, Wang et al. results imply that they had much better acceptance, reflecting more cooperation of their physicians and better compliance with clinical pharmacist services. A review article in 2010 revealed that physicians' acceptance rate in solid organ transplantation were generally above 95%, with the lowest acceptance rate of 82% for liver transplantation [27]. A recent cross-sectional study conducted in a neurology ward in Iran reported a 41.91% acceptance rate among physicians [15]. Although in 2009, a study conducted in a nephrology and infectious diseases ward in Iran reported 95% as an acceptance rate [28].
Of 28 cases of medication interactions, the clinical pharmacist intervened in the following common major interactions: digoxin and amiodarone, itraconazole and atorvastatin, pantoprazole and digoxin, itraconazole and tacrolimus, and ivabradine and endonestrone. A study conducted by Rivkin et al. in 2011 found that clinical pharmacist presence in ICU could reduce drug-drug interactions by 65% [29]. Another study confirmed that clinical pharmacist interventions reduced clinically relevant drug-drug interactions in patients with heart failure [30].
Thirty-nine cases of clinical pharmacist interventions were related to pre-surgery recommendations. Upon physician's request, before transplant surgery, all patients' drugs should be checked in order to decide whether to hold or continue their medications. Therefore, the transplant team could be assured of minimizing the interactions or side effects that may finally result in complications or organ rejection.
In order to assess the effectiveness of pharmacotherapy consultation more accurately in the patients' clinical outcomes, laboratory tests were evaluated before and after clinical pharmacist interventions. According to the results, in 80.43% of the cases, patients' laboratory data improved, whereas only 4.34% of recommendations led to regressive outcomes. This can express the positive impact of the clinical pharmacist interventions on patient care. Comparing to our rates, in Wang et al. article, the studied parameters had a higher improvement rate (94.2%) after clinical pharmacist interventions and no regressive outcomes (Table 4) [23].
According to table 1, it can be concluded from the overview of the results that clinical pharmacists had a positive impact on raising awareness, improving patient's treatment, and preventing organ rejection. Slightly significant recommendations accounted for the majority of recommendations (35.46%), while significant and much significant ones were quite similar (%25.58 and 23.83%, respectively). Therefore, according to these percentages, the absence of clinical pharmacists would lead to drug-related problems and an increased risk of organ rejection. In Wang and colleagues' study, 58.2% of all recommendations were significant. However, comparing to their study, our study had a larger rate of recommendations in extreme and much significant categories [23].
One of the factors that can be considered as a measure of the success of the transplant team is the incidence of post-surgery infection. Twelve severe infections were recorded after surgery. Since the infections are likely to be caused by not reaching the target goal of antibiotics, the recommendations in each case were evaluated. Out of 20 recommendations that were made, only 35% (n=7) of them had been accepted by the physicians. Overall, there were nine mortalities recorded out of 46 transplant patients. Only one of these mortalities was due to infection that leads to organ rejection. In this case, the dose adjustment recommendations were ignored by the physicians. A previous study reported a 22% infection rate among heart transplant patients in a period between

the surgery and discharge [31]. Therefore, antibiotics therapy is considered essential, and physicians must have better compliance with antibiotics recommendations and use up-to-date guidelines to prevent infections.

Clinical pharmacists contribute to reducing the duration of hospital admission, readmissions and healthcare costs in transplant patients. In one of the most recent studies, a 7-year observational study done by Duwez M et al, on lung transplant patients, the clinical impact of pharmacist's intervention was evaluated and the type of interventions which had the most value for patient care have been determined [32]. Another study conducted by Prom A et al, a one-year study on 59 heart transplant recipients ,who were referred to an outpatient clinic, showed that clinical pharmacist integration resulted in higher percentage of patients at goal blood pressure and fewer 1-year hospital readmissions [33]. Yet, further studies are recommended to compare the type and rate of clinical pharmacist interventions among different heart transplant centers and to seek more effective ways for promoting the involvement of clinical pharmacists in the transplant patient care.

Since all studies have a number of limitations, this study had several limitations as well. The small sample size and lack of the control group were the main limitations of our study.

4. Conclusion

This study highlights the vital role of clinical pharmacists in transplant patient care and treatment programs. Clinical pharmacists ought to be considered as an indispensable part of transplant team as their intervention can lead to the reduction in organ rejection rate, postoperative infections, adverse drug reactions and interactions as well as enhancing appropriate drug use and dose adjustment. However, the adherence of physicians to updated guidelines and their attitudes towards clinical pharmacists' role and recommendations should not be underestimated.

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Conflict of interest

The authors declare that they have no conflict of interest.

Ethics

This study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran with the number of IR.SBMU.PHNM.1395.662.

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