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Assessment of a reconciliation and information programme for heart transplant patients*

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KEYWORDS

Pharmaceuticalcare; Drug reconciliation; Medication-related problems; Heart transplant

Abstract

Introduction: The objective is to assess a pharmaceutical care programme for heart transplant patients upon patient admission and discharge.

Material and methods: Observational study of heart transplant patients, performed during the first quarter of 2007. Upon admission, the patient was interviewed regarding home treatments, adherence, allergies, and adverse effects, his/her prescriptions were compared with the last discharge report (drug reconciliation). At time of discharge, treatment was checked against the last hospital prescription (reconciliation) and an informative report was drawn up and personally delivered to the patient. Subsequently, a satisfaction questionnaire was carried out by telephone. Drug-related problems were recorded using Atefarm® software.

Results: The programme was applied to 24 patients upon admission and 23 upon discharge. No drug interactions were detected. Treatment adherence was higher than 90%. 37.5% of patients informed of an adverse reaction. Medication-related problems were identified in 16 patients (45.7%) for 6.6% of medications, most of which (38%) were for infection prophylaxis; medication omission was the most frequently-detected error. Positive evaluation of the information that was received was higher than 90%.

Conclusions: Pharmacotherapeutic follow-up upon admission and discharge resolves and prevents problems while improving patienti informedness and satisfaction. Limitations on personnel prevent the population's requests from being met.

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PALABRAS CLAVE

Atención farmacéutica; Conciliación de tratamiento; Problemas relacionados con los medicamentos; Trasplante cardíaco

Evaluación de un programa de conciliación e información al paciente trasplantado cardíaco

Resumen

Introducción: El objetivo es evaluar un programa de atención farmacéutica al ingreso y al alta hospitalaria del paciente trasplantado cardíaco.

Material y métodos: Estudio observacional realizado el primer trimestre de 2007 en pacientes trasplantados cardíacos. Al ingreso, se entrevistó al paciente sobre tratamientos domiciliarios, adherencia, alergias, efectos adversos, y se comparó la prescripción con el último informe de alta (conciliación). Al alta, se comparó el tratamiento con la última prescripción hospitalaria (conciliación) y se elaboró un boletín informativo, entregándolo personalmente al paciente. Posteriormente, se realizó un cuestionario telefónico sobre satisfacción. Los problemas relacionados con los medicamentos (PRM) fueron registrados en la aplicación Atefarm®.

Resultados: El programa al ingreso se aplicó a 24 pacientes y al alta a 23. No se detectaron interacciones. La adherencia al tratamiento fue superior al 90%. El 37,5% de los pacientes comunicó alguna reacción adversa. Se identificaron PRM en 16 pacientes (45,7%), en un 6,6% de los medicamentos, la mayoría (38%) pertenecientes a profilaxis infecciosa, siendo la omisión del medicamento el error principalmente detectado. La valoración positiva de la información recibida superó el 90%.

Conclusiones: El seguimiento farmacoterapéutico al ingreso y al alta resuelve y previene problemas y favorece la información y satisfacción del paciente. Las limitaciones de personal impiden cumplir las demandas de la población.

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Introduction

All heart transplant (HT) recipients must receive immunosuppressants to prevent rejection and prophylaxis against infectious complications, particularly during the early months. Given their considerable therapeutic complexity, these patients are considered a target population that should receive pharmaceutical attention.

According to published articles, the discrepancies between the medications patients take before being admitted and that prescribed upon admission reach levels of 30% to 70%. The patients' risk of pharmacotherapeutic disease on admission is high. More than 12% experience adverse effects in the following two weeks. The programme considered problems (MRPs) in the admission and discharge phases, a drug conciliation procedure was developed ensuring that each patient is prescribed the necessary drugs for his/her clinical state. The programme considered any drugs the patient was on before admission, except where they were specifically modified by the doctor, and validated that prescription details were correct (dose, frequency, channel and treatment time). 4,11

Hospital admission and discharge offer the opportunity of improving patients' pharmacotherapy by preventing and/or identifying and resolving MRPs and the possibility of increasing knowledge about their treatment.

The purpose of the present study is to evaluate a pharmaceutical attention on admission programme (PAAP) and a pharmaceutical attention on discharge programme (PADP) based on drug conciliation, information and satisfaction for the heart transplanted patient.

Material and methods

Study design

Descriptive observational study.

Scope

The study was carried out between January and March 2007 in two hospital units providing care to heart transplant patients: Cardiology (63 beds) and Cardiovascular Surgery (18 beds).

Population and sample size

Heart transplant patients attended in the hospital during that time were included. The PAAP programme was applied to patients who already had transplants, and the PADP programme to de novo transplant patients.

Pharmaceutical care procedures

For the PAAP programme, we identified heart transplant patients by using the assisted electronic prescription programme (PRISMA®), consulted the summarised medical history programme (MIZAR®) to rule out de novo transplants and learned about the patient's habitual treatment in the discharge report from his/her latest hospitalisation, comparing it with the treatment prescribed upon admission (conciliation). The patient was later interviewed using the standardised questionnaire for the pharmacy service with three groups of questions: 1) use of drugs, medicinal plants,

homeopathic products, nutritional supplements, etc. which may cause an interaction with the prescribed treatment; 2) adherence to the treatment and 3) adverse effects and possible allergies.

For the PADP programme, the nursing staff from the hospital units informed the pharmacy about patients scheduled for discharge. After obtaining the discharge report from the MIZAR® programme, we performed an overall analysis and treatment validation. Treatment shown on the discharge report was compared with the last hospital prescription (conciliation). In the event of any questions or MRPs, we consulted with the prescribing doctor, nursing staff or the patient to resolve the situation.

We next used the software application INFOWIN® to create a leaflet consisting of a page summarising the prescription, scheduling, summarised drug information to facilitate proper use, and a brief list of their indications, interactions, contraindications and adverse effects.

After that, the pharmacist met with the patient to review the prescribed drugs and the general recommendations about their use, placing an emphasis on the patient's knowledge of the disease, treatment and adverse effects. The patient was given all of the documents that had been prepared. We checked for duplicates and interactions between the prescribed drugs and any of the medications, medicinal plants and foods normally consumed by the patient and not indicated in the discharge report. Additionally, we asked if the patient would be willing to participate in a telephone survey seven days after discharge to assess acceptance of the intervention in terms of usefulness and satisfaction, and its effectiveness in terms of comprehension, presentation and MRP management. Both the INFOWIN® programme and the satisfaction survey belong to the Consúltenos programme, an initiative of the Head Office for Quality and Patient Care and the Valencian Society of Hospital Pharmacy.

Measuring the results

The variables and indicators used to evaluate the programmes PAAP and PADP are shown in Table 1.

The MRPs detected in the process of reconciling treatments on admission and treatments on discharge were analysed as a whole and classified by type, category, phase during which they occurred, immediate cause and remote cause (system failure) according to the classification by Jiménez et al. 12 The laser® method was used to evaluate MRPs. This method examines processes to identify patients whose pharmacotherapy could be improved, intervention by the pharmacist, pharmacotherapeutic follow-up, evaluation (individual) and results (population-based) from the pharmaceutical care programmes 13; data was registered in the Atefarm® programme 2006.0.047.

Explanations for the adverse reactions reported by patients were given according to the five criteria in the *Sistema Español de Farmacovigilancia* (Spanish pharmacology vigilance system) by applying the official algorithm.¹⁴

Only direct costs were analysed, including hospital costs from purchasing drugs at laboratory sale price (LSP) and the cost of pharmacists' time spent identifying PRMs and intervening. For the drug costs generated from pharmacists'

Table 1 Indicators used to evaluate the pharmaceutical care programme

Indicator	Formula
Specific to PAAP	
Interactions	No. of patients with interaction/ no. of patients in PAAPx100
Adherence	No. of patients according to degree of adherence/no. of patients in PAAPx100
Allergies	No. of patients with drug allergy/ no. of patients in PAAPx100
Adverse reactions	No. of adverse reactions/no. of patients in PAAPx100
Specific to PADP	
Patient satisfaction	No. of patients according to degree of satisfaction/no. of patients surveyedx100
Common to PAAP/PAD	P conciliation
Total MRPs	No. of MRPs detected upon admission and discharge
Total MRPs	No. of MRPs detected upon
per patient	admission and discharge/ patient totalx100
Total MRPs per medication	No. of MRPs detected upon admission and discharge/
prescribed	no. prescribed medicationsx100
MRPs with	No. of MRPs detected upon
pharmacist	admission and discharge that
intervention	received a pharmacist's intervention

MRPs indicates medication-related problems; PAAP, pharmacy attention on admission programme; PADP, pharmacy attention on discharge programme.

interventions, we used the number of days of actual treatment, where known. Otherwise, we used a conservative estimate (4 days) (time during which the team responsible for the patient would have modified the treatment without a pharmacist's intervention). ¹³ If the pharmacist's intervention took place upon discharge, the direct costs were calculated according to the hospital's LSPs, since this is the data available on Atefarm®; although this cost does not affect the hospital, it does affect the Spanish National Health System.

Statistical analysis

Statistical analysis was performed using Excel® software. Results are shown as proportions (percentages) with a 95% confidence interval (CI). The formula proposed by Clopper and Pearson¹⁵ was used for the calculations.

	Every day	Often	Sometimes	Never Patients, n (%)	
	Patients, n (%)	Patients, n (%)	Patients, n (%)		
Do you take your medication every day?	23 (95.8) (95% CI: 78.9-99.9)	None	1 (4.2) (95% CI: 0.1-21.1)	None	
Do you take all of the doses for the day?	22 (91.6) (95% CI: 73.0-99.0)	1 (4.2) (95% CI: 0.1-21.1)	1 (4.2) (95% CI: 0.1-21.1)	None	

Results

The study included a total of 35 patients (74.3% male). The mean age upon admission was 50 ± 14 years and the mean post-transplant time was 8.2 months (0.5-72). Of these patients, 21 (60%) were admitted to undergo an endomyocardial biopsy, eight (23%) were to have a de novo HT and six (17%) were admitted for other reasons. Out of the patient total, 12 were placed in the PAAP programme, 11 in the PADP programme and another 12 were included in both programmes.

The PAAP programme included 24 patients. None of the interviewed patients consumed medicinal plants, homeopathic remedies, nutritional supplements etc., and there were no detected interactions with the prescribed treatment. Treatment adherence is shown by the results in Table 2. Only two patients had drug allergies (to codeine and penicillin). Both allergies were listed in the assisted electronic prescription programme so as to send a warning in the event of prescribing these drugs or others in the same drug family that could cause cross reactions. According to the interviews, nine patients (37.5%) (95% CI: 18.8-59.4) reported at least one adverse reaction to the prescribed treatment (16 total reactions). Table 3 lists the signs and/or symptoms described by the patient, the drug to which the reaction was attributed, and the causal relationship. In 14 cases, the adverse effect was related to an immunosuppressant. Since the reactions were not severe, or were already known to the responsible doctor, no pharmacists intervened in this sense.

MRPs relating to drug conciliation were detected in 16 of the 35 patients studied (45.7%). The total number of prescribed medications was 469, and there were therefore 6.6 MRPs per 100 drugs prescribed upon admission or discharge. The mean number of drugs upon admission was 9.9±2.6, and upon discharge, 10±3.4. Thirty-one MRPs occurred, and 19 involved action by a pharmacist. There were no interventions in the other cases, since the medication omitted in the prescription was brought in by the patient, or the MRP had already occurred without any opportunity for a pharmacist intervention.

The 19 MRPs were identified in 13 cases (68.4%) (95% CI: 43.5-87.4) through verbal communication with the patient, in five cases (26.3%) (95% CI: 9.2-51.2) through reviewing the pharmacotherapeutic history, and in one case, during prescription validation.

 Table 3
 Adverse reactions described by the patient upon admission and causal relationship

Sign/symptom	Drug	Causal relationship
Vomiting	Mycophenolate mofetil	Possible
Oedema of the lower limbs	Mycophenolate mofetil	Possible
Nausea	Mycophenolate mofetil	Probable
Diarrhoea	Mycophenolate mofetil	Probable
Hirsutism	Ciclosporin	Possible
Exanthematic eruptions	Ciclosporin	Possible
Hirsutism	Ciclosporin	Possible
Trembling	Ciclosporin	Defined
Hirsutism	Ciclosporin	Conditional
Hirsutism	Ciclosporin	Possible
Trembling	Ciclosporin	Probable
Vision disorders	Ciclosporin	Possible
Hirsutism	Ciclosporin	Probable
Fungal mouth infection	Deflazacort	Probable
Hot flashes	Amlodipine	Possible
Sensation of heat	Amlodipine	Defined

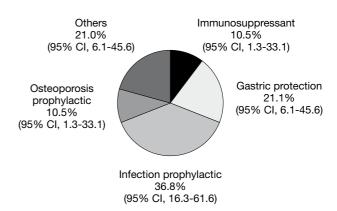


Figure Therapeutic groups of the drugs involved in medication-related problems (n=19). CI indicates confidence interval.

Most of the drugs involved in MRPs (38%) belonged to the infection prophylaxis group used for HT (Figure). The category in which the MRPs generally fell was indication (need for additional treatment) (Table 4).

Table 4 Categorising medication-related problems

Table 4 Categorising medication	-related problems
MRP Category	MRP (95% CI), %
Indication (need for additional treatment and unnecessary medication)	79 (54.4-94.0)
Adherence (non-compliance)	10.5 (1.3-33.1)
Effectiveness (underdosing and inadequate medication)	10.5 (1.3-33.1)
Safety (overdosing)	10.5(1.3-33.1)
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CI indicates confidence interval; MRP, medication-related problems.

The immediate cause of the error (52.6%) (95% CI: 28.9-75.6) was memory lapse or inattention on the part of the prescribing doctor in ten cases; in seven cases, (36.8%) (95% CI: 16.3-61.6) it was lack of knowledge about the patient, and in two cases (10.5%) (95% CI: 1.3-33.1) it was lack of knowledge about the medication. In all cases, the remote cause or system failure was attributed to lack of standardisation.

In a preliminary assessment, 68.4% (95% CI: 43.4-87.4) of the detected MRPs would have led to reversible damage (with no changes in the patient's vital signs) and required treatment modification.

The pharmacist recommendations were, in 10 cases (52.6%) (95% CI: 28.9-75.6), to start the drug that had been omitted; in three cases (15.8%) (95% CI: 3.4-39.6), suspend the medications that the patient had not taken since the last outpatient appointment and which were erroneously prescribed upon admission, and in two cases (10.5%) (95% CI: 1.3-33.1), personalise the dosage method.

1. Were you interested in the spoken information you received?	Very 21 (95.4) (CI: 72.0- 98.9)	Quite 1 (4.6) (CI: 0.1- 21.2)	Somewhat None	Not particularly None	Not at all None
2. Were you interested in the written information you received?	Very 21 (95.4) (CI: 72.0- 98.9)	Quite 1 (4.6) (CI: 0.1- 21.2)	Somewhat None	Not particularly None	Not at all None
3. Was your discharge delayed due to pharmacist's intervention?	Very None	Quite None	Somewhat None	Not particularly 4 (18.2) (CI: 4.9-38.8)	Not at all 18 (81.8) (CI: 56.3-92.5
4. If you were, do you think it was worth the trouble?	Very much 17 (77.3) (CI: 51.6- 89.8)	Quite 5 (22.7) (CI: 7.5- 43.7)	Somewhat None	Not particularly None	Not at all None
5. How would you rate the treatment you received from the pharmacist?	Very good 18 (81.8) (CI: 56.3- 92.5)	Good 4 (18.2) (Cl: 4.9- 38.8)	Adequate None	Poor None	Very poor None
6. Did you understand all of the information presented by the pharmacist?	Everything	Almost everything	Some of it	Almost nothing	Nothing
	16 (72.7) (CI: 47.1-86.8)	6 (27.3) (CI: 10.2- 48.4)	None	None	None
7. Were you able to ask all of your questions?	Everything	Almost everything	Some	Not many	None
	15 (68.2) (CI: 42.7-83.6)	7 (31.2) (CI: 13.2-52.9)	None	None	None
8. Do you feel you have a better knowledge of your medications?	Much better		Somewhat better	Not particularly	Not at all
	17 (77,3) (CI: 51.6-89.8)	5 (22,7) (CI: 7.5-43.7)	None	None	None

The impact of the pharmacist's intervention was calculated with reference to the initial severity of the MRP according to the potential pharmacotherapeutic condition and the end severity according to actual morbidity at the end of follow-up. Therefore, in most cases (84.2%) (95% CI: 60.4-96.6), the pharmacist's intervention did contribute to a therapeutic improvement, and had a direct effect in one case (5.3%) (95% CI: 0.1-26.0). The suitability of the intervention was considered significant in 84.2% (95% CI: 60.4-96.6) of all cases, and very significant in 15.8% (95% CI: 3.4-39.6) in which it prevented failure of a vital organ, a severe adverse effect or treatment failure. All of the pharmacist actions were accepted by the prescribing doctor, and they involved a non-significant cost increase of €181.20, since most consisted of starting an unprescribed medication.

The PADP programme was applied in 23 patients. After discharge, 22 completed the satisfaction survey (Table 5).

Discussion

The heart transplant patient is characterised by the need for long-term immunosuppressant treatment with a narrow treatment interval and multiple adverse effects and interactions. Lack of adherence to immunosuppressants contributes to 20% of all rejection episodes and to 16% of graft losses, which shows the importance of proper compliance. 16 It is estimated that 20% to 50% of all patients do not take their medication exactly as prescribed, and are referred to as non-compliant. 17,18 In our study, the treatment adherence reported by the patients was very high, despite the fact that a high percentage of patients (38%) experienced adverse reactions. This method for measuring adherence (interview) is a subjective method that is not as reliable as others such as counting tablets, measuring drug levels in blood etc. and any method based on objective data, and it tends to overestimate the results. 19 Even so, the interview is similar to the validated Morisky interview for determining adherence to chronic treatment in cardiovascular patients, which has four yes or no answers. An attempt has been made here to improve the interview by increasing the answer levels in order to make the test more consistent.²⁰ In our experience, the heart transplant patient is one who is aware and concerned about his/her treatment, and therefore tends to be compliant.

Patients on several drugs are at high risk for suffering adverse reactions⁸; 37.5% of the patients suffered from one or more, and all of them were mild, but most were caused by immunosuppressant treatment.

Most published studies that refer to the conciliation procedure use the term "discrepancy" (any difference between the medications the patient was taking at home and those prescribed upon admission) and classify discrepancies as intentional (treatment changes based on the patient's clinical state or therapeutic interchange) and unintentional. ^{4,11} Our study only analysed unintentional discrepancies, which are generally the ones to generate an MRP. These studies classify unintended discrepancies as omission errors (involving lack of prescription of a drug used before hospitalisation) or addition errors (adding an unnecessary drug). This classification is similar to that used

in our study which groups MRPs as omitted drugs (omission errors) and unnecessary or erroneous drugs (addition errors). Other classes of errors defined by the laser® Method were also included.

Published studies indicate that the percentage of patients with conciliation errors upon hospitalisation varies between 22% and $65\%^{5,6,8}$ and affects as many as 70% of all medications.7 Upon discharge, between 12% and 62% of prescribed medications have conciliation errors^{7,8} and as many as 66% occur when the patient is transferred to another care level.8 In our study, the conciliation errors upon discharge and admission were evaluated overall since the number of patients included in each phase was not very high, given the very defined, limited population. As a group, 45.7% of the patients experienced a conciliation error, and 6.6% of the total medications were involved. The differences between our study and published studies could be due to the fact that those studies included patients admitted to various services with different diseases, and most were elderly6 with multiple illnesses. In contrast, our study focuses on a specific type of younger patient who generally knows his/her medication well and is frequently readmitted, so both the patient and the treatment are well-known to the prescribing doctor.

Most of the identified errors involved omission (52%) of infection and osteoporosis prophylactics; this is also the most frequent omission error according to the published literature (42-57%).^{5,6,8} Cardiovascular drugs, ansiolytics and analgesics are the drugs that most frequently create medication errors, although these studies were not performed in heart transplant patients.^{5,21}

Studies suggest that 61% to 72% of all conciliation errors are unlikely to cause any damage. ^{5,6} In our case, most of the MRPs (68.4%) were classified as errors that would cause reversible damage requiring treatment modification, and only 15.8% would require additional treatment, a longer stay or hospital admission. All cases of remote causes or system failures were attributed to lack of standardisation, as the drug conciliation procedure has not yet been normalised in our hospital.

The cost of the conciliation procedure has been estimated at \$11 per patient upon admission and \$64 if there are clinically significant discrepancies. This situation is favourable if we compare it with \$2013 to \$2595 in additional costs that would be generated by the appearance of adverse effects. In our study, we took into account the cost invested by the pharmacist to identify the MRP during the conciliation process and the cost of the drug in question; in most cases, adding medications to the patient's treatment produces a positive result. This situation could also be considered favourable since the omitted medications were mainly prophylactics. This could cause a significant cost increase due to an increase of infections and/or osteoporosis.

The information sources we used to obtain the patient's treatment record before admission were discharge reports from previous hospitalisations in our centre and an interview with the patient and/or family members. However, other studies^{5,8,21,22} also use inspections of the patient's medication, reviews of primary care centre reports and consults with the pharmacy division.^{6,11} One limit to our activity in treatment conciliation is the frequent lack of reports from primary care physicians, the pharmacy office or from stays in other

hospitals.^{5,8} Many of the conciliation errors, particularly those upon admission, could be eliminated by use of a single health record containing prescriptions from primary care, the hospital clinical history and previous hospitalisation reports.^{8,9} This approach would facilitate the integration of medical assistance for patients. At present, the Region of Valencia employs strategies to unify clinical histories. These strategies aim to facilitate health professionals' access to information on treatments by improving distribution of primary care and pharmacy office reports.

The satisfaction survey performed after discharge concluded that all of the patients were interested in the information they received and it helped them to better understand their medication, creating in turn improved treatment compliance and fostering the patient's coresponsibility in his/her treatment.²³ In fact, society calls for and approves of this type of initiative as a necessary health care resource.^{24,25} One intervention study²⁶ shows that including the pharmacist in the hospital admissions process to explain the treatment to the patient and identify and correct medication errors, and to perform further follow-up by telephone, can decrease the number of visits to the emergency room.

The population included in our study was limited by the study duration, the hospital's district, the number of transplant patients (35 in 2006) etc., which gave us a small, well-defined population for which increasing the study numbers for internal comparisons was difficult. One comparison with other transplant patient populations (kidney, liver, lung, etc.) would give us a better perspective on this type of study. Despite the study's limitations, the procedure was applied in nearly 85% of the cardiac patients admitted during the study period, since the mean monthly admission rate is 14 patients.

The model we present in this study could be used generally in other hospitalised patients at a high risk for pharmacotherapeutic disease. However, personnel limitations prevent us from meeting the population's needs, and we require more hospital pharmacists or a better distribution of medical care tasks.

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Conflict of interest

The authors affirm that they have no conflicts of interest.

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