The Participation of the Pharmacist in the Design and Follow-up of the Drug Treatment Plan for Patients With a Cardiovascular Condition

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Abstract

Objectives: To systemise the pharmaceutical care provided to patients with chronic diseases. To evaluate the pharmacist's participation in the drug treatment plan, studying their intervention in the reconciliation of the patient's habitual treatment and the detection and resolution of drug-related problems.

Method: A multicentre study based on the comparison of 2 cohorts: one with the intervention of the pharmacist and one without. Inclusion criteria were as follows: patients over the age of 70 with chronic cardiovascular conditions being treated with more than 6 drugs. They were selected between 24-48 hours from admittance; a control patient was chosen for each patient in the intervention group. The pharmaceutical intervention consisted of medication reconciliation on admittance, drug treatment monitoring and reconciliation on discharge. Drug-related problems, their seriousness, the pharmaceutical intervention, the degree of resolution, and the clinical outcomes on discharge were all recorded. A total of 24 hospitals participated, with a total of 356 patients: 180 in the intervention cohort and 176 in the control one.

Results: A total of 602 drug-related problems were identified: 66.9% belonging to the intervention group and 33% to the control group. Interventions were made in 359 (89%) patients belonging to the intervention group, 66% were resolved after the pharmaceutical intervention, producing a total or partial improvement in the patient in 36.3% of cases.

Conclusions: Pharmaceutical care has been systematised, providing an instrument that enables all the hospitals to work in a standardised manner. The active participation of the pharmacist in the healthcare team contributes to preventing and resolving drug-related problems.

Key words: Pharmaceutical care. Drug-related problems. Drug treatment monitoring. Pharmaceutical intervention. Medication.

Diseño y seguimiento del plan farmacoterapéutico del paciente con enfermedad cardiovascular

Objetivos: Sistematizar la atención farmacéutica al paciente con una enfermedad crónica. Evaluar la participación del farmacéutico en el plan farmacoterapéutico mediante el estudio de su intervención en la conciliación del tratamiento habitual del paciente y en la detección y resolución de problemas relacionados con los medicamentos.

Método: Estudio multicéntrico basado en la comparación de dos cohortes, una con intervención del farmacéutico y la otra no. Los criterios de inclusión fueron: pacientes mayores de 70 años con enfermedad cardiovascular crónica y tratamiento con más de 6 fármacos. Se seleccionaban a las 24-48 h de su ingreso; por cada paciente del grupo intervención se seleccionaba uno de control. La intervención farmacéutica consistía en la conciliación del tratamiento en el momen-

SEFH Project in collaboration with Lacer laboratory and Antares Consulting (Pharmacologic plan design and follow-up). Twenty-four hospitals have participated and the development group was formed by pharmacists from 9 hospitals.
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to del ingreso, el seguimiento farmacoterapéutico y la conciliación en el momento del alta. Se registraban los problemas relacionados con los medicamentos, su gravedad, la intervención farmacéutica, el grado de resolución y los resultados clínicos en el momento del alta. Han participado 24 hospitales con un total de 356 pacientes: 180 de la cohorte de intervención y 176 de la de control.

Resultados: Se ha identificado un total de 602 problemas relacionados con los medicamentos, el 66,9% perteneciente al grupo de intervención y el 33% al de control. Se ha intervenido en 359 (89%) de ellos pertenecientes al grupo intervención; un 66% se resolvió tras la intervención farmacéutica, que en el 36,3% de los casos produjo una mejoría total o parcial en el paciente.

Conclusiones: Se ha sistematizado la atención farmacéutica y se ha proporcionado un instrumento que permite trabajar de forma homogénea en todos los hospitales. La participación activa del farmacéutico en el equipo de salud contribuye a prevenir y resolver problemas relacionados con los medicamentos.

Palabras clave: Atención farmacéutica. Problemas relacionados con los medicamentos. Seguimiento farmacoterapéutico. Intervención farmacéutica. Conciliación de la medicación.

INTRODUCTION

The main objective of the professional work of the pharmacist is to achieve improvements in patients' health results and quality of life, through safe, efficacious pharmacotherapy. In his daily activities and the pharmaceutical care he provides, the hospital pharmacist is professionally responsible for the results obtained in the patient.

The pharmacist can develop and introduce different clinical programmes that can be based on therapeutic initiatives involving dose optimisation, switches between therapeutic equivalents or by interventions of the pharmacist deriving from the detection of problems related to medication (PRM).

PRM represent a serious clinical problem. It has been observed that 6.5% of hospitalised patients present PRM, 28% of which are avoidable.[1] The results of a meta-analysis of prospective studies published in 1998 by Lazarou et al established a rate of serious PRM of 6.7% and a rate of fatal PRM of 0.3% in patients admitted to hospitals in the EU, these adverse effects representing the fourth and sixth most common causes of death.[2]

In our country, several studies have been conducted into the occurrence of DLP in different areas of the hospital setting.[3-6] In a review of the patients admitted to hospital as a result of PRM published in the year 2002, significant dispersion was seen both in terms of the estimations of frequency, (1%-28%; average, 4%), and in the proportion of potentially avoidable incidents (325-80%; average, 59%).[7] The important variations observed could be due to several factors such as differences in attitude when reporting these types of events, the use of different methodologies, the definitions, indicators, measurement instruments, design of the sample, and statistical analysis.[3]

There are many studies showing that when a pharmacist participates and is included in the healthcare team and in the patients' pharmaceutical care, there is a significant reduction in the number of preventable adverse events, leading to a clinical benefit for the patients.[8-10]

The study Design and Follow-up of the Pharmacoologic Plan (DSPFT, *Diseño y Seguimiento del Plan Farmacoterapéutico*) came into being as a result of an interest in developing professional practices and generating changes in behavioural models by way of a standard pharmaceutical intervention. The project focuses on identifying and resolving PRM, and improving the quality of care and the patients' clinical results.

The general objectives of this study are to systemise the pharmaceutical care process of patients with chronic conditions and evaluate the participation of the pharmacist in the patient's drug treatment plan, studying his intervention in the reconciliation of the habitual treatment and in the detection and resolution of PRM.

METHOD

Design

Multi-centre, almost experimental design based on a comparison of 2 cohorts. The first of them received the intervention of a pharmacist and the second was the comparison group that received no intervention. The information was collected prospectively in the intervention cohort and retrospectively, after release from hospital, in the control group. By gathering the information from the control group after release from hospital, the ethical conflict was prevented, as they all received the usual treatment whilst in hospital.

All the pharmaceutical services followed the same sequence of activities, as shown in Figure.

Scope

Twenty-four hospitals from around Spain. The study took place in 2005 and lasted for 1 year.

Studied Population

A total of 356 patients (180 intervention and 176 control), admitted to the medical and cardiovascular departments of participating hospitals, admitted with cardiovascular conditions. In order to calculate the size of the sample, it was assumed that the proportion of patients with PRM resolved during the pharmaceutical intervention was high, around 70%. Assuming a 25% loss in the patient selection process, it was necessary to select 400 patients in the intervention group to be able to estimate, with a precision of 5%, the percentage of patients whose PRM would be resolved after the intervention of the pharmacist. The same number of patients would be needed for the control group.

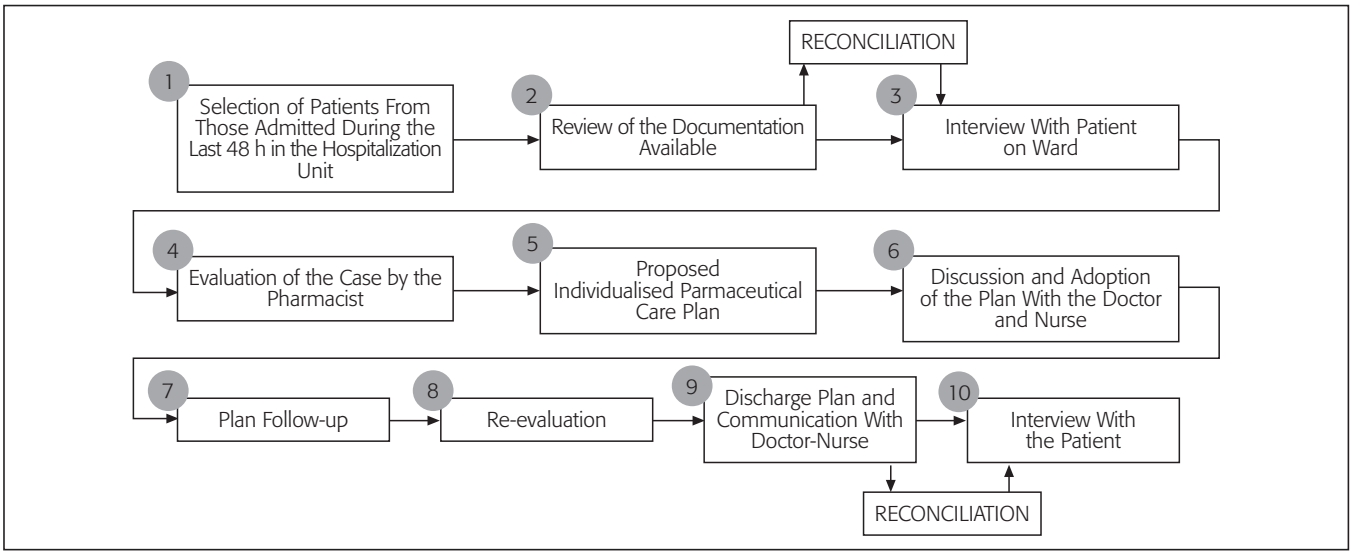

Figure. *Sequence of activities of the study process for the Design and Follow-up of the Pharmacologic Plan.*

Inclusion Criteria

To participate in the study, patients were required to comply with the following inclusion criteria: *a)* aged ≥70; *b)* presence of cardiovascular pathology (arterial hypertension, ischemic cardiopathy, or heart failure); and *c)* at the time of hospitalisation the patient must have been taking at least 6 medications, with a minimum of 2 of these belonging to the group C, cardiovascular system (according to the ATC classification[11]).

Exclusion Criteria

Moderate to severe cognitive impairment, except when a family member/carer agreed to participate in the pharmaceutical intervention.

Study Groups

– Exposed cohort: patients complying with the inclusion criteria, detected by the pharmacist at 24-48 h of hospitalisation (index case) and followed until release from hospital
– Non-exposed or control cohort: patients who, complying with the inclusion criteria, have been admitted on the same date as the index case or up to 7 days earlier

If there were no patients complying with the inclusion criteria, none were selected. The control group was used to simulate what happened in the absence of the programme.

With regard to the description of the intervention, the sequence of activities in the study consisted of the 10 steps shown in Figure.

Once the patient has been selected and assigned to the intervention or control group, the following processes began:

1. The patient was interviewed, and information was gathered about lifestyle habits (diet, physical exercise, smoking, alcohol, etc), drug treatments and treatment compliance (Morinsky-Green test).
2. Reconciliation of treatment: review of domiciliary treatment and treatment at the time of hospitalisation, an evaluation of the discrepancies found with the doctor and nurse responsible for the patient.
3. Pharmacotherapic monitoring of the patient during hospital stay, identifying and resolving the PRM by reviewing the clinical history and communication with the doctor and nurse responsible for the patient.
4. Hospital release plan: reconcilliation of the treatment on release and verbal and written information to the patient for his treatment using Infowin® software.

Data Collection

A software programme was developed to enable to study data to be entered using a Personal Digital Assistant (PDA), and then send them to a web server.

Variables

– Main variable: type of PRM (Table 1) and its resolution
– Secondary variables: seriousness of the PRM (Table 2), intervention recommended (Table 3), and its effects on the patient, degree of acceptance of the intervention, factors associated with the resolution of PRM, and measurement of clinical results (hypertension: blood pressure at the time of admittance and release; angina: days until disappearance of pain; heart failure: modification of the dyspnoea and oedema)

Table 1. Types of Problems Related to Medication[a]

PRM 1	Indication not treated	The patient does not receive the necessary medication
PRM 2	Unnecessary medication	The patient receives a medication in the absence of an indication
PRM 3	Uneffective medication	The medicine received by the patient is not effective, regardless of the dose or regimen
PRM 4	Subtherapeutic dose	The medication received by the patient is not effective, because of the dose or regimen
PRM 5	Overdose	The patient is receiving a dose of the medication which is too high and therefore unsafe
PRM 6	Adverse reactions; side effects; drug-drug interactions	The patient is receiving an unsafe medication since it causes adverse reactions, side effects, interactions and allergies
PRM 7	Incorrect choice of medication	The patient receives an inappropriate medication for his pathology
PRM 8	Error on receiving the medicine	Problem in the patient as a result of not receiving a medication or taking another one

[a]PRM indicates problems related to medication.

Table 2. Severity of Problems Related to Medication[a]

Severity Code	Description
I	PRM that do not harm the patient and do not require changes in treatment
II	PRM that require changes to the treatment or higher levels of monitoring
III	PRM that cause changes to the vital signs, require additional tests or invasive procedures
IV	PRM that require additional treatment, lengthening the stay, or hospitalisation
V	PRM requiring transfer to the ICU or which cause permanent harm to the patient
VI	PRM that cause the death of the patient

[a]ICU indicates intensive care unit; PRM, problem related to medication.

The PRM was defined as a health problem linked to the drug treatment that interfered or was capable of interfering with the health results expected for the patient.[12]

Statistical Analysis

A descriptive analysis was performed of the baseline characteristics, in both the intervention and the control cohorts, by determining the average central trend and proportion distribution, and analysing potential differences between the 2 groups using Student *t* or χ^2 tests. A further divariate analysis was performed on the PRM found (type, severity, and resolution) in both groups by calculating the proportions and performing χ^2 tests to study possible differences. The SPSS v11 statistical package was used to do this.

RESULTS

The sociodemographic and clinical characteristics of the patients included in the study are set out in Table 4, showing both groups to be totally compatible, with the exception of obesity, which was slightly more predominant in the intervention group.

Table 5 gives the results of the total number of PRM detected by type, their degree of severity and the percentage of resolution of PRM in the intervention group. A significantly higher proportion of PRM were identified in the intervention group in comparison to the control group ($P<.001$). Of the 602 PRM observed, there is information available regarding their resolution in 359. These all belonged to the intervention group. The remaining (44 PRM) were detected but no intervention was possible as the patients had already been released, transferred to another hospital, or were PRM occurring at weekends.

The most frequent interventions made to resolve the PRM were those involving the indication for the medication and decreasing the dose. Among all of these, the interventions leading to the highest resolution rate of PRM were the decrease in dose (74%), withdrawal of the medication (72%) and monitoring of plasma levels (71%) (Table 6). However, some interventions had little or no effect on the patient (Table 7).

Table 3. Interventions Recommended

Start medication
Withdraw medication
Change medication
Increase dose
Reduce dose
Modify the route of administration
Increase frequency
Decrease frequency
Modify treatment duration
Control drug strength

Table 4. Baseline Patient Characteristics[a]

Characteristics	Intervention (n=180)		Control (n=176)		*P*
	No.	Percentage	No.	Percentage	
Female sex	98	54.4	92	52.3	.681
Average age (SD)	79.8 (6.2)	81.2 (6.6)		0.049	
Inclusion criteria					.951
Hypertension	120	66.7	113	64.2	
Angina	15	8.3	18	10.2	
Infarction	7	3.9	8	4.5	
Heart failure	38	21.1	37	21	
Risk factors					
Renal failure	48	26.7	39	22.3	.564
Liver failure	8	4.4	3	1.7	.316
COPD	51	28.3	60	34.1	.360
Diabetes	82	45.6	62	35.2	.115
Obesity	42	23.3	35	19.9	<.001
Anxiety	43	23.9	32	18.2	.395
Smoking	20	11.1	22	12.5	.336
Alcohol	6	3.3	5	2.8	.189

[a]COPD indicates chronic obstructive pulmonary disease; SD, standard deviation.

Table 5. Distribution of Problems Related to Medication[a]

	Intervention (n=403)		Control (n=199)		*P*
	No.	Percentage	No.	Percentage	
Number of PRM detected	403	66.9	199	33.1	<.001
Types of PRM					.013
Indication not treated	98	24.3	65	32.7	
Unnecessary drug	76	18.9	40	20.1	
Ineffective drug	19	4.7	3	1.5	
Subtherapeutic dose	27	6.7	16	8	
Overdose	54	13.4	22	11.1	
Adverse reactions/side effect/interaction	79	19.6	36	18.1	
Incorrect choice of drug	31	7.7	17	8.5	
Error on receiving the treatment	19	4.7	–	–	
Severity					.059
No damage	86	21.3	53	26.6	
Change treatment or greater control	293	72.7	127	63.8	
Change vital signs/increase tests/invasive	13	3.2	15	7.5	
Increase treatment/stay/admittance	10	2.5	4	2	
ICU/permanent damage	–	–	–	–	
Death	1	0.2	–	–	
Resolution of PRM					–
Resolved	237	66	–	–	
Not resolved	122	34	–	–	

[a]ICU indicates intensive care unit; PRM, problems related to medication.

Table 6. Resolution of Problems Related to Medication According to the Recommended Information

Intervention	Resolution PRM				
	PRM Resolved		PRM Not Resolved		Total
	No.	Percentage	No.	Percentage	No.
Start treatment	60	65.9	31	34.1	91
Withdraw treatment	89	72.4	34	27.6	123
Change treatment	17	54.8	14	45.2	31
Increase dose	18	66.7	9	33.3	27
Lower dose	29	74.4	10	25.6	39
Change route of administration	8	38.1	13	61.9	21
Increase frequency	3	60.0	2	40.0	5
Decrease frequency	2	33.3	4	66.7	6
Modify total duration of treatment	1	50.0	1	50.0	2
Control treatment strength	10	71.4	4	28.6	14
Total	237	66.0	122	34.0	359

Table 7. Effects of the Intervention on the Patient

Intervention	Result of the Intervention						
	Total Improvement		Partial Improvement		No Variation		Total
	No.	Percentage	No.	Percentage	No.	Percentage	No.
Start treatment	16	16.5	24	25.3	51	53.8	91
Withdraw treatment	18	14.6	18	14.6	87	70.7	123
Change treatment	4	12.9	8	25.8	19	61.3	31
Increase dose	10	33.3	12	40.7	5	18.5	27
Lower dose	10	25.6	8	20.5	21	51.3	39
Change route of administration	–	–	–	–	21	100.0	21
Increase frequency	–	–	–	–	5	100.0	5
Decrease frequency	1	16.7	2	33.3	3	50.0	6
Modify treatment duration	–	–	–	–	2	100.0	2
Control treatment strength	1	7.1	2	14.3	11	71.4	14
Total	60	16.2	74	20.1	225	61.6	359

The relevance of the intervention by the pharmacist was greater in the treatment recocilliation, as hospitalisation and release were the times when the majority of the pharmaceutical interventions took place.

The extent to which the intervention of the pharmacist was accepted by the doctor was 85.2%, with total agreement in 80.5% of cases. A total of 85% of interactions between the pharmacist and the doctor took place in person to person meetings.

In the analysis of the factors associated with the resolution of the PRM that appears in Table 8 it was seen that among the patient characteristics that the resolution was related to the gender, age, underlying cardiac disease (heart failure), and severity (PRM that do not cause damage or merely a change of treatment); in contrast, the resolution was not related to the type of department where the patient was admitted.

The results of the multiple regression analysis showed that none of the patient characteristics were associated with the resolution of the PRM. Only the level of acceptance of the intervention by the doctor was shown to have any relationship with the resolution of the PRM, increasing the likelihood of resolution when acceptance was good (odds ratio [OR] = 4.7; 95% CI, 1.2-18.6).

The comparison of the clinical results on release showed no significant differences between the intervention and control cohorts, as can be seen from Table 9, neither did the vital status of the patients in both groups.

DISCUSSION

The rate at which PRM has been observed in hospitalised patients varies a great deal from author to author. Studies have been published showing a rate of between 2.1% and 73%.[13-16] In this study the rate of patients with PRM was 66.9% in the intervention group and 33% in the control group. However, these values are difficult to compare with other studies, as the scope of the

Table 8. Resolution of Problems Involving the Treatment According to Patient Characteristics[a]

	PRM Resolved		PRM Not Resolved		Total
	No.	Percentage	No.	Percentage	No.
Female[b]	140	71.4	56	28.6	196
Average age (SD)[c]	80.4 (6.7)		78.4 (5.8)		359
Severity: damage[c]					
Yes	211	74.6	72	25.4	283
No	26	34.2	50	65.8	76
Total	237	66.0	122	34.0	359
Severity: change treatment[c]					
Yes	196	74.2	68	25.8	264
No	41	43.2	54	56.8	95
Total	237	66.0	122	34.0	359
Severity: change vital signs /> stay/death (NS)					
Yes	15	78.9	4	21.1	19
No	222	65.3	118	34.7	349
Total	237	66.0	122	34.0	359
Underlying cardiac condition[c]					
Hypertension	137	59.1	95	40.9	232
Angina	15	65.2	8	34.8	23
Infarction	11	64.7	6	35.3	17
Heart failure	74	85.1	13	14.9	87
Total	237	66	122	34	359
Type of service (NS)					
Medical	30	66.7	15	33.3	45
Surgical	10	52.6	8	47.4	19
ICU	197	66.8	98	33.2	295
Total	237	66.0	122	34.0	359

[a]ICU indicates intensive care unit; NS, no significant; SD, standard deviation.
[b]$P<.05$; [c]$P<.001$.

Table 9. Clinical Result at the Time of Release

Arterial Hypertension		**No.**	**Average**	**SD**	***P***
Systolic blood pressure	Control	113	130.3	20.3	.704
	Intervention	120	131.3	21.8	
Diastolic blood pressure	Control	113	70	11.1	.667
	Intervention	120	69.3	12.6	
Heart Failure			**Days to Improvement**		
Dyspnea	Control	48	4.8	3.4	.695
	Intervention	51	4.5	3.2	
Oedema	Control	36	3.6	3.2	.146
	Intervention	45	5.1	5.3	
Ischemic Cardiopathy			**Days Until Pain Disappears**		
Disappearance pain after angina	Control	23	2.6	3	.401
	Intervention	18	3.4	3.1	

pharmaceutical actions aimed at identifying the PRM in hospitalised patients depends on a variety of factors, such as the characteristics of the hospital, the number of pharmacists and the pharmaceutical care model implemented, as well as the methodology used for their documentation.[16] Also, some studies include mistakes made when the filling out of medical prescriptions and/or the prescription of drugs not included in the hospital's pharmacotherapic guide as PRM, which we consider are indicators of prescription quality rather than true PRM. With regard to the most common types of PRM identified, it is difficult to make comparisons with other studies because of the different classification of the type of PRM and the interventions taking place, however, the results are similar to those in a similar pharamaceutical care model where the greatest percentage of interventions is related to the indication, helped by the fact that the pharmacist has a greater amount of information available when he visits the clinical unit.[15-18]

With regard to the severity of the PRM there were no differences between the groups. The most frequent level of severity was severity level 2, which was also the case in other studies published using the same scale and with a similar scope of pharmaceutical care.[4,13,14,19]

The distribution of the different types of recommendations made in the intervention group corresponds to the types of PRM identified, and most of them are given during the reconcilliation of the patients' treatment on hospitalisation and release. The fact that the intervention was not possible in 11% of the PRM detected in the intervention group was caused by the fact that the patient had already been released or sent to another hospital or the PRM occurred on a weekend, making it necessary to work jointly with the doctor in charge of the patient in order to programme releases and transfers and the need for continuous pharmaceutical care. The level of acceptance of the pharmaceutical intervention by the doctor was high (85.2%), although lower than in other studies in which the pharmacist is integrated into the healthcare team, where it reaches almost 90%,[14,15,19,20] but higher than studies where the intervention of the pharmacist took place from the pharmacy department.[13]

An important percentage (66%) of the PRM was resolved after the intervention of the pharmacist, a higher percentage than seen in other studies[4-5] although the heterogenicity of these studies made comparison difficult. The results in the patients were, in most cases, total or partial improvement in 36.3% of the cases, although no change was seen in the remainder and other authors reported similar percentages of improvement after the intervention of the pharmacist[13] and higher percentages in other studies.[19] However, comparisons could not be made as different valuation scales were used. Of the variables associated with the degree of resolution of the PRM, only the level of acceptance of the pharmaceutical intervention by the doctor increased the probability of resolution.

The clinical results on release were not significantly different between the 2 groups, due to the efficacy of the treatment prescribed for these pathologies on the clinical medical variables and the short duration of the hospital stay to see the results in health.

Limitations of the Study

The main limitation is that it is an observational study. The clinical study is the ideal method for evaluating the results of the pharmaceutical care, however, due to the complexity of this it was decided to use a cohort design. The size of the sample (356 patients) may also have been a limitation, as was indicated in the section on calculating the size of the sample, and insufficient to reach conclusions in this type of study. However, introducing pharmaceutical care programmes using existing resources in hospital is not an easy task, and this meant that in some hospitals it was not possible to carry out the pharmacologic monitoring in the number of patients assigned. Also, in the control group, when the data was collected retrospectively after release from hospital, and in the majority of cases there was no information available regarding the resolution of PRM or their effects in the patient. The statistically significant difference that exists between the number of PRM detected in the intervention group and the control group showed that when the patient was intensively monitored, the number of PRM detected by the pharmacists was larger. It is impossible to take into account that this result may also indicate a bias in differential monitoring. Following up the patient with cardiovascular pathology in the short term during the hospital

Annex. List of Participating Hospitals

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Hospital General de Vic	Dr C. López
Hospital Universitario La Fe	Dr R. Marqués
Hospital Arquitecto Marcide	Dr R. Taboada
Hospital Santa Caterina	Dr E. de Puig
Hospital de Mollet	Dr A. Parrilla
Hospital Universitario San Cecilio	Dr M. González
Hospital de Cruces	Dr E. Chavarri
Hospital Santa Marina	Dr F. Leyva
Hospital Universitario Puerta del Mar	Dr E. Rodríguez
Hospital Universitario Reina Sofía	Dr M.A. Calleja
Hospital Son Dureta	Dr I. Martínez

stay does not allow health results to be measured, and is limited to the improvement of the symptoms only.

In spite of the many limitations, the study has permitted a work method to be established for the reconcilliation of the treatment when admitted and released and the carrying out of drug treatment monitoring of the patient.

Finally, the DSPFT is a methodology for the systemisation of pharmaceutical care, providing a tool that enables work to be done in a standardised way in all hospitals. The results suggest that the active participation of the pharmacist in the healthcare team contributes to preventing and resolving drug-related problems.

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