

Risk Assessments of Drug-Related Problems for Cardiac Surgery Patients

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Cardiac surgeries are among the most frequently performed operations worldwide and require highly individualized patient care provided by specialists.¹ For these surgeries to be successful, patient-specific conditions should be evaluated during and after the hospital stay, and drug therapy should be optimized.²

In general, accurately recording surgical patients' medications during admission and transferring medical records between all surgical periods are crucial but challenging practices.³ However, they can be achieved by performing comprehensive medication reconciliation between transition periods, which should be part of a standard practice for the drug treatment process.⁴

Patients undergoing cardiac surgery are at high risk for drug-related problems (DRPs) due to comorbidities, polypharmacy, and complexity of drug treatment.⁵ Among DRPs, medication errors are commonly seen at admission but can also occur during all surgical processes. It has been reported that 67% of patients experience at least 1 medication error due to a failure to take their medication history comprehensively at admission.^{6,7} Of those errors, 39% are generally classified as moderate or serious, with the most common error (79.6%) being medication omission.⁶ In a study conducted among general surgery patients, the most common medication error was found to be (dis)continuation of home medications at hospital (50%), followed by dose discrepancies (20%) and dosing frequency discrepancies (16%).⁸ In addition, discrepancies in evaluation of patients' previous medication records while prescribing via an electronic order system have been reported.⁹ For patients undergoing cardiac surgery, medication omission is the most common medication error (82.8%).⁵

Although limited strategies for surgical patients are available in the literature,¹⁰ study results have shown that integrating a clinical pharmacist into the perioperative care team can reduce the number of DRPs,³ improve drug therapy,¹¹ decrease problems with delayed resumption of interrupted drugs,^{12,13} and prevent postoperative complications.³

For all patients, a hospital stay carries the risk of developing DRPs.¹⁴ Polypharmacy, major surgeries, and frequent transitions are the main areas of focus for preventing DRPs.¹⁵ A framework

ABSTRACT

OBJECTIVES: Patients undergoing cardiac surgery are considered at high risk for developing drug-related problems (DRPs) due to comorbidities and complexity of drug treatment. This study aimed to identify DRPs in patients undergoing cardiac surgery and to develop and implement a framework to reduce potential risks associated with drug treatment.

STUDY DESIGN: Prospectively designed quasi-experimental study.

METHODS: This study consisted of observational (risk assessment and framework development) and interventional (framework implementation) periods and was conducted at a department of cardiovascular surgery in a university hospital. An expert panel evaluated the causes of DRPs. Then a framework was developed in consensus to identify safeguards to be implemented during the interventional period.

RESULTS: A total of 200 patients (100 patients per study period) were included. During the observational period, a total of 275 DRPs and 487 causes were identified; 74.5% of DRPs were not solved. For the risk analysis, 487 causes were evaluated and only 32.6% were considered acceptable risk. By implementing the framework in the interventional period, 215 DRPs and 304 causes were identified and 386 interventions were recommended by a clinical pharmacist. A total of 342 (88.6%) interventions were accepted by a health care team, and 128 (59.5%) DRPs were completely solved. For the risk analysis, 304 causes were evaluated and 84.9% were considered acceptable risk ($P < .001$ compared with the observational period).

CONCLUSIONS: It is possible to reduce risk levels or prevent occurrence of DRPs by implementing a framework for risk management developed by a multidisciplinary care team in areas such as cardiac surgery where time is limited.

Am J Manag Care. 2024;30(5):e140-e146. doi:10.37765/ajmc.2024.89541

for patient safety and precautionary activities (safeguards and security measures) is specified in the 2021-2030 Global Patient Safety Action Plan of the World Health Organization to reduce DRPs.¹⁶ In addition, the Institute for Healthcare Improvement specifies tools that can be used for ensuring patient safety, including fishbone diagrams and risk analysis methods.¹⁷ In general, different methods can be used in combination, depending on the subject to be investigated.^{18,19} Along with risk analysis, frameworks (ie, critical maps of health care processes) can be established and used to improve quality of care for different groups of patients.

This study aimed to identify the prevalence of DRPs in cardiac surgery patients during the entire hospital stay (preoperative and postoperative periods) to determine the causes and consequences of DRPs and to develop a framework to reduce potential risks associated with drug treatment. As a secondary outcome, we aimed to demonstrate the contribution of incorporating a clinical pharmacist into the treatment process for patients undergoing cardiac surgery.

MATERIALS AND METHODS

Study Design

This study was designed prospectively as quasi-experimental and consisted of 2 periods: observational (risk assessment and

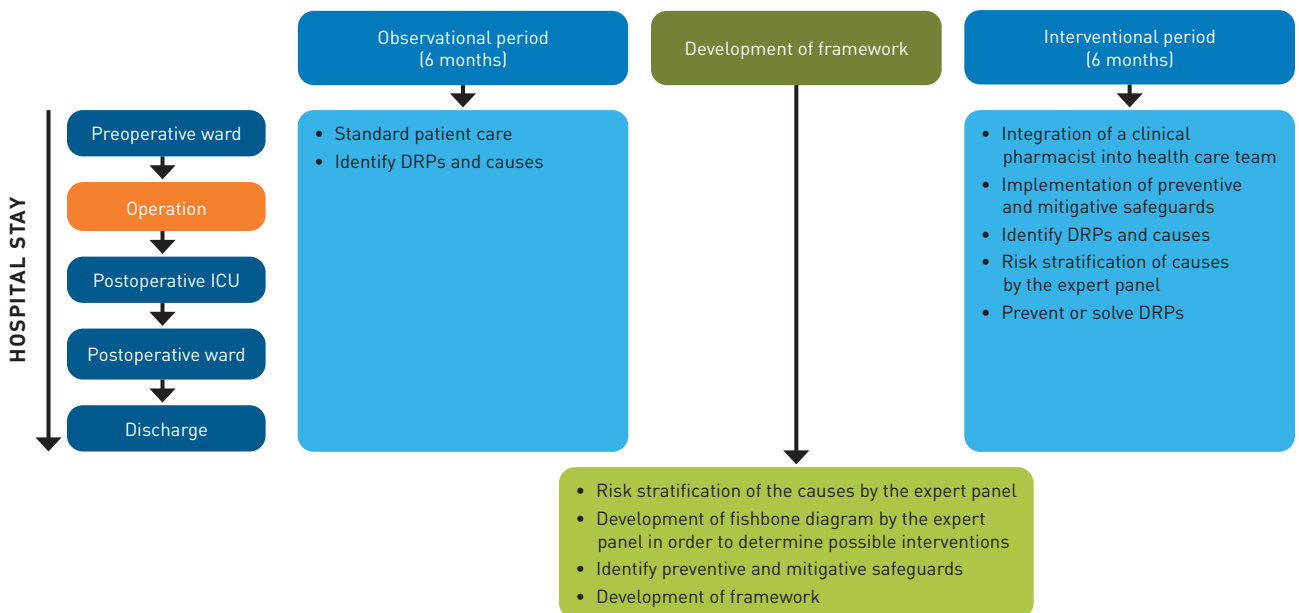
TAKEAWAY POINTS

- ▶ Patient and drug safety are critical issues in the provision of health care.
- ▶ Patients undergoing cardiac surgery are at high risk for drug-related problems due to comorbidities, polypharmacy, and complexity of drug treatment.
- ▶ This study's findings can help busy practitioners in areas such as cardiac surgery quickly focus on preventing drug-related problems.
- ▶ This study's results can also raise awareness about risk management in hospital settings and encourage health system leaders to determine strategies and develop policies to ensure patient safety during the drug treatment process.

framework development) and interventional (framework implementation). The study was conducted at Hacettepe University Hospitals' Department of Cardiovascular Surgery in Ankara, Türkiye. Patients included in the study were 18 years and older, were admitted to the hospital for elective cardiac surgery during the study period, and gave written consent. The study design is shown in **Figure 1**. The study setting provides care with 25 beds in service (wards) and 10 beds in the intensive care unit (ICU). No clinical pharmacy services were available in the department before the study commenced.

For the observational period of the study, patients hospitalized between November 2019 and May 2020 were included and DRPs throughout the hospital stay were identified and recorded by a clinical pharmacist. An expert panel (consisting of 2 cardiovascular surgeons, 1 service nurse, 1 ICU nurse, and 1 clinical pharmacist)

FIGURE 1. Study Design



DRP, drug-related problem; ICU, intensive care unit.

individually interpreted the causes of DRPs and performed a risk assessment of each cause. After the risk assessment, a framework was developed by the expert panel in consensus. Identified DRPs were classified by using the Pharmaceutical Care Network Europe (PCNE) Classification for Drug-Related Problems version 9.00 (PCNE version 9.00). The PCNE classification system has 3 domains for problems, 8 domains for causes of problems, 5 domains for planned interventions, 3 domains for intervention acceptance, and 4 domains for status of DRPs. In the risk assessment method, occurrence of a DRP was defined as the top event, the causes of DRPs were defined as causes of the top event, problem types of DRPs were defined as results of the top event, and planned interventions for and status of DRPs were defined as preventive and mitigative safeguards for the top event.

For the interventional period of the study, hospitalized patients were included and the developed framework and the contribution of a clinical pharmacist were integrated into the treatment process. For the patients, DRPs were identified and resolved by a clinical pharmacist. Identified DRPs were categorized using the PCNE version 9.00. The causes of DRPs were interpreted, and risk assessment of each cause was performed once again by the same expert panel after implementation of the framework.

The primary outcome of this study was to determine the frequency, types, and risk levels of DRPs during the entire hospital stay. The secondary outcome was to evaluate the impact of clinical pharmacy services within the developed framework.

This study was approved by the Hacettepe University Non-Interventional Clinical Studies Ethics Committee (GO 19/1028), the Hacettepe University Clinical Studies Ethics Committee (KA-20002), and the Türkiye Ministry of Health, Pharmaceuticals, and Medical Devices Agency (20-AKD-51).

Study Population

According to previous literature and the volume of patients per month in the department of cardiovascular surgery, the sample size calculation was based on the number of DRPs (at least 1 DRP at each care step) to be detected during the hospitalization process with a medium effect size between the observational and interventional periods of the study. Therefore, we determined that we needed a minimum of 128 patients in the study, at least 64 patients in each period, with an effect size of 0.50, a power of 80%, and a margin of error of 5% within the specified time. Sample size was calculated using G*Power 3.0.10 software (University of Düsseldorf). Considering potential loss, we decided to include a total of 200 patients (100 patients for each period).

Data Collection Process

DRPs were identified by a clinical pharmacist (in either the observational or interventional period) and categorized according to PCNE version 9.00. The risk assessments on the causes of DRPs were performed by the expert panel, and the risk was evaluated individually by using the Fine-Kinney method, which includes

3 different scores—probability, frequency, and severity. The final score is obtained by multiplying the 3 scores and is then classified according to the risk score table as acceptable, possible, substantial, or high risk.

After the risk analysis in the observational period, the expert panel discussed potential areas that contribute to the occurrence of DRPs and created a fishbone diagram to identify risk management strategies for patients undergoing cardiac surgery. Identified and stratified potential preventive and mitigative safeguards were integrated into the risk model, which then led to the design of the framework for the study.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics 23.0 (IBM Corp) and R (R Foundation for Statistical Computing). Categorical variables were expressed in numbers and percentages. Continuous variables were presented as mean and SD for parametric variables and median and IQR or minimum/maximum for nonparametric variables. The normality of continuous variables was tested using the Shapiro-Wilk test for normality. When comparing 2 independent groups in terms of numerical variables, the Student *t* test was used for parametric variables and the Mann-Whitney *U* test was used for nonparametric variables. Chi-square tests for categorical variables were performed. A *P* value less than .05 was considered significant.

RESULTS

A total of 200 patients (100 patients per study period) were included in the study. The patients' demographics and medical histories are shown in **Table 1**. There was no significant difference in terms of demographic data, comorbidities, and surgery type between the patients in the observational and interventional periods of the study. During the observational period, a total of a 275 DRPs (mean [SD] per patient, 2.75 [1.73]) and 487 causes associated with the problems were identified in 100 patients, and 74.5% of DRPs were not solved (**Table 2**). Among the total DRPs, 25.0% were observed at admission, 20.0% at postoperative ICU, 49.1% at postoperative ward, and 5.8% at discharge. The expert panel independently conducted risk analysis for the 487 causes and classified 159 (32.6%) as acceptable risk, 140 (28.7%) as possible risk, 102 (20.9%) as substantial risk, and 86 (17.7%) as high risk.

After the individual risk assessments, the expert panel had 6 meetings, during which they identified vulnerable areas in the care process and situations that may lead to DRPs and then created a fishbone diagram for risk analysis. The diagram consisted of 5 categories: person related, environment related, material related, method related, and system related. Because person-, environment-, and system-related areas required comprehensive bureaucratic and financial institutional interventions (such as standard operational procedures and software development and integration), the expert panel decided to implement the interventions (known as preventive and mitigative safeguards) mainly for material- and method-related

areas, where a clinical pharmacist can be smoothly integrated into the care process.

Therefore, in the final framework, preventive safeguards (medication reconciliation, drug review, face-to-face training for health care professionals, transfer forms, patient education materials) and mitigative safeguards (medication counseling for patients, interventions for DRPs, follow-up for the DRP status) were determined for the entire hospital stay (Figure 2). In the interventional period of the study, a clinical pharmacist was integrated into the multidisciplinary health care team to implement suggested preventive and mitigative safeguards into practice.

By implementing the framework in the interventional period (n=100 patients), 215 DRPs (26.5% at admission, 22.3% at postoperative ICU, 39.1% at postoperative ward, and 12.1% at discharge) and 304 causes were identified and 386 interventions (5 only monitoring, 214 at physician level, 10 at patient level, and 157 at drug level) were recommended by a clinical pharmacist. A total of 342 (88.6%) interventions were accepted by the health care team, and 128 (59.5%) DRPs were solved (63.1% at preoperative ward, 64.5% at postoperative ICU, 57.1% at postoperative ward, and 50% at discharge).

The expert panel independently conducted risk analysis for the 304 causes and classified 258 (84.9%) as acceptable risk, 23 (7.6%) as possible risk, and 23 (7.6%) as substantial risk. A significant difference was found between the observational and the interventional periods in terms of identified risk levels in the patient care process (P < .001). Risk scores of the causes of DRPs in each care setting are shown in Figure 3.

To assess the effects of the implemented framework on patients' quality of life, the expert panel evaluated scores from the 2 summary measures of the 36-Item Short Form Health Survey (SF-36)—the Physical Component Summary (physical function, physical role, pain, and general perception of health) and the Mental Component Summary (energy, social function, emotional role difficulty, and mental health)—and examined differentials between the periods. Observed changes in the mean scores of SF-36 for patients in the observational period and in the interventional period were found to be significantly improved (Table 1).

TABLE 1. Characteristics of Patients

Variables	Observational period (n = 100)	Interventional period (n = 100)	P
Male gender, %	60	63	.663
Age in years, median (IQR)	62.0 (14.5)	59.50 (15.50)	.171
Marital status, married, %	78	78	.947
Drug allergy, %	6	7	.774
Education, middle school and higher, %	63	56	.313
Comorbidities*	n = 107	n = 121	.154
Hypertension, n (%)	48 (44.9)	52 (43.0)	
Diabetes, n (%)	29 (27.1)	33 (27.3)	
Dyslipidemia, n (%)	11 (10.3)	14 (11.6)	
Hypothyroidism, n (%)	5 (4.7)	11 (9.1)	
Obstructive lung disease, n (%)	12 (11.2)	4 (3.3)	
Other, n (%)	2 (1.9)	7 (5.8)	
Diagnosis for cardiac surgery*	n = 143	n = 127	.048*
Coronary artery disease, n (%)	45 (31.5)	57 (44.9)	
Valve-related problems, n (%)	60 (42.0)	36 (28.3)	
Aortic diseases, n (%)	31 (21.7)	24 (18.9)	
Others, n (%)	7 (4.9)	10 (7.9)	
Surgery type*	n = 123	n = 129	.546
Valve surgery, n (%)	55 (44.7)	33 (25.5)	
Coronary surgery, n (%)	43 (34.9)	58 (44.9)	
Combination of valve and coronary surgery, n (%)	9 (7.3)	8 (6.2)	
Minimally invasive valve surgery, n (%)	2 (1.6)	5 (3.8)	
Others, n (%)	14 (11.3)	25 (19.3)	
Hospital stay length in days, median (IQR)	11 (7)	10.5 (4.5)	.540
Postoperative complications, %	58	40	.011*
Admission to ED 1 month after discharge, %	14	7	.106
Number of medications, median (IQR)			
Preoperative ward	5.0 (3.5)	5.00 (3.00)	.907
Postoperative ICU	9.5 (4.0)	10.00 (3.00)	.773
Postoperative ward	8.5 (4.5)	9.00 (3.00)	.062
Discharge	7.0 (3.0)	8.00 (4.00)	.014*
Median (IQR) changes in the scores of SF-36 summary components (Δ: differential)			
Δ (hospital admission – discharge)			
Mental Component Summary	-16.5 [-27.0 to -4.7]	-10.0 [-16.4 to -3.4]	<.001*
Physical Component Summary	-54.7 [-64.9 to -41.2]	-53.7 [-65.7 to -44.6]	.32
Δ (hospital admission – 1 month after discharge)			
Mental Component Summary	-7.4 [-11.2 to 1.7]	14.9 (7.5-29.1)	<.001*
Physical Component Summary	3.0 [-2.4 to 12.8]	16.4 (9.7-26.8)	<.001*
Δ (discharge – 1 month after discharge)			
Mental Component Summary	8.1 (0-27.6)	29.8 (22.0-40.5)	<.001*
Physical Component Summary	137.2 (106.5-194.5)	206.0 (112.1-275.6)	<.001*

ED, emergency department; ICU, intensive care unit; SF-36, 36-Item Short Form Health Survey.

*P < .05.

*Each patient could be included in more than 1 row; percentages are calculated out of the larger n representing the sum of all rows.

CLINICAL

TABLE 2. DRPs Classified According to PCNE Version 9.00

Variables	Observational period	Interventional period	P
Problems	n=275	n=215	.018
Treatment effectiveness, n (%)	110 (40.0)	67 (31.2)	
Treatment safety, n (%)	83 (30.2)	91 (42.3)	
Other, n (%)	82 (29.8)	57 (26.5)	
Causes	n=487	n=304	< .001*
Drug selection, n (%)	142 (29.2)	100 (32.9)	
Drug form, n (%)	2 (0.4)	0 (0)	
Dose selection, n (%)	21 (4.3)	51 (16.8)	
Treatment duration, n (%)	68 (14.0)	27 (8.9)	
Dispensing, n (%)	33 (6.8)	5 (1.6)	
Drug use process, n (%)	72 (14.8)	34 (11.2)	
Patient related, n (%)	35 (7.2)	6 (2.0)	
Patient transfer related, n (%)	112 (23.0)	73 (24.0)	
Other, n (%)	2 (0.4)	8 (2.6)	
Recommended interventions	n=487	n=386	N/A
No intervention, n (%)	487 (100)	5 (1.3)	
At physician level, n (%)	—	214 (55.4)	
At patient level, n (%)	—	10 (2.6)	
At drug level, n (%)	—	157 (40.7)	
Intervention acceptance	n=487	n=386	N/A
Intervention accepted, n (%)	—	342 (88.6)	
Intervention not accepted, n (%)	—	3 (0.7)	
Other, n (%)	487 (100)	41 (10.6)	
Status of the DRP	n=275	n=215	< .001*
Problem status unknown, n (%)	—	2 (0.9)	
Problem solved, n (%)	9 (3.3)	128 (59.5)	
Problem partially solved, n (%)	61 (22.2)	26 (12.1)	
Problem not solved, n (%)	205 (74.5)	59 (27.4)	

DRP, drug-related problem; N/A, not applicable; PCNE version 9.00, Pharmaceutical Care Network Europe Classification for Drug-Related Problems version 9.00.

* $P < .05$.

DISCUSSION

In this study, DRPs among patients undergoing cardiac surgery were identified across the entire hospital stay, a risk analysis was carried out for the treatment process, and a framework was developed for each process to reduce risks associated with drug treatment. The impact of the framework (along with integration of a clinical pharmacist) on the treatment process and on patients' quality of life was determined by the risk analysis.

To our knowledge, this is the first study to evaluate DRPs via risk analysis in cardiac surgery patients. This study's findings have shown

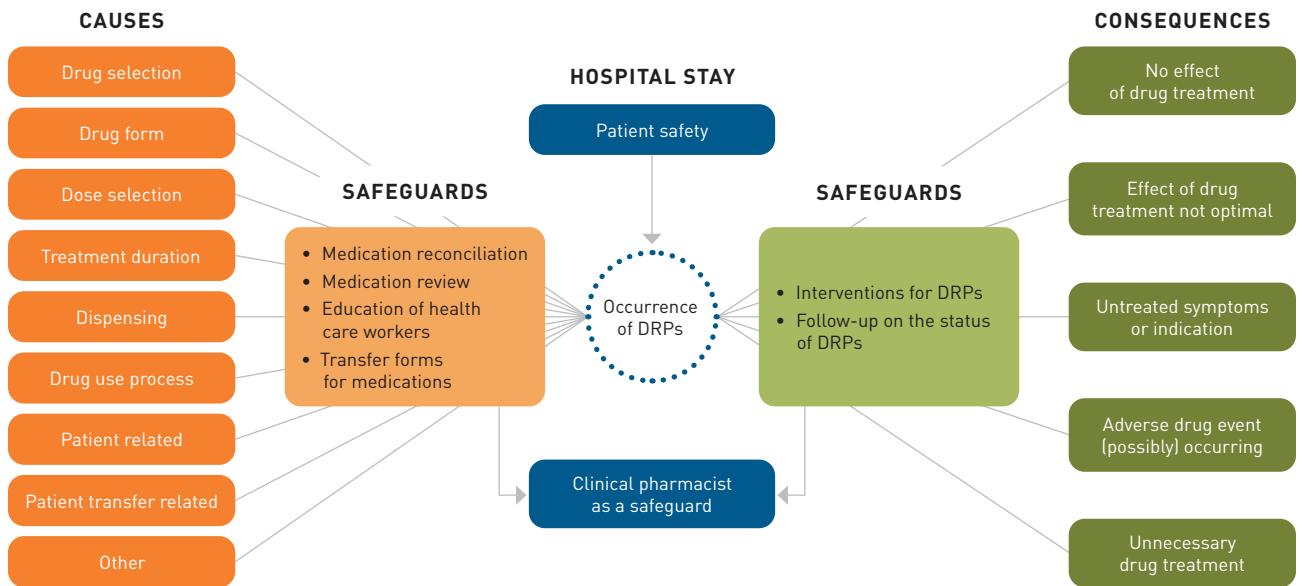
that proactive risk management performed by a multidisciplinary care team contributes to identification, risk assessment, and resolution of DRPs and eventually improves quality of life for patients who undergo cardiac surgery. As a result of the interventions made by the clinical pharmacist, a significant decrease was achieved in the number of DRPs and the rate of resolved DRPs increased vs the observational period.

Risk scores for the causes of DRPs rated by the expert panel differed between the study periods, which indicates that implementation of preventive and mitigative safeguards performed by the clinical pharmacist is valuable. Although it is not possible to completely eliminate DRPs during the treatment process, it is crucial to predict and prevent DRPs. Therefore, the acceptance rate of the interventions suggested by pharmacists can be considered as a positive outcome for developed frameworks. In studies conducted in surgical and medical wards, the acceptance rates of interventions suggested by a clinical pharmacist varied from 36.9% to 91.9%.^{5,20-24} In addition, it has been reported that 67.3% to 74.1% of DRPs were completely solved and 4.8% were partially solved as result of the interventions.²¹⁻²⁴ In the observational period of this study, no intervention was made and the majority of DRPs were not solved. However, by implementing the framework, interventions were made at the physician, patient, and drug levels by a clinical pharmacist; the highest acceptance rate in the literature was achieved; and more than half of the DRPs were resolved. These findings show the strength of chosen preventive safeguards in the framework and the impact of a clinical pharmacist on patient safety.

Hospitalized patients are generally at risk for development of DRPs, which can arise due to factors related to people, environment, system, methods, and materials.²⁵ Study findings have indicated that the number of DRPs per patient is 1.05 to 2.6 for medical wards, 0.3 to 1.3 for surgical wards,^{23,24,26-29} and 1.7 for cardiovascular surgery wards.³⁰ It has been argued that the surgical ward carries less risk in terms of DRPs compared with the medical ward due to shorter length of stay, less medication use, and less complex treatment plans.²⁴ However, because the cardiovascular surgery ward accommodates patients with major surgeries, multiple comorbidities, urgent surgery needs, and polypharmacy status, it can be considered a high-risk setting in terms of DRPs. During the observational period of this study, 2.75 DRPs per patient were detected, which is similar to the medical ward, whereas the rate was 2.15 DRPs per patient in the interventional period. Based on these findings, patients hospitalized in the cardiovascular surgery ward should be evaluated as diligently as patients hospitalized in the medical ward and clinicians should be more vigilant about the development of DRPs.

DRPs mostly occur at admission or discharge due to a lack of medication reconciliation,^{21,31} which may originate from medication discrepancies.^{5,31} Transition between ICU and wards may also pose a risk for surgical patients, and the rate of DRPs can vary throughout the hospital stay.^{5,22,32,33} Findings from a randomized controlled study that examined the importance of medication reconciliation at transition points between the ICU and the ward showed that DRPs were detected at the transition points in 60% of patients.²⁰ In this study, DRPs were identified across the entire hospitalization

FIGURE 2. Developed Framework



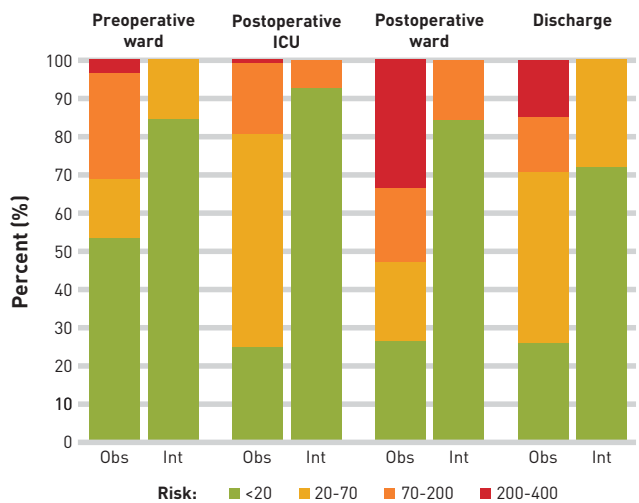
DRP, drug-related problem.

period, but they particularly increased at the transition between postoperative ICU and postoperative ward (20.0% vs 49.1% during observation period and 22.3% vs 39.1% during intervention period). As expected, most DRPs at postoperative ICU (64.5%) and postoperative ward (57.1%) were completely solved in the intervention period by the involvement of a clinical pharmacist.

Moreover, it is important to know the level of significance of the DRPs in clinical practice, to investigate the root causes, and to take mitigative/preventive actions to address them for a more proactive approach. A limited number of studies in the literature have evaluated DRPs in terms of significance. In a study conducted among patients undergoing cardiac surgery, it was emphasized that 83% of interventions for DRPs were clinically significant (interventions may decrease mortality, organ damage, or hospital stay length, which can be caused by DRPs).⁵ Moreover, in a study investigating the significance of medication review at ICU and interservice transition points, an expert panel reviewed 743 DRPs and classified 24.8% as major, 13.1% as intermediate, 53.4% as minor, and 8.9% as having no clinical effect.²⁰ Although the risk-assessment studies demonstrate varying degrees of benefit on quality of care, different methodologies make it difficult to compare the findings.³⁴⁻³⁶ Most of the causes of DRPs evaluated during the observational period of this study were classified as possible, substantial, or high risk according to the expert panel, whereas most of the causes of DRPs were classified as acceptable risk in the interventional period, which showed that appropriate interventions can improve patient safety.

DRPs may cause an increase in hospitalization and morbidity and a decrease in quality of life³⁷; therefore, prevention of DRPs

FIGURE 3. Risk Scores of the Causes of DRPs in Each Care Setting



DRP, drug-related problem; ICU, intensive care unit; int, interventional; obs, observational.

will contribute to improved patient quality of life.²⁶ Besides a decrease in the prevalence of high-risk DRPs in this study, quality of life as a humanistic outcome improved by the implementation of a developed framework. There was a significant improvement observed in the mental and physical summary components of SF-36 scores at admission, discharge, and 1 month after discharge between the 2 periods of this study.

Limitations

No clinical pharmacist was available in the cardiovascular surgery department before the study commenced, which could have made it challenging for health care professionals to understand the role of a clinical pharmacist in the treatment process. To prevent the Hawthorne effect, limited information about the study was given to health care professionals during the observational period. However, the presence of a clinical pharmacist in the wards may have caused health care workers to become more vigilant. Findings of the study cannot be generalized to the entire cardiac surgery population because the study was conducted in a single center. The aforementioned outcomes should be investigated in future studies to contribute to the development of policies that ensure patient safety during the drug treatment process.

CONCLUSIONS

Patient and drug safety are critical issues in the provision of health care. It is possible to predict and minimize the occurrence of DRPs by using preventive and mitigative safeguards. Given the fact that anticipated efforts do not necessarily act as preventive safeguards, it is important to use a proactive risk assessment to maintain patient safety during drug treatment. Clinical pharmacists can function as a safeguard against the risk associated with drug treatment, contribute to sustainability of patient and drug safety, and improve health-related outcomes in areas such as cardiac surgery. ■

Acknowledgments

The authors are thankful to all the health care workers in the cardiovascular surgery department of Hacettepe University Hospitals in Ankara, Türkiye. There has been no significant financial support for this work that could have influenced its outcome.

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Source of Funding: None.

Author Disclosures: The authors report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

Authorship Information: Concept and design (BK-C, MK, AA, MY, AB-E); acquisition of data (BK-C, MK, AA); analysis and interpretation of data (BK-C, MK); drafting of the manuscript (BK-C, MY, AB-E); critical revision of the manuscript for important intellectual content (AA, MY, AB-E); statistical analysis (MK); provision of patients or study materials (AA); and supervision (AA, MY, AB-E).

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