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Article

Analysis of the Application Value of the Six Sigma Methodology in Nursing Management after Percutaneous Coronary Intervention

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Abstract

Objective: The incidence of postoperative complications after percutaneous coronary intervention (PCI) is relatively high, seriously affecting the prognosis of patients. This study explores the application value of the Six Sigma methodology in the preventive management of complications after PCI. **Methods**: The clinical data of 102 patients who underwent PCI in our hospital from March 2021 to January 2022 were retrospectively analyzed. In accordance with different management methods, these patients were divided into the reference group (n = 49, conventional management method) and the observation group (n = 53, Six Sigma methodology). The anxiety and depression levels, quality of life, cardiac function indexes (left ventricular ejection fraction, left ventricular end-diastolic volume, left ventricular end-systolic volume, and stroke volume), and incidence of complications were compared between the two groups. **Results**: Before management, no difference was observed in anxiety and depression levels, quality of life, and cardiac function indexes in both groups ($p > 0.05$). After management, the observation group demonstrated lower anxiety and depression levels, higher quality of life, and lower incidence of complications than the reference group did ($p < 0.05$), with no significant difference in cardiac function indexes ($p > 0.05$). **Conclusions**: The Six Sigma methodology can improve the quality of life and reduce the incidence of postoperative complications, with a high promotion and application value in nursing management after PCI.

Keywords

Six Sigma methodology; percutaneous coronary intervention; postoperative complications; preventive management

Introduction

In recent years, percutaneous coronary intervention (PCI) has made significant progress and can effectively treat complex coronary artery diseases [1]. However, these advancements have resulted in the treatment of increasingly complex patient populations, including acute coronary syndrome, chronic total occlusion, calcified coronary disease, and cardiogenic shock. Despite improvements in equipment and surgical safety, complications related to PCI may still occur [2]. Common complications such as local thrombosis, perforation, systemic ischemic events, thrombosis caused by postoperative antiplatelet therapy, coronary stent infection, and various postoperative adverse cardiovascular events greatly affect the prognosis and quality of life of patients [3,4].

The complexity of PCI procedures and the increasing risk to patients require healthcare professionals to identify and treat complications [5]. The Six Sigma methodology was first proposed for industrial quality control and gradually applied to hospital management [6]. Hospitals realize the set goals through the "define, measure, analyze, improve, and control" process [7]. On the basis of the low patient satisfaction score in the vascular interventional radiology department, especially related to the waiting time of registration and examination/treatment, Godley M and Jenkins JB [8] applied the Six Sigma methodology to reduce the waiting time and improve patient satisfaction. Moffatt S *et al*. [9] showed that the Six Sigma methodology can be successfully used to optimize the nursing path in healthcare and reduce the hospitalization time of patients. Obviously, the Six Sigma methodology has a high fit with the preventive management of complications after PCI. However, few studies have been conducted on the combination of the Six Sigma methodology and PCI. Therefore, this study implemented Six Sigma management in the perioperative period of PCI, with the aim of enhancing the nursing quality, reducing complications after PCI, and improving the prognosis of patients.

Materials and Methods

Research Subjects

The clinical data of 108 patients who underwent PCI in our hospital from March 2021 to January 2022 were retrospectively analyzed, with 6 cases excluded, resulting in 102 patients included. In accordance with different man-

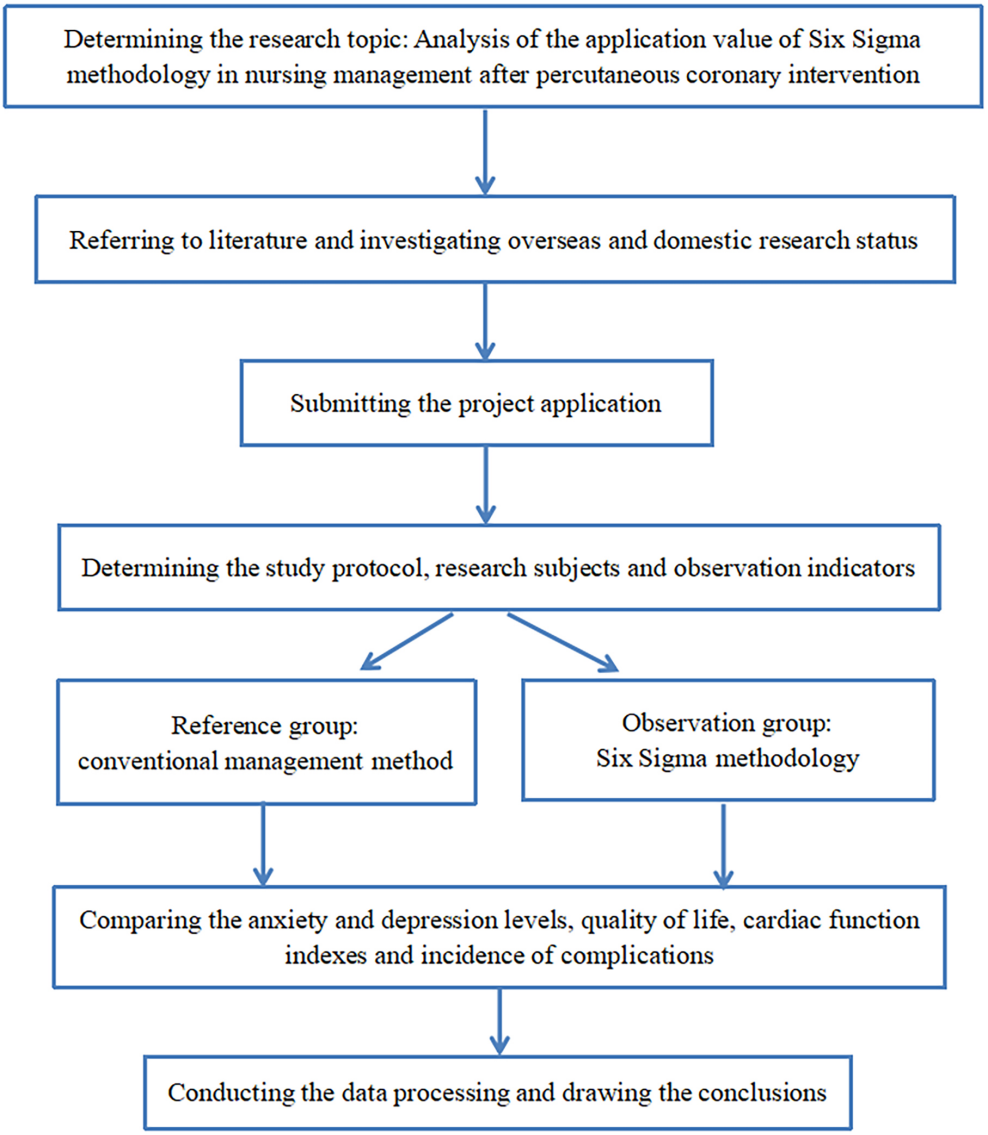

Fig. 1. Flowchart of the study.

agement methods, these patients were divided into the reference group (n = 49, conventional management method) and the observation group (n = 53, Six Sigma methodology). This study conforms to the principles of the Declaration of Helsinki (2013) [10] and was approved by the medical ethics committee of Taihe County People's Hospital (approval no. 2020-132). The flowchart of this study is shown in Fig. 1.

Inclusion criteria: (1) Patients were <80 years old; (2) patients met the surgical indications of PCI; (3) patients underwent PCI treatment for the first time; (4) patients had complete clinical data; and (5) patients signed an informed consent.

Exclusion criteria: (1) Patients with serious postoperative complications, such as massive hemorrhage and pericardial tamponade; (2) patients with malignant tumors; (3) patients with blood coagulation dysfunction; and (4) patients with mental disorders.

Methods

Reference Group

The reference group was treated with routine management. The medical staff monitored the electrocardiogram 24 hours after surgery to closely observe changes in vital signs such as heart rate, blood pressure, and heart rhythm, and advised them to stay in bed for 24 h. Patients should take anti-platelet aggregation drugs such as aspirin and clopidogrel to avoid thrombosis in the stent and adhere to a principle of "eating little but often" to keep the bowels unobstructed.

Observation Group

The observation group was treated by using the Six Sigma methodology.

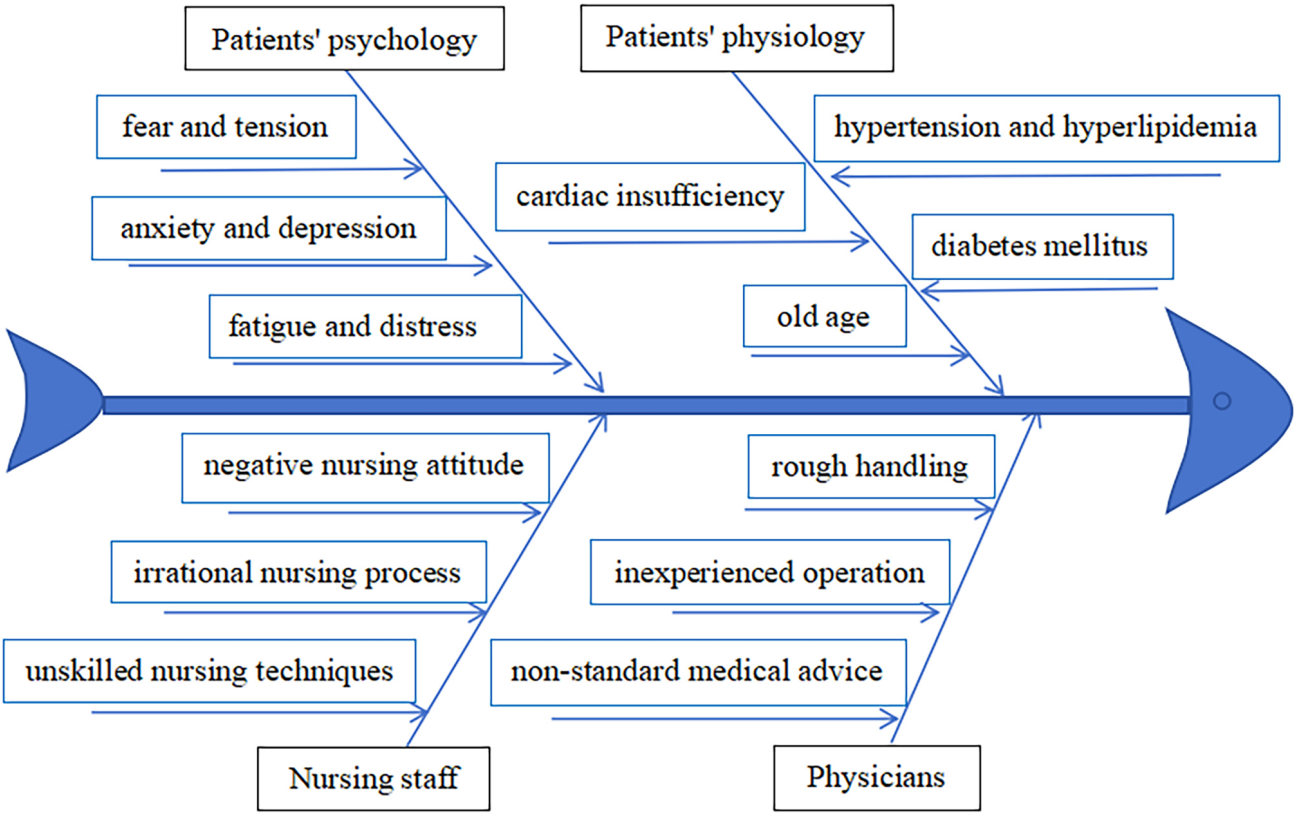

Fig. 2. Fishbone diagram of complications after percutaneous coronary intervention (PCI).

(1) Define: First, the research topic was defined as "application analysis of the Six Sigma methodology in preventive management of complications after PCI". Then, a management team consisting of 3 experienced physicians and 13 nurses was established to explain the surgical process and possible complications of PCI for patients.

(2) Measure: By communicating with patients, the medical staff understood their main demands and concerns and carried out personalized and targeted nursing work for improving nursing quality. The medical staff summarized the types of complications after PCI in our hospital.

(3) Analyze: The team members adopted the brainstorming method to draw a fishbone diagram and analyzed the causes of complications after PCI, mainly from the two aspects of patients and medical staff, thus further developing strategies to improve management methods (Fig. 2).

(4) Improve: The team members utilized the analysis results to make targeted improvements.

Nursing staff: (1) A reward and punishment mechanism was formulated to enhance the service awareness of nursing staff and cultivate their positive work attitude. Simultaneously, a weekly experience exchange meeting was conducted to enhance the patient–nurse communication efficiency. (2) Before surgery, the nursing staff explained the surgical process so that the patients can better understand the surgery and ease their concerns. (3) After surgery, nurses should be aware of the puncture of the radial artery during surgery, the amount of heparin used, and the use of anticoagulant drugs before and after surgery; master the measures to avoid or treat wound bleeding; and identify the risk factors of bleeding, thereby preventing severe complications such as vagus nerve reflex and radial artery occlusion caused by excessive hemostatic pressure or long compression time after PCI, as well as symptoms such as numbness, hematoma, and skin cyanosis at the puncture site. (4) Nursing staff guided patients to take anticoagulant drugs on time, correctly identify the puncture site, and perform proper exercises to prevent thrombosis. (5) Long-term antiplatelet therapy after surgery can cause serious gastrointestinal mucosal damage to a certain extent, leading to gastrointestinal ulcers and gastric bleeding. In this regard, nurses should implement predictive nursing intervention; closely observe the patients' vital signs, feces condition, and coagulation time; and detect abnormalities early and cope with them in a timely manner to promote the rehabilitation and reduce the risk of postoperative complications. (6) Improper care during transradial coronary intervention can induce adverse skin reactions, such as hematoma, blisters, bleeding, and congestion, and then increase pain degree. Therefore, nurses should strengthen the wound management of patients to avoid infection and report any abnormal situations to physicians immediately. (7) Patients with coronary heart disease have a risk of chest pain during the perioperative period, such as chest tightness, chest pain, and

Table 1. General information in both groups (M [P_{25}, P_{75}], n [%]).

Items	Reference group (n = 49)	Observation group (n = 53)	χ^2/z	*p*
Age (years, M (P_{25}, P_{75}))	68.00 (64.00, 75.50)	68.00 (61.50, 73.50)	−0.885	0.376
Sex			0.023	0.879
Male	27 (55.10)	30 (56.60)		
Female	22 (44.90)	23 (43.40)		
BMI (kg/m^2, M [P_{25}, P_{75}])	20.80 (19.60, 22.35)	20.30 (19.15, 21.90)	−1.377	0.169
Disease types			0.005	0.943
Angina pectoris	20 (40.82)	22 (41.51)		
Myocardial infarction	29 (51.18)	31 (58.49)		
Degree of coronary artery stenosis			0.011	0.995
Mild	8 (16.33)	9 (16.98)		
Moderate	24 (48.98)	26 (49.06)		
Severe	17 (34.69)	18 (33.96)		
Medication history				
Nitrate drugs	24 (48.98)	24 (45.28)	0.140	0.709
Statin drugs	46 (93.88)	51 (96.23)	0.008	0.928
Antiplatelet drugs	49 (100.00)	53 (100.00)	0.000	1.000
Hospitalization time (days, M [P_{25}, P_{75}])	7.00 (6.00, 8.00)	7.00 (6.00, 8.50)	−0.452	0.651
Underlying diseases				
Hypertension	25 (51.02)	24 (45.28)	0.336	0.562
Hyperlipidemia	28 (57.14)	29 (54.72)	0.061	0.805
Diabetes mellitus	20 (40.82)	23 (43.40)	0.070	0.792
NYHA Functional Classification			0.006	0.938
Grade II	17 (34.69)	18 (33.96)		
Grade III	32 (65.31)	35 (66.04)		

BMI, body mass index; NYHA, New York Heart Association.

Table 2. Anxiety and depression levels in both groups (M [P_{25}, P_{75}], points).

Items	Time	Reference group (n = 49)	Observation group (n = 53)	z	*p*
HAMA scores	Before management	14.00 (12.00, 15.00)	13.00 (11.00, 14.00)	−1.300	0.194
	After management	10.00 (9.00, 11.00)	6.00 (5.00, 9.00)	−7.203	<0.001
HAMD-24 scores	Before management	16.00 (14.00, 18.00)	18.00 (14.00, 19.50)	−0.862	0.389
	After management	10.00 (8.50, 13.00)	7.00 (5.00, 9.00)	−6.149	<0.001

HAMA, Hamilton Anxiety Scale; HAMD-24, Hamilton Depression Scale-24.

fatigue. Before the patients experience chest pain, nurses should provide preventive chest pain care, closely monitor electrocardiographic changes, observe the presence or absence of ischemia, and strengthen inquiries and communication with the patients. When the patients experience chest pain again, nurses should immediately notify the physicians and follow the instructions to administer medication.

Physicians. (1) To improve the operation techniques, the hospital carried out department training for physicians, focusing on targeted learning. (2) The hospital established a feedback channel and collected the patients' opinions through interviews to improve patient satisfaction with the physicians. (3) Physicians conducted adequate preoperative evaluation and provided appropriate psychological counseling for patients with higher risks to enhance their confidence.

(5) Control. The medical staff attached importance to the concept and link of control in the Six Sigma methodology, identified problems, and proposed solutions, thus constantly improving the management methods.

Both nursing groups lasted from the first day after surgery to the day of discharge, and various observation indicators were measured on the day of discharge.

Observation Indicators

(1) Anxiety and depression levels. The Hamilton Anxiety Scale (HAMA) [11] and the Hamilton Depression Scale-24 (HAMD-24) [12] were used to measure the anxiety and depression levels of patients on admission and the day of discharge. Each item in the HAMA scale were scored using a five-level scoring method of 0–4 points, with a total score of 0–56 points. A higher score indicated the more severe anxiety level of patients. Most of the items in the HAMD-24 scale adopted a score standard of 0–4 points, and some items were scored using a score standard of 0–2

Table 3. Quality of life in both groups (M [P_{25}, P_{75}], points).

Indicators	Time	Reference group (n = 49)	Observation group (n = 53)	Z	*p*
PF	Before management	57.00 (54.50, 61.50)	59.00 (54.50, 62.00)	−0.722	0.470
	After management	67.00 (63.00, 71.50)	77.00 (73.00, 82.00)	−7.197	<0.001
RP	Before management	57.00 (52.50, 62.00)	57.00 (54.00, 61.50)	−0.450	0.653
	After management	70.00 (68.00, 72.00)	75.00 (72.00, 77.00)	−6.449	<0.001
BP	Before management	55.00 (53.00, 58.00)	56.00 (53.00, 57.50)	−0.057	0.954
	After management	71.00 (68.00, 74.00)	74.00 (71.50, 78.00)	−4.399	<0.001
GH	Before management	56.00 (52.00, 60.00)	58.00 (55.00, 62.50)	−1.739	0.082
	After management	76.00 (74.00, 78.00)	81.00 (79.00, 82.00)	−7.444	<0.001
VT	Before management	64.00 (62.00, 66.00)	64.00 (61.00, 66.00)	−0.662	0.508
	After management	72.00 (68.50, 77.00)	79.00 (72.50, 82.00)	−4.784	<0.001
SF	Before management	65.00 (63.00, 68.00)	65.00 (61.00, 67.00)	−1.395	0.163
	After management	70.00 (67.50, 73.50)	74.00 (72.00, 76.50)	−5.505	<0.001
RE	Before management	65.00 (62.00, 68.00)	64.00 (61.50, 68.00)	−0.417	0.676
	After management	69.00 (67.00, 72.00)	79.00 (76.00, 83.00)	−8.631	<0.001
MH	Before management	64.00 (62.00, 68.00)	65.00 (63.00, 67.50)	−0.300	0.764
	After management	75.00 (72.00, 78.00)	80.00 (77.50, 83.50)	−6.349	<0.001

PF, physical function; RP, physical health; BP, body pain; GH, general health; VT, vitality; SF, social function; RE, role limitation due to emotional problems; MH, mental health.

points, with a total score of 0–64 points. A higher score indicated the severe depression level of the patients.

(2) Quality of life. The Short From-36 Health Survey (SF-36) [13] was employed to assess the quality of life of patients on admission and the day of discharge, comprising eight health dimensions: physical function (PF), role limitation due to physical health (RP), body pain (BP), general health (GH), vitality (VT), social function (SF), role limitation due to emotional problems (RE), and mental health (MH). A higher score indicated better quality of life.

(3) Cardiac function indexes. Ultrasound cardiography examinations were performed on patients with coronary heart disease by using a color Doppler ultrasound diagnostic apparatus (Aplio i900, Canon, Tokyo, Japan) on admission and the day of discharge, with a probe frequency of 2.5 MHZ. The left lateral position of the patients was taken for detection. The medical staff placed the probe between the 3–5 ribs on the left side of the sternum and then selected the parasternal long-axis view of the left ventricle and the subxiphoid four-chamber view to observe the cardiac cavity size, blood vessel diameter, mitral valve thickness, active extent in ventricular wall, coordination, and myocardial echo intensity to measure the left ventricular end-diastolic and end-systolic diameters. They then automatically calculated the left ventricular ejection fraction (LVEF, normal range: 50%–70%), left ventricular end-diastolic volume (LVEDV, normal range: 108–132 mL), left ventricular end-systolic volume (LVESV, normal range: 29–61 mL) and stroke volume (SV, normal range: 60–80 mL).

(4) Incidence of complications. The incidence of coronary artery dissection, coronary artery perforation, no-reflow, coronary artery occlusion, vagus nerve reflex, numbness, hematoma and skin cyanosis at the puncture site, thrombosis formation, gastrointestinal ulcer, gastric bleeding, chest pain and distress, bending guide wire or catheter, and instrument detachment was calculated, and the total incidence of complications was compared between the two groups.

Statistical Methods

Data were processed using SPSS 26.0 (IBM Corp., Armonk, NY, USA). The categorical variables were expressed as (n [%]) and analyzed by chi-square test. The Shapiro–Wilk method was utilized to test the normal distribution of continuous variables. The data conforming to a normal distribution were expressed as (mean ± standard deviation) and subjected to *t*-test, while the data not adhering to a normal distribution were represented by (M [P_{25}, P_{75}]) and tested by the Mann–Whitney U test. A significance level of $p < 0.05$ was considered statistically significant.

Results

General Information in Both Groups

No significant difference existed in age, sex, body mass index (BMI), and other general data between the two groups ($p > 0.05$), as detailed in Table 1.

Anxiety and Depression Levels in Both Groups

After management, the observation group demonstrated significantly lower anxiety and depression levels than the reference group did, with no significant difference before management ($p > 0.05$) (Table 2).

Table 4. Cardiac function indexes in both groups (M [P_{25}, P_{75}]).

Items	Time	Reference group (n = 49)	Observation group (n = 53)	z	*p*
LVEF (%)	Before management	41.00 (32.50, 46.00)	40.00 (35.50, 46.00)	−0.164	0.869
	After management	52.00 (47.00, 60.00)	54.00 (47.00, 59.00)	−0.168	0.867
LVEDV (mL)	Before management	82.00 (77.00, 85.00)	79.00 (75.50, 87.00)	−0.761	0.446
	After management	103.00 (96.50, 106.00)	100.00 (95.50, 104.00)	−1.580	0.114
LVESV (mL)	Before management	30.00 (25.00, 36.00)	30.00 (25.00, 35.50)	−0.023	0.981
	After management	35.00 (29.00, 39.00)	31.00 (28.00, 38.50)	−0.598	0.550
SV (mL)	Before management	54.00 (45.00, 58.00)	49.00 (43.00, 55.00)	−1.691	0.091
	After management	59.00 (54.00, 65.50)	58.00 (53.50, 61.00)	−1.444	0.149

LVEF, left ventricular ejection fraction; LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume; SV, stroke volume.

Table 5. Incidence of complications in both groups (n [%]).

Types	Reference group (n = 49)	Observation group (n = 53)	χ^2	*p*
Coronary artery dissection	1 (2.04)	1 (1.89)		
Coronary artery perforation	1 (2.04)	1 (1.89)		
No-reflow	1 (2.04)	0		
Coronary artery occlusion	1 (2.04)	1 (1.89)		
Vagus nerve reflex	1 (2.04)	1 (1.89)		
Numbness at the puncture site	1 (2.04)	0		
Hematoma at the puncture site	2 (4.08)	0		
Skin cyanosis at the puncture site	1 (2.04)	0		
Bleeding at the puncture site	1 (2.04)	0		
Thrombosis formation	1 (2.04)	1 (1.89)		
Gastrointestinal ulcer	2 (4.08)	0		
Gastric bleeding	0	0		
Chest pain and distress	1 (2.04)	1 (1.89)		
Bending guide wire or catheter	0	0		
Instrument detachment	1 (2.04)	1 (1.89)		
Total incidence	15 (30.61)	7 (13.21)	4.560	0.033

Quality of Life in Both Groups

After management, the observation group exhibited significantly higher quality of life than the reference group did, with no significant difference before management ($p > 0.05$), as shown in Table 3.

Cardiac Function Indexes in Both Groups

Both groups demonstrated no significant difference in LVEF, LVEDV, LVESV, and SV levels before and after management ($p > 0.05$) (Table 4).

Incidence of Complications in Both Groups

The incidence of complications in the observation group was significantly lower than in the reference group ($p < 0.05$), as shown in Table 5.

Discussion

This study found that compared with the conventional management method, the Six Sigma methodology can significantly alleviate the anxiety and depression levels, improve the quality of life, and effectively reduce the incidence of postoperative complications in patients with PCI. However, no difference was observed in LVEF, LVEDV, LVESV, and other cardiac function indexes between the two groups. The Six Sigma methodology has achieved certain results in this study, thus playing an active role in improving patients' mental health and preventive management of complications.

PCI continues to progress at an expanding rate, and an increasing number of complex coronary heart disease can be treated [14]. However, complications are prone to occur after PCI, affecting the prognosis of patients [15]. An increasing incidence rate of coronary heart disease has augmented the hospital burden with critical patient management problems. Thus, nursing management needs to be

strengthened, the risk of complications must be reduced, and the prognosis of patients should be improved [16].

The Six Sigma methodology can alleviate anxiety and depression levels, promote mental health, and improve the quality of life of patients. The reasons may be related to its philosophical roots, namely, the people-oriented concept. On the basis of this concept, the Six Sigma methodology has transformed nursing experiences and services [17]. People-oriented care, as an important part of contemporary care, focuses on the whole person, respects patients' willingness, and provides individual-oriented care services [18,19]. In addition, the Six Sigma methodology further enhances the quality of life of patients by simplifying medical procedures and improving care level [20,21]. In this study, the medical services provided by the medical staff on the basis of the Six Sigma methodology have achieved remarkable results. Daly A *et al*. [22] adopted the Six Sigma methodology to focus on patients' demands and actual situation, thus determining the areas that need to be improved and providing specific solutions. Yang L *et al*. [23] found that the Six Sigma methodology helps reduce the incidence of anxiety and depression in patients with end-stage renal disease and should be widely used in clinical practice.

The Six Sigma methodology can greatly reduce the incidence of postoperative complications in patients with PCI and further effectively provide guidance and reference for clinical practice. In this study, from the two aspects of physicians and nursing staff, the observation group summarized the types of complications that are prone to occur during PCI, comprehensively analyzed the causes of postoperative complications using a fishbone diagram, and then formulated improvement strategies for each cause, thereby effectively controlling the occurrence of postoperative complications. Zimmermann GDS *et al*. [24] pointed out that the Six Sigma methodology is effective in different healthcare environments and can play an active role in personnel training. Davies C *et al*. [25] applied the Six Sigma methodology to improve the efficiency of day care units in private hospitals, exerting a positive effect on optimizing nursing time and improving personalized patient care. In addition, Shi ZY *et al*. [26] found that the application of Six Sigma methodology can reduce the surgical site infection rate.

However, this study has some shortcomings. (1) Given the retrospective nature of this study, the data were extracted from existing records, which may cause selective bias and cannot directly infer causal relationships. (2) Limited by time, manpower, and financial resources, this study collected relatively few research subjects, leading to poor statistical efficiency. Subsequent research needs to select a larger sample size. (3) The difference of long-term value between different management methods was not investigated on account of the short follow-up time. In the future, the follow-up time of the study should be extended to comprehensively evaluate the clinical effect of the Six Sigma methodology. (4) This study did not conduct a detailed stratified analysis of different types of patients with PCI and did not fully consider the heterogeneity among patients. Future research should be improved in these respects.

Conclusions

The Six Sigma methodology can improve quality of life and reduce the incidence of postoperative complications, with a high promotion and application value in nursing management after PCI.

Availability of Data and Materials

The datasets used and/or analyzed during the current study were available from the corresponding author on reasonable request.

Author Contributions

SJC and YYS designed the study; all authors conducted the study; JW and FFC collected and analyzed the data. HZL and RRM participated in drafting the manuscript, and all authors contributed to critical revision of the manuscript for important intellectual content. All authors gave final approval of the version to be published. All authors participated fully in the work, take public responsibility for appropriate portions of the content, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or completeness of any part of the work are appropriately investigated and resolved.

Ethics Approval and Consent to Participate

This study conforming to the principles of Declaration of Helsinki (2013) has been approved by the medical ethics committee of Taihe County People's Hospital (approval No.: 2020-132). Patients signed an informed consent.

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Conflict of Interest

The authors declare no conflict of interest.

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