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A Randomized Controlled Trial on the Efficacy of Blended Care on Anxiety and Discomfort among Patients Undergoing Percutaneous Coronary Intervention at a Selected Hospital's Coronary Care Unit, Bangalore

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Abstract

Cardiovascular disease (CVD) encompasses a range of disorders impacting the heart and blood vessels, with coronary artery disease (CAD) standing as the most prevalent type. CAD results from the process of atherosclerosis and is a long-term condition that can culminate in severe outcomes such as heart attacks and even fatality. Patients undergoing PCI experience emotional and psychological problems. Among those, anxiety was prevalent among 42% of patients with cardiac diseases, 50% of patients with acute coronary syndrome (ACS), and 63% of patients with heart failure (HF). A randomized controlled trial was conducted to assess the efficacy of blended care on anxiety and discomfort among patients undergoing percutaneous coronary intervention at a selected hospital coronary care unit in Bangalore. The data has been collected using a purposeful random sampling technique. The result proves that blended care will reduce anxiety and discomfort among percutaneous coronary intervention patients.

Keywords: Blended care, anxiety rating scale, discomfort rating scale, percutaneous coronary intervention, coronary care unit

INTRODUCTION

Cardiovascular disease (CVD) refers to a group of conditions that impact the heart and circulatory system. The most common type of heart disease is coronary artery disease (CAD), which stems from atherosclerosis. This chronic condition has the potential to lead to critical incidents, such as heart attacks and fatalities. In India, CVD has emerged as the leading cause of death, accounting for a quarter of all mortalities. The major contributors to CVD deaths are ischemic heart disease and stroke, which together account for more than 80% of these fatalities [1–3].

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Treatment for CVD has been developed by several procedures, such as angioplasty, the fitting of a pacemaker, surgery like CABG, and heart transplant. Among these procedures, angioplasty is the most common method of treatment for acute and chronic blocking of the coronary vessels.

OBJECTIVES OF THE STUDY

Primary Objective

1. To assess the efficacy of blended care on anxiety and discomfort among patients undergoing

percutaneous coronary intervention.

Secondary Objectives

1. To explore the relationship between anxiety and discomfort prior to intervention with various baseline and clinical factors.
2. To correlate the anxiety and discomfort among patients undergoing percutaneous coronary intervention.

METHODOLOGY

Research Approach

Quantitative research approach

Research Design

Randomised control trial, pre-test and post-test control group design, single blinded study

Population

Patients undergoing percutaneous coronary intervention.

Sample Size

35 samples were in the experimental group, and 35 samples were in the control group. The sample size was calculated using independent sample t test, paired t test, chi-square, and coefficient correlation.

Sampling Technique

Purposive random sampling-lottery method.
The researcher will be planning to take subjects in each group.
(Experimental, Control group) considering attrition of subjects.

Setting

Coronary care unit (66 bedded) and approximately 200 patients in a month in tertiary care hospital, Bangalore.

Description of Tool

The tool consists of demographic baseline variables and clinical variables. Demographic variables such as, age in years, gender, religion, educational status, occupation, marital status, type of family, monthly income in rupees, area of residence, and number of children.
Clinical variables are do you have of previous hospitilization, are you using any therapy for reducing anxiety, do you have any co morbid illness, vital signs, PCI insertion site.

DESCRIPTION OF THE TOOL

- *Tool 1: Anxiety rating scale:* The scale consists of 20 items with a six-point Likert scale, such as: at no time, mild of the time, slightly less than half of the time, slightly more than half the time, most of the time, all the time, with scores ranging from 0 to 5 and the total score is 100. 1–33 indicate mild anxiety, 34–66 indicate moderate anxiety, 67–100 indicate severe anxiety.
- *Tool-2: Discomfort rating scale:* The score ranges from 1 to 4 and the total score is 28. Score 08–14 indicates mild discomfort, 15–21 indicate moderate discomfort, 22–28 indicate severe discomfort.

Intervention Protocol

Experimental group: Blended Care

Blended care: Face-to-face and digitalized instruction can be given to reduce the anxiety level among patients undergoing percutaneous coronary intervention (Table 1).

Table 1. Experimental group: Blended care.

• *Face-to-face interaction*	• Preoperative	• Clearly explain about the procedure PCI and teaching about the anxiety reducing measures and discomfort reducing measures.

• *Digital teaching*	• preoperative	• Explain about the CAD function of the heart, PCI, environment of the cath lab, aftercare (PCI), and prevention of re-occurrence of CAD. Provide digital teaching material, to patient as well as family members.

DATA COLLECTION PROCEDURE

Obtained permission from the ethical department. To conduct the research study, permission was obtained from the administrative department of the hospital and the head of the department of the CCU. During the pre-intervention stage, participants provided informed consent and had their initial baseline and clinical variables collected, along with their anxiety levels, using a specific scale. The selection of participants was carried out through a lottery system as part of a purposive sampling strategy, ensuring data collection. After obtaining informed consent, the researcher gathered data on baseline and clinical variables, along with measures of anxiety and discomfort. Participants were then evenly divided, with 35 assigned to the experimental group and another 35 to the control group, ensuring a randomised allocation. Subjects who fell into the purposive sampling method by using the lottery method in the experiment and the control group's pre-interventional level of anxiety were assessed by an anxiety rating scale. Subjects who fell into the experimental group had a pre-interventional assessment done using an anxiety rating scale and given blended care on the first day by the researcher. Then the post-intervention assessment was done on the 2nd and 3rd days by using the anxiety rating scale and the discomfort rating scale by the researcher assistant, who was blinded to the post-intervention. The control group only received hospital-routine care.

RESULTS

- *Section A:* Description of baseline and clinical variables of patients undergoing PCI in both the experimental and control groups.
- *Section B:* To determine the efficacy of blended care on anxiety and discomfort among patients undergoing percutaneous coronary intervention at a selected hospital coronary care unit.
- *Section C:* To determine the association between the pre-interventional anxiety and selected baseline and clinical variables, a chi-square test of association will be used.
- *Section D:* To correlate the anxiety and discomfort among patients undergoing percutaneous coronary intervention, Pearson's correlation coefficient will be computed for the anxiety and discomfort scores for the interventional group.

Table 2. Baseline characteristics of study participants in experimental and control groups (N = 70).

Baseline characteristics	**Experimental group (n = 35)**		**Control group (n = 35)**	
	F	***%***	***F***	***%***
1. Age (in years)				
a. Up to 50	12	34.3	9	25.7
b. Above 51	23	65.7	26	74.3
2. Gender				
a. Male	29	83	27	77
b. Female	6	17	8	23
3. Religion				
a. Hindu	30	86	20	57
b. Muslim	5	14	15	43
4. Educational status				
a. Primary education	10	29	4	11
b. Secondary education	2	6	4	11
c. Higher secondary education	11	31	13	37
d. Graduate and above	12	34	14	40
5. Occupational status				
a. Agriculture	4	11	1	3
b. Homemaker	3	9	7	20
c. Business	10	29	14	40
d. Private employee	8	23	7	20
e. Government employee	1	3	0	0
f. Retired	4	11	2	6
g. Unemployed	5	14	4	11

6. Marital status				
a. Married	31	89	33	94
b. Widow/widower	4	11	2	6
7. Type of family				
a. Nuclear family	15	43	24	69
b. Extended family	20	57	11	31
8. Monthly income (in ₹)				
a. <10000	15	43	13	37
b. 10001–30000	7	20	14	40
c. 30001–50000	11	31	6	17
d. >50000	2	6	2	6
9. Area of residence				
a. Urban	19	54	19	54
b. Rural	16	46	16	46
10. Number of children				
a. 1	2	6	1	3
b. 2	17	49	16	46
c. >3	16	45	18	51

Table 3. Description of clinical variables of study participants in experimental and control groups (n = 70).

Clinical characteristics	**Experimental group (n = 35)**		**Control group (n = 35)**	
	F	***%***	***F***	***%***
11. Previous hospitalization				
Yes	35	100	35	100
12. Using any therapy for anxiety				
No	35	100	35	100
13)Any comorbid illness				
a. Yes	21	60	19	54
b. No	14	40	16	46
14. (a) Level of heart rate beats/minute				
60–80	25	71.4	23	65.7
81–100	10	28.6	12	34.3
(b) Blood pressure (mm/hg)				
Normal (<130/85 mmHg)	15	42.9	14	40
High normal (130–139/85–89 mmHg)	9	25.7	8	23
Grade-1 hypertension (140–159/90–99 mmHg)	7	20	6	17
Grade-2 hypertension (≥160/100 mmHg)	4	11.4	7	20
15. Catheter insertion site				
a. Radial approach	3	9	8	23
b. Femoral approach	32	91	27	77

Table 4. Mean and SD level of anxiety between experimental and control group regarding blended care undergoing percutaneous coronary intervention (N = 70).

Level of anxiety	**Experimental group**		**Control group**		**Difference in mean**	**T value (P-value)**
	Mean	***SD***	***Mean***	***SD***		
Pre intervention	23.37	10.53	21.77	9.226	1.6	0.607 (0.439)
1st post intervention	8.37	5.225	16.09	7.732	7.72	4.942 (0.030) *
2nd post intervention	4.00	5.434	12.54	7.942	8.54	11.286 (0.001) *

**Significant at the level of P = 0.05*

To correlate the anxiety and discomfort among patients undergoing percutaneous coronary intervention.

Table 5. Mean and SD of the level of discomfort between the experimental and control group regarding blended care underwent percutaneous coronary intervention (N = 70).

Level of discomfort	Experimental group		Control group		Difference in mean	T value (P-value)
	Mean	*SD*	*Mean*	*SD*		
1st post intervention	8.31	1.157	7.89	1.132	0.43	0.036 (0.850)
2ndpost intervention	7.23	0.731	7.26	0.741	0.03	0.128 (0.722)

Table 6. Repeated measure ANOVA comparison with the domain of anxiety in experimental and control group (N = 70).

Group	Test	Anxiety	
		Mean±SD	P-value
Experimental group	Pre-intervention	23.37±10.530	F=9.187 **P<0.003****
	1st post intervention	8.37±5.225	
	2nd post intervention	4±5.434	
Control group	Pre-intervention	21.77±9.226	
	1st post intervention	16.09±7.732	
	2nd post intervention	12.54±7.942	

Table 7. Repeated measure ANOVA comparison with the domain of discomfort in experimental and control group.

Group for comparison		Mean difference	p-value
Experimental group	1st post intervention	1.566	0.85
Control group	2ndpost intervention	0.162	0.722

Table 8. Correlation between the level of anxiety and discomfort among patients undergoing percutaneous coronary intervention (N = 35).

Variables	Karl Pearson's correlation value	p-value
Pre interventional anxiety 1st Post interventional discomfort	r = 0.534**	0.0001
Pre interventional anxiety 1st Pre interventional discomfort	r = 0.141	0.243
1st Post interventional anxiety 1st Post interventional discomfort	r = 0.247*	0.039
1st Post interventional anxiety 2nd Post interventional discomfort	r = 0.255*	0.033
2nd Post interventional anxiety 2nd Post interventional discomfort	r = 0.192	0.112

Analysis of the study during the post-intervention level of anxiety among patients who underwent percutaneous coronary intervention between the experimental and control groups. The pairwise comparison with Bonferroni adjustments showed that there was a statistically a statistically significant improvement in the level of anxiety at the $p<0.01$ level, which clearly infers that blended care was found to be effective in reducing anxiety among the patients who underwent percutaneous coronary intervention in the experimental group. In discomfort, there was no significant difference in the experimental group (Tables 2–8).

The between group comparison shows that a significant difference in the reduction of anxiety was observed in the 1st postintervention (0.003) and 2nd postintervention (0.001), which was found to be statistically significant at $p<0.005$ and $p<0.001$ levels, respectively. These findings clearly infer that the effectiveness of blended care on anxiety among patients underwent percutaneous coronary intervention, in which the patients in the experimental group had a decreased level of anxiety compared to the patients in the control group [4–6].

DISCUSSION

In this study, a randomized controlled trial design with single-blinding was adopted to determine the effectiveness of blended care on anxiety and discomfort among patients undergoing percutaneous

coronary intervention at a coronary care unit in Bangalore. Seventy samples were allocated to the experimental group (n = 35) and the control group (n = 35) using a lottery method. The experimental group received a blended care intervention throughout the preoperative period. Pre-anxiety levels were assessed in both the experimental and control groups using an anxiety rating scale. Subsequently, blended care was provided to the experimental group, while the control group received standard hospital care. Post-intervention assessments were conducted on the 2nd and 3rd days to evaluate anxiety and discomfort using the anxiety rating scale and discomfort rating, respectively, administered by a trained researcher assistant. To assess the efficacy of blended care on anxiety and discomfort among patients undergoing percutaneous coronary intervention, independent samples t-tests, paired t-tests, and repeated measures ANOVA were employed. Comparisons were made between the interventional and control groups [7–10].

NURSING IMPLICATIONS

Nursing Education

The importance of blended care can be taught to student nurses and staff nurses to prepare for quality care.

Nurse educators need to arrange sessions regarding knowledge of blended care.

The nurse educator must motivate the staff nurses and nursing students to perform instructions as part of their daily routine.

Blended care—face-to-face and digitalized instruction—can be given to reduce the anxiety level among patients undergoing percutaneous coronary intervention.

Nursing Administration

The nurse administrator can formulate written policies regarding blended care to reduce the level of anxiety among patients undergoing percutaneous coronary intervention in cardiac care units.

Thereby the nurses are kept in pace with evidence-based practice.

Nursing Practice

Nurses working in the coronary care unit should be trained and involved in providing blended care to reduce further complications of anxiety, such as recurrent ischemic events, arrhythmias, and sudden cardiac deaths.

Nursing Research

It can be used as evidence-based practice for reducing the level of anxiety and discomfort. Comparable research can be conducted to evaluate the anxiety levels in patients receiving coronary interventions across various environments over extended periods.

Recommendations

The study can be replicated using a larger sample.

A similar study can be conducted among other populations, like medical and surgical problems.

CONCLUSION

Anxiety is inevitable during pre-procedure care, and it may even lead to life-threatening conditions for patients undergoing percutaneous coronary intervention. Managing anxiety during the pre-procedural state improves the quality of life of patients undergoing coronary interventions. Blended care is highly cost-effective, which has positive effects on healing and reduces anxiety and discomfort among patients undergoing coronary interventions. Hence, the researcher concluded that blended care

is an effective method to reduce anxiety among patients undergoing percutaneous coronary interventions.

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