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Original Article

The Effect of Family-Centered Education on the Quality of Life of Reproductive Age Women with a History of Heart Valve Replacement

Ali Mohammadpour ¹, Masoumeh Pashaei ²,*, Reza Ghasemi ³, Maliheh Eshagh-Zadeh ², Mozhdeh Taheri Afshar ⁴, Mohsen Yaghubi ⁵,**

- 1. Department of Nursing, Social Determinants of Health Research Center, Gonabad University of Medical Sciences, Gonabad, Iran
- 2. Department of Medical-Surgical Nursing, Faculty of Nursing and Midwifery, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Iran
- 3. Department of Cardiology, 9 Dey Educational Hospital, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Iran
- 4. Department of Medical-Surgical Nursing, Shahid Beheshti Hospital, Babol University of Medical Sciences, Nowshahr, Iran
- 5. Department of Extra-Corporeal Circulation (ECC), Razavi Hospital, Mashhad, Iran
- * Corresponding author: *Masoumeh Pashaei, Department of Medical-Surgical Nursing, Faculty of Nursing and Midwifery, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Iran. Email: Pasheim1@thums.ac.ir
- **Mohsen Yaghoubi, Department of Extra-Corporeal Circulation (ECC), Razavi Hospital, Mashhad, Iran. Email: n.m.yaghubi@gmail.com

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Abstract

Background: Patients undergoing surgical replacement of cardiac valves face various physical, psychological, and social problems. This situation leads to changes in quality of life parameters, especially in women of reproductive ages.

Objectives: This study aimed to determine the effect of family-centered education on the quality of life of women of reproductive age with a history of cardiac valve replacement.

Methods: This randomized intervention-control prospective study was performed on 62 patients and their companions. Participants were selected in terms of inclusion criteria and randomly assigned to control and test groups. First, the quality of life questionnaire participants completed SF-36. Then, the test group received a family-centered education program in four sessions. Immediately after the intervention and one month later, we measured patients' quality of life. Data were analyzed using SPSS version 23 using Chi-square, independent t-test, Mann-Whitney U, Wilcoxon, and Friedman test.

Results: The results of the Friedman test showed that the mean score of total quality of life was significantly different in the intervention group (P = 0.02), but this difference was not significant in the control group (P = 0.23).

Conclusion: Based on the results of this study, family-centered education can improve the quality of life of women of reproductive age with a history of cardiac valve replacement. The purposeful, scientific, and guided family interactions with the patient and the patients' close relationship and dependence on relatives and families can be considered the leading cause of this effect.

Keywords: Quality of Life, Valvular Heart Disease, Women's Health

1. Background

Women's health is one of the indicators

of development from the United Nations perspective. This vital parameter in low and

middle-income countries is more complex than in other countries due to some demographic changes (1). Now, fertility ages are essential because of their impact on significant changes in women's health (2). In this period, they have many comorbidities, such as iron deficiency anemia (3), fertility disorders (4), sexual dysfunction (5), cancer (especially endometrial and breast cancers), and heart disease (6).

Cardiovascular diseases (CVDs) significant since they are the most common chronic diseases of the 21st century and are regarded as the leading cause of death worldwide (7). This disease affects 17.9 million people annually across the world, including women (8). Although advances in medical science have led to medical treatments for cardiac patients, heart surgery is the only option for many patients (9). In Iran, 35 to 50 thousand cardiac surgeries are performed each year, with coronary artery bypass grafting the first and valve replacement surgery the second, half of which are mechanical valves and the other half biological valves (10).

After discharge, these patients often experience numerous problems such as pain, fatigue, limb swelling, intolerance of activity, sleep disturbances, wound care and drug use, anxiety and depression, ineffective adaptation to illness, and fear of their future status (11). However, women of childbearing age also face many problems, especially in the post-valve replacement period. Pregnancy in women with valvular heart disease is associated with increased maternal mortality and adverse fetal outcomes (12).

Care after heart valve replacement is a long process and requires recognition, adjustment, and improvement of patients' hemodynamic function and psychological and social interactions (13). Due to the nature of the surgery and the limited facilities available in health centers, in many interventions, the major part of recovering

and continuing home care is done by the patient and their family (14-15). In the meantime, patients' families lack effective care delivery because of a lack of information about the disease, understanding of the patient's needs, and knowing how to care for them. So, one of the basic needs of patients and their families is the educational need to be considered an entire facility for patients' families (1).

Family-based education is a process in which family members receive training to enhance their skills and abilities to help a family member with a disease. Iranian families often care for their patients so that rich resources can improve their quality of life following valve replacement surgery [16-18]. Therefore, concerning insufficient evidence on the role of family-centered education and its role in the quality of life of women after heart valve replacement, the present study aimed to determine the effect of this issue on the quality of life of women in reproductive age with a history of heart valve replacement.

2. Objectives

Patients undergoing surgical replacement of cardiac valves face various physical, psychological, and social problems. This situation leads to changes in quality of life parameters, especially in women of reproductive ages. This study aimed to determine the effect of family-centered education on the quality of life of women of reproductive age with a history of cardiac valve replacement.

3. Methods

This study is a randomized case-control clinical trial prospective study that was started in June 2018 and completed in December 2019. The sample of this study included all the women of reproductive age with a history of cardiac valve replacement

who were referred to 9 Day and Razi hospitals in Torbat Heydariyeh, Iran.

After considering inclusion and exclusion criteria, the patients were randomly divided into two groups.

The inclusion criteria include Obtaining the patients' consent or immediate family patients' consent (which were approved by the ethics committee of the university), women with a history of tricuspid, mitral, pulmonary, and aortic valve replacement, at least one year of has passed since the heart valve replacement, having an active member of the patient's family to attend the training, exposure to reproductive ages (15 to 49 years), no history of coronary artery bypass graft surgery (CABG), average left ventricular ejection fraction (more than 45%), and lowest reading and writing ability for the patient and active family member.

The exclusion criteria include Withdrawal from the continued study by the patient and active family member, any condition for the patient and their involved family member to take interventional measures or to have a significant effect on the quality of life, such as physical, psychological, family and economic crisis, the presence of the patient and their active family member in any other educational program related to heart valve replacement (except routine programs).

We used the method of block randomization. The patients were randomly divided into intervention and control groups, based on blocks field with four alternative chances for each patient. These fields were determined as chance codes (such as 2121) for each patient.

The sample study was determined 62 by considering means space, confidence intervals of 95%, power of study 80%, and hypothesis of the same study (1) and mean deviations S1= 16.40 and S2= 12.86, and means X1 = 60.61 and X2 = 50.10 that in each group, intervention, and control, was placed, 31 patients.

Demographic variables include the age of the participants, the number of pregnancies, the number of abortions, the time of pregnancy, the valve replacement time, married status, the level of education, the income level, and the history of the prior disease, was recorded.

The first demographic questionnaire and the standard Quality of Life (SF-36) questionnaire were completed based on self-report or interviews. In the intervention group, family-centered face-to-face training sessions, during four sessions of 30 to 40 minutes, were held with the participation of the patients and one of their active family members.

A brief explanation of valvular heart disease, anatomy, signs and symptoms, heart valve surgeries, contraceptive methods, and sleep disorders was provided in the first session. To enhance their physical function, the patients and their active family members were trained.

In the second session, talk about fears and worries and the problems with community presence, provide practical solutions to concerns, describe the physical and emotional role played, and finally answer patient concerns about sexuality and related emotions.

In the first period of the third session, the active member entered the session and talked with them about three behavior methods with the patients: behavior with empathy, respect, and kindness. Then, the patient entered the session and talked to them about mental health and vitality, problem-solving, and answering questions. In the fourth session, discuss general health and observe the diet, medications, regular and sustained referred to the physician, routine and periodical paraclinical tests. In the final, the questions were answered.

The research instruments were completed at the end of the fourth session (immediately after intervention) and one month after the intervention. All the intervention and control group patients were followed up for one month. In the control group, routine care was done.

The SF-36 questionnaire, designed by Ware et al. in 1992 (20), is a reliable instrument for the assessment of general QOL that measures eight health-related domains: physical functioning (PF-10 items), role limitations due to physical problems (RP-4 items), pain (BP-2 items), general health perceptions (GH) (5 items), vitality (VT) (4 items), social functioning (SF) (2 items), role limitations due to emotional problems (RE) (3 items), and perceived mental health (MH) (5 items), and health transition (HT) (1 item).30 Each section is scored on a 0-100 Likert scale, and higher scores indicate better health than others. The Persian version of a short form of the SF-36 questionnaire was validated by Montazeri et al. with a Cronbach's α coefficient of 0.77-0.90 (19).

Statistical Package did the statistical analysis for the Social Sciences (SPSS) software version 23. The data were analyzed using a descriptive statistics method, variance analysis, Fisher's exact test, Mann–Whitney U, Wilcoxon signed-rank test, and Friedman test. The level of significance was considered to be 0.05.

The aim of the study was explained to the patients, and their written informed consent was obtained according to the Declaration of Helsinki. Furthermore, it was explained that the patients could withdraw from the study at any time.

4. Results

Sixty-two participants were included in the study (n=31 in the training group and n=31 in the Control group). The two groups were homogeneous in terms of age, the number of pregnancies, the number of abortions, the time of pregnancy, the valve replacement time, married status, the level of education, the income level, and the history of the prior disease.

The most important results of this study were the significant differences between some quality of life parameters before and after intervention among participants. These findings showed there were differences significant between social functioning (p=0.002),general health (p<0.001), and pain (p<0.012) before intervention and immediately after the intervention. These findings are shown in Table 1.

Table 1. The comparison between the total quality of life score and its parameters in case and control							
groups (*= significant differences)							
Quality of Life parameters	Control group	intervention group	Mann Whitney II tost				
	Mean±S.D	Mean±S.D	Mann-Whitney U test				
Physical functioning	24.13±1.87	24.13±1.74	Z= -3.64 P= 0.96				
Physical roles	5.52±0.99	5.97±1.19	Z= -1.21 P= 0.22				
Emotional roles	21.52±6.29	23.87±3.32	Z= -0.88 P= 0.37				
Vitality	17.55±5.5	18.81±3.11	Z= -0.38 P= 0.70				
Mental health	4.23±1.11	4.55±0.81	Z= -0.62 P= 0.53				
Social functioning	7.26±1.82	8.61±1.43	Z= -3.11 P= 0.002*				
General Health	19.10±6.04	24.61±4.15	Z= -3.64 P< 0.001*				
Pain	7.77±2.43	9.06±1.4	Z= -2.5 P= 0.012*				
Total score	107.87±22.62	119.61±13.01	Z= -1.86 P= 0.06*				

Also, there was a significant difference between some of the quality of life parameter scores, such as social functioning (p=0.001),

general health (P< 0.001), and pain (P= 0.008), one month after the intervention; as a midterm follow-up, in intervention and control

groups. Table 2 demonstrates the differences between the total quality of life parameters.

There were no significant differences between the total quality of life score before the intervention, immediately after it, and one month later in the control group (P=0.08 and

P=0.11, respectively). However, this parameter showed a significant difference between the quality of life score before and immediately after intervention (P=0.001) and one month after intervention (P=0.005) in the intervention group.

Table 2. The comparison between the total quality of life score and its parameters in case and control
groups one month after intervention (*= significant differences)

Quality of Life parameters	Control group	intervention group	Mann-Whitney U test	
Quality of Life parameters	Mean±S.D	Mean±S.D		
Physical functioning	24.13±1.97	24.29±1.61	24.29±1.61 Z= -0.37 P= 0.71	
Physical roles	5.47±0.93	6.03±1.19	Z= -0. 85 P= 0.39	
Emotional roles	21.39±6.04	23.81±3.43	Z= -1.12 P= 0.26	
Vitality	17.71±5.25	18.97±3.12	Z= -0.59 P= 0.55	
Mental health	4.58±0.76	4.55±0.81	Z= -0.62 P= 0.53	
Social functioning	7.16±1.84	8.61±1.40	Z= -3.3 P= 0.001*	
General Health	19.10±6.01	24.81±4.19	Z= -3.87 P< 0.001*	
Pain	7.74±2.33	9.03±1.44	Z= -2.66 P= 0.008*	
Total score	107.87±21.99	120.10±13.00	Z= -2.11 P= 0.035*	

The comparison of the total quality of life score and its parameters before the intervention, immediately after it, and one month after intervention in the control group revealed that physical role (P=0.03) and emotional role (P=0.01) had significant relationships. Although, in the intervention group, general health (P<0.001), social functioning (P<0.001), mental health (P<0.001), and emotional role (P=0.01) had significant differences demonstrated in Table 3.

This study showed that general health participants' quality of life scores before the intervention had no significant difference (P=0.8). In contrast, immediately intervention (P<0.001) and one month after it (P<0.0001), the median general health score showed a significant difference. Also, the Friedman test revealed that the general health score had a significant difference only in the intervention group (P<0.001), which was enhanced over time. This finding paralleled with an emotional role (P=0.01), social functioning (P=0.001), vitality (P=0.001), and pain (P<0.001) of the participants in the quality of life score that show a significant difference only in the intervention group; so

that the mean score of this parameter was increased over the time. On the other hand, the physical functioning (P>0.05) and physical role (P>0.05) did not show any significant differences in both intervention and control groups. This study's novel finding revealed no significant difference in mental health participants' quality of life scores in the intervention group (P=0.49), but this item significantly differed in the intervention group (P=0.01). This parameter played a different role in the time, as the mean score of mental health participants in quality of life was decreased in the intervention group and enhanced in the control group in the time trend.

The relationships between the age of the participants and quality of life parameters show there was a statistical relationship between an emotional role (P=0.04), general health (P=0.01), and the total score of the quality of life (P=0.04) in the negative direction, that means by the increasing of the age, the total score of the quality of life was decreased. Also, the relationship between quality of life parameters and the participant's living area shows there was a significant relationship between general health (P=0.001), emotional

role (P=0.002), vitality (P=0.001), physical role (P=0.002), mental health (P<0.001), pain (P=0.001) and total quality of life score (P=0.004) and the location of the participant's

living area. This finding revealed that participants living in urban areas had a higher quality of life than rural participants.

Table 3. compares the total quality of life score and its parameters three times.							
Quality of Life parameters	Before intervention	Immediately after intervention	One month after the intervention	Friedman test			
	Mean±S.D	Mean±S.D	Mean±S.D				
Physical functioning	24.19±2.27	24.13±1.74	24.29±1.61	² =0.92χ			
				df=2			
				P=0.63			
Physical roles	5.97±1.6	5.97±1.19	6.03±1.19	² =1.07χ			
				df=2			
				P=0.58			
Emotional roles	20.77±6.68	23.87±3.32	23.81±3.43	2 =8.34 χ			
				df=2			
				P=0.01			
Vitality			18.97±3.12	² =14.64χ			
	16.52±5.3	18.81±3.11		df=2			
				P=0.001			
Mental health	4.65±1.14	4.55±0.81	4.55±0.81	² =0.08χ			
				df=2			
				P=0.95			
Social functioning	7.39±1.97	8.61±1.43	8.61±1.4	2 =18.72 χ			
				df=2			
				P<0.001			
General Health	19.48±6.01	24.61±4.15	24.81±4.19	² =23.63χ			
				df=2			
				P<0.001			
Pain		9.06±1.4	9.03±1.44	² =19.12χ			
	7.55±2.4			df=2			
				P<0.001			
Total score	106.52±23.97	119.61±13.01	120.10±13.00	²=0.92χ			
				df=2			
				P=0.63			

Other demographic data such as the age of the active family member, the number of pregnancies, child, abortions, the time of pregnancy, the valve replacement time, married status, the level of education, the income level, types of valves, type of insurance, the family history of the valve replacement and the history of the prior disease, had not any significant difference with the quality of life score and its parameters.

5. Discussion

This study aimed to determine the effect of Family-Centered Education on the Quality of Life of women of reproductive age with a history of heart valve replacement. According to the results of this study, the quality of life score of participants in the intervention group was higher than the control group. This finding was paralleled with the Ghavidel et al. [1] results. They evaluated Family-Centered Education's effect on patients' Quality of Life after coronary artery bypass graft surgery. Those studies show that the quality of life parameters scores after the intervention were statistically higher than those of the control group. Another study that evaluated the effectiveness of a longterm education program in patients with prosthetic heart valves [15] showed the same results as our research. Although the educational method differed in similar studies, the overall results were identical to our findings.

Other studies investigating the

effectiveness of the Family-Centered Education model on the quality of life of patients with myocardial infarction show a significant difference in eight parameters of quality of life between before and after the intervention (11). These findings were consistent with our results. On the other hand, Najjar et al. (21) show no significant difference between the quality of life after individual counseling in the intervention and control group. This paradox may be due to the diverse populations of the studies. Patients with myocardial infarction have multiple anxiety disorders that may be considered an obstacle to educational materials in the acute phase of this disease. However, the same study (22) showed that the Family-Centered education multimedia software method was more effective than the Patient-Centered education method in patients after acute myocardial infarction. The population of this study was similar to that of Najjar et al. (21); nevertheless, those findings are consistent with our research. Implementing virtual training can be a novel method differentiating future studies from other studies in this field.

Based on the specific aim of our study, the comparison of the quality of life in women of reproductive age with a history of heart valve replacement in intervention and control groups after short-term (1 month) and intervention revealed that the quality of life score in participants with family-centered education was significantly higher than others. This finding was consistent with other studies (23) that introduced this teaching method as an effective way to enhance quality of life.

Simpson et al. (24) show a significant relationship between age and quality of life parameters. In our study, there was a significant relationship between emotional role, general health, and the total score of quality of life with the age of the participants in a negative direction. Nevertheless, unlike our results, other demographic variables,

such as marital status and level of education in the study, had no significant relationship with quality of life parameters that differed from ours. Other studies (25-26) found a meaningful relationship between age and quality of life, consistent with our findings. This study had limitations, including a lack of long-term follow-up. Further studies will help resolve these limitations and improve the basis of evidence-based caring.

6. Conclusion

Based on the high prevalence of cardiac disease (27) among the Iranian population and many problems with these patients, especially women with valvular heart replacement and in reproductive age, continuous care is needed to alleviate mental and physical issues, reduce the problems caused by inadequate access to medical care, especially by nurses, and finally the patient's inability to take care of themselves. The constant interaction of family members with the patients and the close relationship and influence of patients with relatives and family can be the leading cause of this impact. This study shows that Family-Centered Education can enhance the quality of life of these patients.

Availability of data and materials: The dataset presented in the study is available on request from the corresponding author during submission or after its publication.

Conflicts of interest: The authors declare no conflict of interest in this study.

Consent for publication: The signed Consent to Publish send to the Publisher to permission of the Authors to publish the Work.

Ethics approval and consent to participate: This study was approved by the ethics committee of Gonabad University of Medical Sciences (IR.GMU.REC.1397.083) and complied with the Declaration of

Helsinki; informed consent has been obtained from the subjects). The study was conducted in accordance with the principles of the Helsinki Declaration.

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Authors' contribution: A. M. P: Contributed to the conception of the work, revising the draft, approving the final version of the manuscript, and agreeing on all aspects of the work; M. P.: Contributed to the data analysis and interpretation, critical revision, and approval of the final version of the manuscript; R. Gh.: Contributed to acquiring data, drafting the manuscript, and approving the final version; M. E. Z. and M. T. A.: Contributed to the conception and design of the study, critical revision, and approval of manuscript's final version; the Contributed to the conception and design of the study, data interpretation, drafting of the manuscript and critical revision, and approval of final version.

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