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Original Article

Effects of the Sounds of Different Mechanical Mitral Valves on Quality of Life at Different Follow-Up Times: A Single-Center Study

Jiang-Shan Huang, MM,[1,2,‡] Kai-Peng Sun, MM,[1,2,‡] Ning Xu, MM,[1,2] Qiang Chen, MD,[1] Liang-Wan Chen, MD,[1] and Yur-Ren Kuo, MD[3]

Objective: To compare the effects of the sounds of different types of mechanical mitral valves on the quality of life (QoL) of patients at different follow-up times.
Methods: We collected data from 150 patients who underwent mechanical mitral valve replacement. Three time points were assessed, including at discharge, the third postoperative month (POM3), and the twelfth postoperative month (POM12). The SF-36 and a self-questionnaire were used to assess the QoL.
Results: Regarding the SF-36 scores, the ATS valve was superior to the Sorin and SJM valves in terms of some items. Moreover, the scores at discharge of all three mechanical valve groups were lower than those at POM3 and POM12. For the self-questionnaire scores, with the increase in postoperative time, the number of patients affected by the mechanical valve sounds decreased gradually. Considering the relevant influencing factors, older women were more likely to be affected by the valve sounds than were younger individuals and men.
Conclusion: The overall postoperative QoL improved for patients who underwent mechanical mitral valve replacement. In the comparative study, the impact of the ATS valve was better than those of the Sorin and SJM valves, but this difference gradually disappeared over time.

Keywords: heart valve diseases, SF-36, quality of life, mitral valve replacement

[1]*Department of Cardiovascular Surgery, Union Hospital, Fujian Medical University, Fuzhou, China*
[2]*Department of Cardiac Surgery, Fujian Provincial Maternity and Children's Hospital, Affiliated Hospital of Fujian Medical University, Fuzhou, China*
[3]*Division of Plastic Surgery, Department of Surgery, Kaohsiung Medical University Hospital, Kaohsiung, Taiwan*

Received: October 18, 2019; Accepted: November 11, 2019
Corresponding author: Qiang Chen, MD. Department of Cardiovascular Surgery, Union Hospital, Fujian Medical University, Fuzhou 350001, China
Email: chenqiang2208@163.com
‡These authors contributed equally to this study and share first authorship.

Introduction

Since the first artificial heart valve replacement was performed in the 1960s, the number of times artificial heart valves have been used in the treatment of valvular heart disease has increased rapidly worldwide.[1)] Recently, it has been reported that surgical techniques, anesthesia, and cardiopulmonary bypass are becoming increasingly more advanced.[2,3)] At the same time, the quality of artificial heart valves has improved, as the hemodynamics, anti-thrombic properties, and durability associated with artificial heart valves significantly improved. However, in terms of mechanical valve sound-related issues, it is important to continue to learn how to further improve the quality of life (QoL) of patients with mechanical mitral valves. Through a literature search, many articles on the effects of

mechanical mitral valve sounds on QoL were found, but few articles have focused on the effects of changes in mechanical mitral valve sounds over time on patients' QoL.[4–7] We conducted this study to compare the different types of prosthesis mechanical mitral valves (ATS, Sorin, and SJM) and assess the effects of different prosthesis valve sounds on patient QoL at different follow-up times.

Patients and Methods

We set the alpha value at 0.05 and the statistical power value at 0.9. After performing a power analysis using Gpower 3.1.9, we found that at least 40 patients should be included in this study. Finally, we set the number of patients to be included at 50.[8]

We reviewed 150 patients who underwent mechanical mitral valve replacement, 50 of whom were using an ATS mechanical mitral valve, 50 of whom were using a Sorin mechanical mitral valve, and 50 of whom were using an SJM mechanical mitral valve. According to the different mechanical valves used, the patients were divided into three groups that were named after the corresponding valve brand. Patients undergoing thoracoscopic surgery, simultaneous aortic valve replacement or coronary artery bypass surgery were not included in this study. Patients with a preoperative cardiac functional level of III-IV, a large left atrium, postoperative mechanical valve dysfunction, severe arrhythmia and severe pulmonary hypertension, or multiple organ dysfunction were also excluded from this study. All patients were enrolled voluntarily in the study, and those unwilling to sign the consent form or unable to complete the questionnaire were excluded. At the time of discharge, at the third postoperative month (POM3), and at the twelfth postoperative month (POM12), we used a sound level meter to measure the valve sounds, a Chinese version of the SF-36 and a self-questionnaire to evaluate the effect of the different mechanical valve sounds on the QoL of the patients.

A high-end professional sound level meter (Tecman sound level meter, which was made from Hong Kong Tekman electronic instrument Co., LTD., model TM 834) was used in this study. It was connected to an ordinary stethoscope through an external 10-cm-long pipe. In a sound insulation room, the patient was placed in a supine position, then the stethoscope was put on the position of the largest cardiac sound in the precardiac area. We take the median through multiple measurements as our result.

We compared the SF-36 scores for eight subscales (physical functioning, social functioning, role-physical, role-emotional, mental health, vitality, bodily pain, and general health) among the different mechanical valve groups and evaluated the QoL of the patients and the change in the QoL at different postoperative time points. We used a self-administered questionnaire to measure the effect of mechanical valve sounds on QoL, to assess the effect of mechanical valve sounds on QoL over time and whether there was a difference among the different mechanical valves.

The content of self-questionnaire included the following two aspects: (1) Do you feel the sound of the heart valve interferes with your life? There were four answer choices: not disturbing, somewhat disturbing, quite disturbing, and very much disturbing. In addition, we considered the answers "not disturbing" and "somewhat disturbing" to indicate that the mechanical mitral valve sound has no effect on QoL of patients; the answers "quite disturbing" and "very much disturbing" were considered to indicate that mechanical mitral valve sound has an effect on QoL of the patients. (2) Do the members of your family feel the sound of the heart valve interferes with their life? There were also four answer choices: "never," "occasionally," "often," and "always." In addition, we also considered the answers "never" and "occasionally" to indicate that the mechanical mitral valve sound has no effect on QoL of the members; the answers "often" and "always" were considered to indicate that mechanical mitral valve sound has an effect on QoL of the members.

We also performed a logical regression analysis to assess the impact of age, sex, valve type, left ventricular ejection function (LVEF) and body surface area (BSA) on QoL.

We used SPSS Statistics 23 (International Business Machines Corporation, Armonk, NY, USA) for statistical analysis. The scores of the SF-36 were analyzed by T tests, and the answers to the self-questionnaire were analyzed by chi-squared tests. Statistical data were expressed as the mean ± standard deviation, and $P < 0.05$ was considered statistically significant. All patients signed informed consent forms, and this study received the support of the ethics committee of Fujian Medical University.

Results

The basic clinical data of patients are shown in **Table 1**. No patients were lost to follow-up. There were no significant differences among the three groups in sex (ATS: 17/33, Sorin: 20/30, SJM: 19/31 $P = 0.87$), age (ATS: 50.5 ± 12.1, Sorin: 48.8 ± 13.5, SJM: 52.8 ± 13.8; $P = 0.31$), BSA

Table 1 General clinical data of patients

Item	ATS	Sorin	SJM	P
Number	50	50	50	/
Gender (M/F)	17/33	20/30	19/31	0.87
Age (year)	50.5 ± 12.1	48.8 ± 13.5	52.8 ± 13.8	0.31
LVEF (%)	51.1 ± 9.5	51.3 ± 11.6	48.1 ± 9.9	0.23
BSA (m^2)	1.43 ± 0.76	1.46 ± 0.66	1.41 ± 0.67	0.94
Heart rate	73.8 ± 14.4	69.9 ± 13.9	71.5 ± 14.2	0.39

BSA: body surface area; LVEF: left ventricular ejection function

Table 2 Quality of life assessment form SF-36

	ATS			Sorin			SJM		
	Discharge	POM3	POM12	Discharge	POM3	POM12	Discharge	POM3	POM12
Physical functioning	60 ± 11	77 ± 18	78 ± 11	57 ± 14	79 ± 15	79 ± 12	62 ± 11	76 ± 14	77 ± 13
Social functioning	60 ± 11	77 ± 15	79 ± 11	56 ± 12	73 ± 12	74 ± 17	56 ± 13	72 ± 15	75 ± 18
Role-physical	70 ± 15	87 ± 11	84 ± 11	65 ± 10	79 ± 14	82 ± 13	66 ± 10	80 ± 13	79 ± 14
Role-emotional	65 ± 9	79 ± 11	78 ± 13	69 ± 13	74 ± 14	70 ± 15	66 ± 13	71 ± 13	70 ± 17
Mental health	72 ± 13	78 ± 16	76 ± 12	70 ± 12	73 ± 11	71 ± 14	67 ± 16	72 ± 11	71 ± 12
Vitality	45 ± 10	52 ± 11	57 ± 13	49 ± 12	54 ± 13	55 ± 12	46 ± 10	50 ± 15	55 ± 12
Bodily pain	68 ± 16	76 ± 13	76 ± 11	65 ± 13	78 ± 13	78 ± 13	69 ± 14	73 ± 13	76 ± 12
General health	49 ± 12	61 ± 9	71 ± 13	52 ± 12	63 ± 14	71 ± 12	52 ± 11	59 ± 14	66 ± 12

POM: postoperative month

(ATS: 1.43 ± 0.76, Sorin: 1.46 ± 0.66, SJM: 1.41 ± 0.67; P = 0.94), LVEF (ATS: 51.1 ± 9.5, Sorin: 51.3 ± 11.6, SJM: 48.1 ± 9.9; P = 0.23), and heart rate (ATS: 73.8 ± 14.4, Sorin: 69.9 ± 13.9, SJM: 71.5 ± 14.2; P = 0.39).

According to the results of the sound level meter measurement of the mechanical valve sounds, there was no statistical difference among the three kinds of the mechanical valves (ATS: 63.6 ± 9.7 dB, Sorin: 67.6 ± 13.5 dB, SJM: 65.7 ± 8.7 dB P = 0.19) at discharge, and there was also no statistical difference at POM3 (ATS: 62.2 ± 10.7 dB, Sorin: 65.1 ± 9.9 dB, SJM: 63.1 ± 10.3 dB; P = 0.357) and at POM12 (ATS: 61.1 ± 8.3 dB, Sorin: 63.4 ± 5.1 dB, SJM: 63.7 ± 6.9 dB P = 0.13). Similarly, there was no statistical difference between each group at discharge, POM3 and pPOM12 (ATS: P = 0.434; Sorin: P = 0.122; SJM: P = 0.299). But the result of ATS always seemed to be the smallest, although the difference was not statistically significant.

The SF-36 scores of patients using the different mechanical mitral valves at the different time points are shown in **Table 2**. (1) Regarding physical functioning, social function, vitality, bodily pain, and general health, there was no significant difference between the ATS, Sorin, and SJM groups at each time point (at discharge, POM3, and POM12). (2) Regarding role physical, the score was higher in the ATS group than in the Sorin and SJM groups at discharge and POM3, but there was no significant difference between the groups at POM12. (3) Regarding mental health, the score was higher in the ATS group than in the Sorin and SJM groups at all time points. (4) Regarding role-emotion, there was no significant difference between the three mechanical mitral valve groups at discharge, and the score for the ATS group was higher than those for the Sorin and SJM groups at POM3 and POM12. However, in the eight aspects of the SF-36, the scores of all the mechanical mitral valve groups at discharge were lower than those at POM3 and POM12, while there was no significant difference in the scores between POM3 and POM12.

The patients' self-response distribution of three mechanical mitral valves of the self-questionnaire at the different time points is shown in **Table 3**. Not disturbing and somewhat disturbing were classified as the no influence group, and quite disturbing and very much disturbing were classified as the influential group. From **Table 3**, it can be found that the ATS (P = 0.30) groups showed no significant difference in the responses at discharge, POM3, and POM12, as did SJM (P = 0.087). While Sorin (P = 0.028) had a significant difference at different follow-up times. At discharge, the effect of the mechanical mitral valve sound of the ATS valve was less than those of the Sorin and SJM valves (P = 0.044). However, there was no significant difference between the ATS, Sorin, and SJM groups at POM3 and POM12 (POM3: P = 0.109;

Table 3 Results of the self-questionnaire: do the patients feel the sound of the heart valve interferes with their life?

	ATS			Sorin			SJM		
	Discharge	POM3	POM12	Discharge	POM3	POM12	Discharge	POM3	POM12
Not disturbing	23	21	29	15	17	21	19	19	20
Somewhat disturbing	20	26	18	18	24	23	15	21	23
Quite disturbing	4	2	2	10	6	4	9	6	3
Very much disturbing	3	1	1	7	3	2	7	4	4
No influence group	43	47	47	33	41	44	34	40	43
Influence group	7	3	3	17	9	6	16	10	7
P		0.30			0.028			0.087	

POM: postoperative month

Table 4 Results of the family self-questionnaire: do the members of your family feel the sound of the valve interferes with their life?

	ATS			Sorin			SJM		
	Discharge	POM3	POM12	Discharge	POM3	POM12	Discharge	POM3	POM12
Never	31	28	29	19	23	21	20	21	24
Occasionally	15	19	19	22	21	24	24	22	22
Often	3	3	2	7	4	4	4	5	3
Always	1	0	0	2	2	1	2	2	1
No influence group	46	47	48	41	44	45	44	43	46
Influence group	4	3	2	9	6	5	6	7	4
P		0.909			0.569			0.727	

POM: postoperative month

Table 5 Correlation analysis of valve sound on quality of life

Item	Category	Patients	Influenced	OR	P value
Age (year)	>60 vs <60	41/59	11/5	3.22	0.054
Gender	F VS M	91/59	12/4	2.08	0.28
	Both >60 and F	30	8	5.1	0.036
Type	ATS vs Sorin	50/50	3/6	0.47	0.487
	Sorin vs SJM	50/50	6/7	0.88	0.766
BSA (m^2)	<1.5 vs>1.5	113/37	12/4	0.98	0.97
LVEF (%)	<55 vs>55	31/119	3/13	0.87	0.84

BSA: body surface area; LVEF: left ventricular ejection function

POM12: P = 0.503). As shown in **Table 4**, there was no statistical difference among the three groups at discharge, POM3, and POM12 (ATS: P = 0.909; Sorin: P = 0.569; SJM: P = 0.727). Similarly, there were also no statistical differences among the three groups at different times (at discharge: P = 0.941; POM3: P = 0.229; POM12: P = 0.394). With the increase in postoperative time, the number of patients and the members of their family affected by mechanical mitral valve sound decreased gradually.

An analysis was performed of the interfering factors related to mechanical mitral valve sounds 1 year after mitral valve replacement. As shown in **Table 5**, there was no statistical relationship between age (OR = 3.22, P = 0.054), sex (OR = 2.08, P = 0.28), valve type (P >0.1), LVEF (OR = 0.87, P = 0.84), or BSA (OR = 0.98, P = 0.97). However, women older than 60 years were 5.1 times more likely to be affected by the valve sounds than were men (OR = 5.1, P = 0.036, 95% CI: 1.107–9.176).

Discussion

In 1960, Starr and his team performed the first artificial heart valve replacement,[1] and the performance of the artificial heart valve has since been greatly improved, and surgical technology is becoming increasingly more advanced. Artificial heart valve replacement, a treatment option for patients with heart valve disease, has become a relatively safe surgical method, with concomitant improvements in postoperative survival. However, it has been reported that a number of patients have complained of the "clicking" sound of the mechanical mitral valve opening and closing affected their QoL.[9] Although a

number of studies have focused on the effect of artificial valve sound on QoL, few studies have investigated the effect of artificial heart valve sounds on patients' QoL at different time points.[4–7)]

Moritz evaluated the sound pressure levels of the CarboMedics (CM) valve, Bjork Shiley (BS) valve, and Duromedicus-Edwards (DE) valve at 1 cm of the chest wall and found that the sound pressure levels of the BS and DE valves were significantly higher.[10)] Similarly, Laurens et al. evaluated the sound pressure levels of CM, BS, and SJM valves at 1 cm from the chest wall and found that the sound pressure levels of BS valves (55.4 dB) were significantly higher than those of the CM valves (46.0 dB) and SJM valves (44.1 dB).[11)] Blome-eberwein et al. compared the sound pressure levels of valves DE, BS, SJM, Medtronic, CM, and Omicarbon at a distance of 10 cm from the chest wall and found that patients' hearing was a factor associated with patients' complaints.[12)] In our direct measurements, the ATS seemed to produce less noise than the other two mechanical valves, but the difference was not statistically significant.

The SF-36 scale was developed on the basis of the MOS scale and studied by Stewartse at the Boston Institute of Health Research,[13)] and it includes eight dimensions: physical functioning (I), social functioning (II), role-physical (III), role-emotional (IV), mental health (V), vitality (VI), bodily pain (VII), and general health (VIII). As it is an important scale for the assessment of QoL, the SF-36 scale has been widely recognized and applied.[14–16)] In the field of cardiac surgery, it has also been reported that the SF-36 scale is suitable for assessing the QoL of patients with heart disease.[17)] In this study, we found that the SF-36 scores of patients with the ATS, Sorin, and SJM valves at POM3 and POM12 were significantly higher than those at discharge, so we inferred that the QoL might improve over time. Although the QoL at POM12 was better than that at POM3, the difference was not statistically significant, which may be related to improve cardiac function, improve physical pain, and adaptation to the valve sounds; such benefits gradually reach a plateau, so further research is still needed. At the time of discharge, the ATS valve was superior to the Sorin and SJM valves in terms of the role-physical and mental health of the patients. At POM3, the ATS valve was superior to the Sorin and SJM valves in terms of the role physical, mental health, and role emotion of the patients. At POM12, the ATS valve was superior to the Sorin and SJM valves in terms of the mental health and role emotion of the patients. We found that the ATS valve, in some aspects, mainly in the psychological aspect, yields a better QoL than the Sorin and SJM valves. Sezai A suggested that the ATS valve has a low sound volume and leads to a high QoL, which is consistent with the research results in this paper.[18)]

Another finding in this article is that the number of patients and the members of the family affected by the sound of the mechanical mitral valve gradually decreased with the increase in the postoperative time, and this effect was more prominent in the ATS group than in the other two groups, which may be due to the structural design of the ATS valve. This result was similar to the objective data we measured directly. The ATS valve was first used in 1992, and its features include an open pivot with a small groove hemisphere on the hinge and a hollow pivot on a conventional bivalve. Since the leaves of the ATS valve open in response to forward cross-valve flow, the valve produces only a closing sound instead of both an opening and a closing sound, which are produced by some valves.[3,19)] The different structural designs may make the sound of the ATS valve quieter than that of other artificial valves. At the time of discharge, the number of patients in the ATS group who were affected by the valve was less than those in the Sorin and SJM groups according to the questionnaire survey. However, this discrepancy in the three kinds of mechanical mitral valves gradually decreased over time. There were no significant differences in the patients' and their family members' level of interference by the mechanical valve noise at 3 months and 12 months after surgery, which may be related to patients' and their family members' adaptation to mechanical mitral valve sounds and improvement in physiological function, but this hypothesis needs further confirmation.

Regarding the factors that affect QoL that are related to mechanical mitral valve sounds, many experts have also performed relevant research. Blome-Eberwein et al. reported that complaints about valve sounds were independent of the patient's age, the patient's sex, the valve type, the valve position, and the patient's heart rate.[12)] Laurens et al. reported that valve sound complaints were not related to the patient's sex, height, weight, or BSA, but younger patients with mitral valve replacement complained more than did older patients with aortic valve replacement.[11)] In this study, we found that the effect of mechanical mitral valve sounds on QoL was independent of the patient's age, the patient's sex, the valve brand, the LVEF, and the BSA. However, interestingly, we found that women older than 60 years were affected

more by the valve sounds than were younger individuals and men. We speculated that this result may be related to the lifestyle and cultural behaviors of elderly women in China. Most elderly women live in rural areas, lack young people's company, are lonely; in addition, they were more likely to be affected by the sound of their artificial valve.

This study was a retrospective case analysis study. All the included patients were recruited from a single heart center, and the sample size was relatively small. Therefore, the data collected may be biased. Subjective indicators were mostly adopted, and there may be certain variation in different populations, but we still believed that it was of certain clinical significance. In addition, the follow-up time was only 1 year, and a long-term follow-up should be performed in future studies to observe the long-term effect of mechanical mitral valve sounds on patients' QoL. A number of other factors that may affect the relationship between valve noise and patients' QoL were not specifically discussed in this study, which including severe arrhythmias, dP/dt, and mechanical valve-related complications, which would be further explored in future studies.

Conclusion

Among the three types of mechanical mitral valves, the ATS valve yielded a slightly better patient QoL than the Sorin and SJM valves. Another result of this study showed that over time, the effect of mechanical mitral valve sounds on QoL reduced, and the QoL improved. The effect of artificial valve sounds on QoL was independent of the patient's age, the patient's sex, the valve type, and the BSA, but women older than 60 years were affected more by the valve sounds than were younger individuals and men.

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Disclosure Statement

All authors declare that they have no competing interests.

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