Original Article

Influence of Prosthetic Heart Valve Sound on a Patient's Quality of Life

Katsuo Nishi, MD,[1] Kiyoyuki Eishi, MD,[2] Yoshisada Shibata, PhD,[3] Jun Amano, MD, PhD,[4] Tatsuo Kaneko, MD,[5] Hitoshi Okabayashi, MD,[6] Yoshiharu Takahara, MD,[7] Shuichiro Takanashi, MD,[8] Kazuo Tanemoto, MD,[9] Hiroki Yamaguchi, MD, PhD,[10] and Kohei Kawazoe, MD, PhD[11]

Purpose: **To elucidate the effects of prosthetic valve sound on a patient's quality of life (QOL).**
Methods: **We compared the valve sounds of ATS, SJM, and Carbomedics (CM) based on assessments by 248 patients who underwent mechanical valve replacements from January 2000 to August 2003 at seven facilities in Japan. We used a self-administered questionnaire for evaluating patients' assessments of valve sounds and the Japanese version of SF-36 for measuring their health-related QOL.**
Results: **With respect to the valve-sound level perceived immediately after surgery, we considered the ATS and SJM valves quieter than the CM valve, but others have considered the ATS valve quieter than the SJM and CM valves. Regarding the time when the valve sound stopped bothering patients, a significant difference was observed between the ATS and CM valves and between the SJM and CM valves. The logistic regression analysis on patients' perceptions of valve sounds indicated that the influences of age, gender, and valve position are significant. Furthermore, a survey with SF-36 indicated that a long valve sound will affect a patient's health-related QOL.**
Conclusion: **The present study suggested that the ATS valve surpassed the other two valves on the whole in audibility of valve sound and patient health-related QOL. However, further studies, including the ongoing prospective study, are necessary for a more comprehensive and accurate evaluation of the ATS valve. (Ann Thorac Cardiovasc Surg 2010; 16: 410–416)**

Key words: heart valve replacement, quality of life, prosthetic valve sound, SF-36

Introduction

Since the world's first prosthetic heart valve replacement was performed in the 1960s, the use of prosthetic (medical) heart valves for the treatment of heart valve disease has rapidly increased worldwide. Improved surgical outcomes have been reported recently, along with improved prosthetic heart valves, providing improved hemodynamics,

From [1]Department of Cardiovascular Surgery, Nagasaki University School of Medicine, Nagasaki; [2]Division of Cardiovascular Surgery, Nagasaki University Graduate School of Biomedical Sciences, Nagasaki; [3]Global Strategic Center for Radiation Health Risk Control, Nagasaki University Graduate School of Biomedical Sciences, Nagasaki; [4]Department of Surgery II, Shinshu University School of Medicine, Nagano; [5]Gunma Prefectural Cardiovascular Center, Gunma; [6]Department of Cardiovascular Surgery, Iwate Medical University Memorial Heart Center, Iwate; [7]Division of Cardiovascular Surgery, Funabashi Municipal Medical Center, Chiba; [8]Department of Cardiovascular Surgery, Sakakibara Heart Institute, Tokyo; [9]Department of Thoracic and Cardiovascular Surgery, Kawasaki Medical School, Okayama; [10]Department of Cardiovascular Surgery, Shin-Tokyo Hospital, Chiba; [11]Department of Cardiovascular Surgery, St. Luke's International Hospital, Tokyo, Japan

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Address reprint requests to Katsuo Nishi, MD: Department of Cardiovascular Surgery, Nagasaki University School of Medicine, 1–12–4 Sakamoto, Nagasaki, Nagasaki 852–8523, Japan.

Table 1. Questions and multiple-choice answers regarding the audibility of valve sound

Question	Answer
Q1: What did you think of the valve sound immediately after the operation?	(a) Inaudible (b) Quieter than expected (c) Noisier than expected
Q2: Is the valve sound audible to you now?	(a) Inaudible (b) Sometimes audible (c) Audible
Q3: Has anyone told you that the valve sound is audible?	(a) Have been told audible (b) Have been told audible a little (c) Have never been told audible
Q4: When did the valve sound stop bothering you?	(a) Immediately after the operation (b) Prior to discharge after the operation (c) By three months after the operation (d) By six months after the operation (e) By one year after the operation (f) More than one year after the operation (g) Still bothering

antithrombogenicity, and durability. However, further improvement of the quality of life (QOL) of patients with prosthetic heart valves, especially those with mechanical valves, would be desirable in regard to the problems associated with postoperative anticoagulation and valve sounds. The QOL of patients with prosthetic heart valve replacement has been evaluated in very few studies. We conducted the current study to compare different types of prosthetic valves (ATS, SJM, and CM [CarboMedics]) and to evaluate the effects of prosthetic valve sounds on QOL.

Patients and Methods

We invited 500 patients to the present study, patients who had undergone prosthetic valve replacement at seven institutions in Japan from January 2000 to August 2003. Of this total, 286 used ATS, 132 used SJM, and 67 used CM; 15 were using others or are unknown. A total of 381 (76.2%) of these patients agreed to participate in the study and provided us with written informed consent. Included were 208 (72.7%) using ATS, 107 (81.1%) using SJM, and 54 (80.6%) using CM; 12 (80%) were using others or are unknown. There was no significant difference in the participatants' valve types (P = 0.2336). We used a self-administered questionnaire for evaluating patients' assessment of valve sounds and the Japanese version of SF-36® version 1 (MOS Short Form 36 Item Health Survey)[1] to measure health-related QOL. This questionnaire included the questions shown in Table 1 along with those about sex, age, height, and weight. Excluded from the analysis wee patients who failed to respond completely to all four questions about valve-sound assessment, those who underwent a double-valve replacement or their second or later valve replacement, and those with implanted pacemakers. Among the 485 participants who used ATS, SJM, or CM, a total of 248 (49.6%) patients (138 males and 110 females) remained for the analysis. The valve-type specific proportion of patients who remained was 63.0% (131/208) for ATS, 73.8% (79/107) for SJM, and 70.3% (38/54); and no significant difference was observed (P = 0.1343).

We compared the frequency of answers to the respective questions in Table 1 among the valve types (ATS, SJM, and CM), using the cumulative chi-square method. We also carried out logistic regression analyses to evaluate the effects of age, gender, valve type, valve position, and body surface area (BSA) on the respective frequencies of patients responding "inaudible" to Q1 and Q2; "I have never been told that the sound is audible" to Q3; and "It still bothers me" to Q4. We evaluated the effects of valve replacement by comparisons, using the Wilcoxon rank-sum test and the respective scores of eight SF-36 subscales (physical functioning, role-physical, body pain, general health, vitality, social functioning, role-emotional, and mental health), between the two groups defined by dichotomized answers to each question shown in Table 1. We used the procedures of FREQ, LOGISTIC, NPAR1WAY, and UNIVARIATE in the SAS® system for calculations.

Table 2. Distribution of patients' characteristics by valve type

Characteristics	Category	Valve typ				P value[a]
		ATS (n = 131)	SJM (n = 79)	CM (n = 38)	Total (n = 248)	
Age (years)		(54, 60, 67)[b] 21–80[c]	(55, 62, 65) 32–79	(53, 58.5, 65) 38–76	(54, 61, 66) 21–80	0.463[e]
Gender	Male	73 (55.7%)[d]	47 (59.5%)	18 (47.4%)	138 (55.6%)	0.469[f]
	Female	58 (44.3%)	32 (40.5%)	20 (52.6%)	110 (44.4%)	
Valve position	Aortic	99 (75.6%)	46 (58.2%)	6 (15.8%)	151 (60.9%)	<0.0001[f]
	Mitral	32 (24.4%)	33 (41.8%)	32 (84.2%)	97 (39.1%)	
Body surface area (cm^2)		(1.46, 1.58, 1.73) 1.19–2.20	(1.49, 1.62, 1.71) 1.30–1.94	(1.46, 1.60, 1.74) 1.19–1.92	(1.47, 1.60, 1,725) 1.19–2.20	0.519[e]

[a]For comparison among three valve types.
[b]The 25th, 50th, and 75th percentiles from the left.
[c]Minimum-maximum.
[d]Number of patients (percentage in each valve-type group).
[e]Based on Kruskal-Wallis test.
[f]Based on exact test for 2×3 table (extension of Fisher's test for 2×2 table).
CM, Carbo Medics.

Results

Table 2 shows the distribution of patients' characteristics. The ATS valve was used in 131 (52.8%) patients, the SJM valve in 79 (31.9%), and the CM valve in 38 (15.3%). The age of patients varied from 21 to 80 years with a median of 61, and no significant difference was observed in the three groups of patients classified by valve type used (P = 0.463). Although the male-to-female ratio exceeded 1.2 in patients with ATS or SJM valves and 0.9 in those with CM, the difference was not significant (P = 0.469). Aortic valve replacement was performed in 151 (60.9%) patients and mitral valve replacement in 97 (39.1%). The proportion of patients having undergone aortic valve replacement differed significantly by valve type (P <0.0001): highest in those with ATS (99/131, or 75.6%), second highest in those with SJM (46/79, or 58.2%), and lowest in those with CM (6/38, or 15.8%). The body surface area varied from 1.19 m^2 to 2.20 m^2 with a median of 1.60 m^2, and no significant difference was observed in the three groups of patients classified by valve type used (P = 0.519).

Patients' assessments of the valve sound are summarized in Table 3 for the three types of valves. Although no significant difference was observed among three valve types in the distribution of answers to each of the four questions (P >0.15), a pairwise comparison showed a significant or marginally significant difference for some questions. With respect to Q1 about the valve-sound level perceived immediately after surgery, the ATS and SJM valves were considered quieter compared with the CM valve; the difference in the perceived sound level between the ATS and CM valves was significant (P = 0.0497), but that between the SJM and CM valves was marginally significant (P = 0.0653). Regarding Q3 about the valve-sound level assessed by others, the ATS valve was considered quieter compared with the other two, though the difference was marginally significant (P = 0.0501 and 0.0796 for the CM and SJM valves). Regarding Q4 about the time the valve sound stopped bothering patients, a significant difference was observed between the ATS and CM valves (P = 0.0423) and between the SJM valves and CM valves (P = 0.00335). The ATS and SJM valves stopped bothering more than 50% of patients before discharge, and the proportion of such patients with CM was less than 30%. We note that although not significant, the patients who chose the worst answers to the respective questions were least frequent in those with ATS valves.

The effects of age, gender, valve type, valve position, and BSA on the valve-sound audibility, which were simultaneously evaluated by logistic regression analysis, are presented in Table 4. These results indicate the following. (1) Positive answers to Q1 will significantly be less frequent by approximately 0.36-fold in females than in males, and negative answers to Q4 will significantly be higher by approximately 5.78-fold in females than in males; (2) Positive answers to Q1, Q2, and Q3 will significantly be more frequent by 1.90, 3.42, and 2.47, respectively, in patients aged 60 years or more compared with those aged less than

Table 3. Distribution of patients' answers to the four questions about valve-sound assessment

Question	Answer	Valve type				*P* value[a]
		ATS (n = 131)	SJM (n = 79)	CM (n = 38)	Total (n = 248)	
Q1: What did you think of the valve sound immediately after the operation?	(a) Inaudible	42 (32.1)[b]	27 (34.2)	8 (21.1)	77 (31.1)	0.281
	(b) Quieter than expected	46 (35.1)	21 (26.6)	12 (31.6)	79 (31.9)	
	(c) Noisier than expected	43 (32.8)	31 (39.2)	18 (47.4)	92 (37.1)	
Q2: Is the valve sound audible to you?	(a) Inaudible	50 (38.2)	29 (36.7)	12 (31.6)	91 (36.7)	0.512
	(b) Sometimes audible	64 (48.8)	33 (41.8)	20 (52.6)	117 (47.2)	
	(c) Audible	17 (13.0)	17 (21.5)	6 (15.8)	40 (16.1)	
Q3: Has anyone told you that the valve sound is audible?	(a) Have been told audible	11 (8.4)	13 (16.5)	6 (15.8)	30 (12.1)	0.159
	(b) Have been told audible a little	16 (12.2)	11 (13.9)	6 (15.8)	11 (13.3)	
	(c) Have never been told audible	104 (79.4)	55 (69.6)	26 (68.4)	185 (74.6)	
Q4: When did the valve sound stop bothering you?	(a) Immediately after operation	49 (37.4)	38 (48.1)	8 (21.1)	95 (38.3)	0.158
	(b) By time of discharge after operation	18 (13.7)	4 (5.1)	2 (5.3)	24 (9.7)	
	(c) By 3 months after operation	13 (9.9)	6 (7.6)	8 (21.1)	27 (10.9)	
	(d) By 6 months after operation	9 (6.9)	5 (6.3)	8 (21.1)	22 (8.9)	
	(e) By 1 year after operation	8 (6.1)	4 (5.1)	1 (2.6)	13 (5.2)	
	(f) More than 1 year after operation	7 (5.3)	1 (1.3)	3 (7.9)	11 (4.4)	
	(g) Still bothering	27 (20.6)	21 (26.6)	8 (21.1)	56 (22.6)	

[a]For comparison among three valve types (based on cumulative chi-square method).
[b]Number of patients (percentage in each valve-type group).
CM, Carbo Medics.

Table 4. Effects of age, gender, valve type, valve position, and body surface area on the frequency of positive and negative answers to questions about sound audibility estimated by logistic regression analysis

Factor	Comparison	Answered "inaudible" to Q1	Answered "inaudible" to Q2	Answered "never been told audible" to Q3	Answered "still being bothered" to Q4
		OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Gender	Female vs. Male	0.36 (0.15–0.77)	0.60 (0.28–1.23)	1.01 (0.46–2.26)	5.78 (2.53–13.7)
Age (years)	≥60 vs. <60	1.90 (1.08–3.41)	3.42 (1.95–6.14)	2.47 (1.36–4.58)	0.71 (0.37–1.37)
Valve type	ATS vs. CM	2.05 (0.81–5.65)	1.21 (0.50–3.01)	1.34 (0.53–3.32)	0.61 (0.22–1.79)
	SJM vs. CM	1.96 (0.77–5.42)	0.98 (0.40–2.45)	0.76 (0.30–1.87)	1.20 (0.43–3.54)
Valve position	Aortic vs. Mitral	0.73 (0.38–1.41)	1.09 (0.58–2.08)	1.57 (0.79–3.16)	3.09 (1.44–6.98)
BSA (m^2)	≥1.5 vs. <1.5	0.58 (0.25–1.30)	0.85 (0.40–1.82)	0.69 (0.29–1.59)	1.14 (0.52–2.52)

Q1: What did you think of the valve sound immediately after the operation?
Q2: Is the valve sound audible to you now?
Q3: Has anyone told you that the valve sound is audible?
Q4: When did the valve sound stop bothering you?
OR, odds ratio; 95% CI, 95% confidence interval; BSA, body surface area.

60; (3) Although not significant, positive answers to Q1 will be higher in patients implanted with ATS or SJM valves compared with those having CM valves; (4) Negative answers to Q4 will be significantly higher by approximately 3.09-fold in patients undergoing aortic valve replacement, compared with those undergoing mitral valve replacement.

Figure 1 compares the median scores of eight SF-36 subscales between two groups of patients (1 and 2) classified according to their responses to Q1, Q2, Q3, and Q4, shown in Table 1: Regarding Q1, patients in the groups who answered (a) and those who answered either (b) or (c) are called "inaudible" and "quieter/noisier than expected," respectively. Regarding Q2, patients who answered (a) and those who answered either (b) or (c) are called "inaudible" and "sometimes audible/audible," respectively; Regarding Q3, patients who answered (a) and those who answered either (b) or (c) are called "not told audible" and "told audible a little/audible," respectively. Regarding Q4, patients who answered one of (a) to (f) and those who answered (g) are called "not bothering now" and "still bothering," respectively.

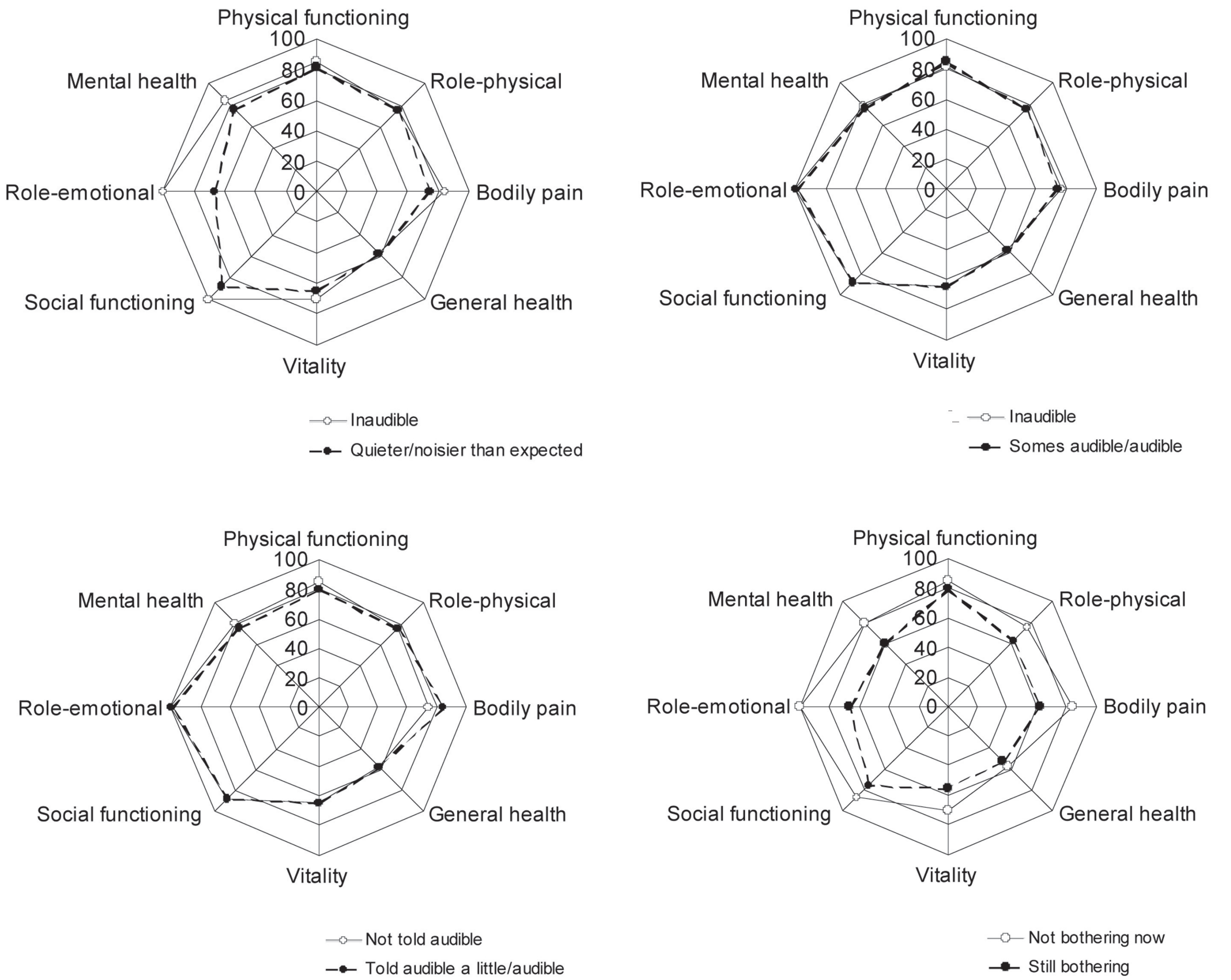
With respect to Q1, the scores of 8 subscales were all higher in the "inaudible" group compared with the "quieter/noisier than expected" group. We find in Fig. 1A that the difference was significant for role-physical (P = 0.0474) (the 1st, 2nd, and 3rd quartiles of the scores were 25, 75, and 100, respectively, in the "inaudible" group, but it was 0, 75, and 100, respectively, in the other groups); body pain (P = 0.0069) (the 1st, 2nd, and 3rd quartiles of the scores were 64, 84, and 100, respectively, in the "inaudible" group, but 52, 74, and 100, respectively, in the others); general health (P = 0.0287) (the 1st, 2nd, and 3rd quartiles of the scores were 52, 57, and 77, respectively, in the "inaudible" group, but 45, 57, and 67, respectively, in the others); mental health (P = 0.0338) (the 1st, 2nd, and 3rd quartiles of the score were 64, 84, and 92, respectively, in the "inaudible" group, but 0, 75, and 100, respectively, in the others). We find in the other groups, however, that although the score of role-emotional tended to be higher in the "inaudible" group than in the others, the difference was slightly insignificant (P = 0.0554) (the 1st, 2nd, and 3rd quartiles of the scores were 33.3, 100, and 100, respectively, in the"inaudible" group, but it was 0, 66.7, and 100, respectively, in the others). With respect to Q2 and Q3, no difference was observed in the scores of all subscales between the two groups (Fig. 1B and 1C). With respect to Q4, the scores of 8 subscales were all significantly higher in the "not bothering now" group compared with the "still bothering" group; the P values were all less than 0.01 except for physical functioning (P = 0.0337) and role-emotional (P = 0.0138) (Fig. 1D).

Discussion

Established as a treatment option for patients with heart valve diseases, prosthetic heart valve replacement has become a reasonably safe surgical procedure. Prosthetic heart valve replacement is expected to improve a patient's prognosis and QOL. Although the mortality, morbidity, and recurrence rates of disease associated with prosthetic heart valve replacement has been evaluated in several studies, the effect of a prosthetic heart valve on QOL has rarely been studied. The QOL may be affected by the valve sound itself, as well as by the patient's mental state, such as fear of anticoagulation-related bleeding events and valve failure.

Moritz et al.[2] evaluated the sound-pressure levels of the CarboMedics (CM) valve, Bjork-Shiley (BS) valve, and Duromedicus-Edwards (DE) valve at 1 cm away from the chest wall and reported significantly higher levels for the BS and DE valves. Laurens et al.[3] evaluated the sound pressure levels of the CM, BS, and SJM valves at 1 cm away from the chest wall and reported significantly higher sound pressure levels for the BS valve (55.4 dB) compared with the CM valve (46.0 dB) and SJM valve (44.1 dB). Blome-Eberwein et al.[4] compared the sound pressure levels of the DE, BS, SJM, Medtronic, CM, and Omicarbon valves at 10 cm away from the chest wall and demonstrated that the audition to the patient was a factor associated with patient complaints.

The typical human auditory threshold ranges from 20 Hz to 20 kHz, or 0 dB to 130 dB in sound-pressure levels. We are supposedly most sensitive to sounds from 2 kHz to 5 kHz. Sezai et al.[5] evaluated the valve sounds produced by the ATS and SJM valves and their effects on patients' QOL and reported that the scores for audibility of the valve sound, disturbance during daytime activities, sleep disturbance, request for replacement with a soundless prosthetic valve, audibility to others, and noise index were significantly lower for the ATS valve than for the SJM valve. An analysis of the closing sounds of the prosthetic valves revealed that the peak frequency of the ATS and SJM valves was around 1.2 kHz and that the SJM valve had another peak frequency at 2 kHz to 7 kHz. The study concluded that the ATS valve sound was less audible compared with that of the SJM valve, since the frequency range of 2 kHz to 7 kHz is consistent with the frequency range of 2 to 5 kHz, considered the range most



A	B
C	D

Fig. 1. Comparison of the median scores of eight SF-36 subscales between two groups of patients classified according to their responses shown in Table 1. **A**. "Inaudible" describes patients who answered (a) to Q1; "quieter/noisier than expected" are those who answered either (b) or (c) to Q1. **B**. "Inaudible" describes patients who answered (a) to Q2; "sometimes audible/audible" are those who answered either (b) or (c) to Q2. **C**. "Not told" describes patients who answered (a) to Q3; "told audible a little/audible" are those who answered either (b) or (c) to Q3. **D**. "Not bothering now" describes patients who answered one of (a) to (f) to Q4; "still bothering" are those who answered (g) to Q4.

sensitive to human ears.

The sound levels of the ATS, SJM, and CM valves assessed by patients in the present study showed the following. (1) The ATS and SJM valves were considered quieter than the CM valve regarding the valve-sound level perceived immediately after surgery (P = 0.0497 for ATS, and P = 0.0653 for SJM); (2) The ATS valve was considered quieter than the other two regarding the valve-sound level assessed by others (P = 0.0501 for CM, and P = 0.0796 for SJM); (3) The ATS and SJM valves were considered superior to CM regarding the time when the valve sound stopped bothering patients (P = 0.0423 for comparing ATS, and P = 0.00335 SJM). Furthermore, a survey with SF-36 indicated that long-lasting valve sounds affect patients' health-related QOL.

Developed with the objective of providing for improved antithrombogenicity, hemodynamics, and QOL, the ATS valve was first used in 1992. Its features include an open pivot with a small grooved hemisphere in the hinge, and a cavity pivot in the conventional bileaflet mechanical valve that caused accumulation of blood components in the hinge with consequent thrombogenicity has been eliminated. The open-pivot design provides a relatively larger surface area for displacement of the leaflet-closing velocities and associated energy. The advantage of this physical design characteristic is further enhanced by the interposition of highly viscous blood between these surfaces, thus providing for a "cushioning" effect. Lastly, because the ATS valve leaflets open in response to transvalvular forward flow, the valves generate only a closing sound as opposed to both an opening and closing sound generated by some valves. Although the ATS valves do generate sound, they generate less sound and sound at different frequency ranges compared to conventional valves having a cavity-pivot design. The current study results suggest that the open-pivot design of the ATS valve may be one of the reasons for a superior evaluation of the perceived valve sound in the immediate postoperative period, the postoperative length of time required for patients to stop being bothered by the sound, and the sound's audibility to others.

As for the other valve-sound-related factors affecting QOL, Blome-Eberwein et al.[4] reported that complaints about valve sounds were not related to age, gender, type of valve, valve position, or heart rhythm. Laurens et al.[3] reported that complaints about the sounds were not related to gender, height, weight, or BSA and that younger patients with mitral valve replacement complained more than older patients with aortic valve replacement. The results of our logistic regression analysis, using factors such as age, gender, valve type, valve position, and BSA, showed that age was a significant factor affecting the patients' perception of valve sounds in daily life postoperatively and the valve sound audibility to others, and that age and the valve replaced were significant factors affecting the postoperative length of time required for patients to stop being bothered by sounds of the valve.

In conclusion, the present study suggested that the ATS valve surpassed the other two valves on the whole in audibility of valve sound and the patients' health-related QOL. However, further studies, including the ongoing prospective study, are necessary for more comprehensive and accurate evaluation of the ATS valve.

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