Original

Mechanical Heart Valve Prosthesis: Relationship Between Sound Pressure Level and Related Complaints

[1&2]Moyijo A. Maishanu, [1]Mark Tettey, [1]Kow Entsua-Mensah, [2]Abubakar Umar

[1]National Cardiothoracic Center, Korle-Bu Teaching Hospital, Accra, Ghana.
[2]Usmanu Danfodiyo University Teaching Hospital Sokoto, Nigeria.

Corresponding author: Moyijo A. Maishanu , *Department of Surgery, Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria. maishanumoyijo@yahoo.com:+2348037661981*

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Abstract

Background: A primary cause of valvular heart disease in developing countries is rheumatic fever. Mechanical heart valves are used as the mainstay of therapy in developing countries. However, these valves have a distinct sound that is audible to the patient and the people around them, increasing the patient's complaints in the postoperative period.

Methods: This is a cross-sectional study where the sound pressure level of mechanical heart valve sounds, valve sound-related complaints, and the association between them were evaluated in 39 patients. A valve sound questionnaire and a sound level meter were used to characterize these variables and a Pearson's Chi-square test was used to identify the association between them. The significance level was set at $p < 0.05$ at a 95% confidence level.

Results: Eighty-nine percent of participants could hear the sound coming from their mechanical valves, but only 31% were disturbed by the valve sounds. The mean sound pressure level ± standard deviation of the mechanical heart valve sounds in this study were 24.7dB ± 3.13 at chest level, 20.47dB ± 1.78 at ear level, and 15.37dB ±0.97 at 1 meter. The study did not find a statistically significant difference in the sound pressure level measurements between patients disturbed by the sounds and patients who experienced no disturbance at the various distances recorded.

Conclusion: There is no difference in sound pressure level between patients with valve sound-related complaints and those without. Sound pressure levels of mechanical valves do not affect the incidence of valve sound-related complaints.

Keywords: Mechanical heart valve sound, sound pressure level, valve sound-related complaints.

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Introduction

The primary etiological factor for heart valve disease in developing countries is rheumatic fever, while degenerative valve disease is the prevalent cause in industrialized countries.[1] The burden of rheumatic heart disease is mainly on the low-income countries with an incidence ranging from 10 to 375 per 100,000 and is commonly seen in the young population.[2] Surgical management of valvular heart disease is mainly to prevent further deterioration in heart function, improve heart function, relieve symptoms, improve the patient's functional status, and prolong life. The choice of valve replacement is usually between mechanical prosthesis and bioprosthesis.[3]

An ideal prosthetic valve should be nonobstructive and completely competent, non-thrombogenic, should not degenerate, should not significantly alter blood components, can be inserted without undue difficulty, and should not disturb the patient.[4] The ideal valve, unfortunately, does not exist, and each of the currently available prosthetic heart valves has its inherent problems that influence the choice of valves used for patients.[5]

The bi-leaflet mechanical prosthetic valve is the most widely used mechanical valve today. This valve design generally consists of two semicircular leaflets, a rigid housing component, and a surrounding sewing ring.[6] The sounds produced by mechanical valves are produced by the continuous contact between the valve parts during opening and closing. The intrinsic properties of the valve like the opening angle and the mass of the leaflets, affect the intensity of the valve sound produced. The larger the mass of the leaflets and the longer the distance the leaflets have to travel before closing (i.e., the opening angle), the greater the sound intensity. During the closure of the valve, the mass and velocity produce mechanical energy on impact, which is partly absorbed by the housing unit. The remaining energy will be expelled as sound, which is then heard as the valve sound or valve click.[7]

The mechanical heart valve click may be audible over a considerable distance and can be annoying to patients and people around them.[8] In fact, anecdotal reports suggest instances where the patient's intolerance to the closing sounds of the valve has led to reoperation and change of a heart valve.[9] Earlier mechanical valves have been associated with more valve sound-related complaints. This problem persists in newer mechanical valves but to a lesser degree, probably because of alterations in the valve designs.[10] In some studies, not a single patient was seen to be without complaints directly related to the valve sounds.[9] More than half of patients with prosthetic valves hear their valve sounds, and most will describe the sound as metallic, like the tick of a clock. A significant number of prostheses are audible to people nearby, but patients perceive the sound between two- and four-fold higher than nearby persons.[7,9] Constant irritation, difficulty falling asleep, disturbance of the patient's partner, inability to concentrate, and social embarrassment are the primary complaints of the mechanical valve closure sound.[10] Some patients also describe fear and nervousness associated with the sounds, while a few feel reassured by the continuous valve sound.[7]

Measurement of mechanical heart valve sounds can be done both in-vivo and in-vitro. The advantage of in-vitro measurement is that the valve sounds can be measured and compared under controlled and identical conditions.[11] For valves that have been implanted already, many in-vivo measurement techniques have been used to identify the sound pressure level, the frequency of the valve sounds, to compare these parameters in different types of commercially available valves, and to relate these parameters to the perception of valve sounds and the valve sound-related complaints.

MATERIALS AND METHODS

Study Setting

The study was carried out at the National Cardiothoracic Centre, Korle-Bu Teaching Hospital, Accra, Ghana. It is a referral center for most West African countries and carries out a multitude of surgeries in both adult and pediatric cardiac and thoracic surgery. Averagely, 22 valve surgeries are performed annually.[12]

Study Design and Population

This is a cross-sectional study of all patients who had heart valve replacement with a mechanical prosthesis at the National Cardiothoracic Centre, Korle-Bu Teaching Hospital, Accra, Ghana between January 2018 and December 2019. The perception of sound as well as the sound pressure level of the mechanical heart valves and their effect on valve sound-related complaints were evaluated in these patients. Those less than 16 years of age were excluded.

Ethical Consideration

Both written and oral informed consent were obtained from all the patients in the study. Ethical clearance was also obtained from the Scientific and Technical Committee/ Institutional Review Board of the Korle-Bu Teaching Hospital, Accra, Ghana.

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Patient Interview

A valve sound questionnaire was used to assess the patient's perception of the valve sounds and the disturbance directly related to the valve sound. It included disturbance under particular circumstances, e.g., at night; it also assessed the family and public reactions to the valve sound. The questionnaire contained five questions that evaluated the valve sound-related complaints of the patients. The questionnaire has been previously used by various studies that assessed the level of disturbance of mechanical heart valves including the works of Koertke et al.[13], Sezai et al.[14], Blome-Eberwein et al.[15], Nishi et al.[16], Laurens et al.[7] and Moritz et al.[17] and has been validated by Golczyk et al.[9] The questions were scored from 0 to 100 points, and an average of the scores was taken. Patients who scored an average of </= 25 were considered undisturbed, 26-50 as mildly disturbed, 51-75 as moderately disturbed, and those with 76 and above as severely disturbed.

Sound Measurement

The sound pressure level (SPL) was recorded in a sound-proof room typically used for audiometry in the Audiology Department. The patients were seated on a chair after removing their upper garments and the participants were examined using a stethoscope for the area where the valve click was heard maximally. The SPL were then measured using a Larson Davis sound level meter, model 824 (Made in the USA by PCB Piezotronics Inc.) conforming to IEC 61672 class 1 standards, ensuring high precision. The sound pressure level was measured at 0cm, 10cm, 50cm and 100cm distances from the point where the valve sound was heard maximally during auscultation. Distances were measured using a standard tape measure with a precision of ± 1mm. The SPL at the patient's ear level was also recorded. The sounds of the mechanical valve were recorded for 30 seconds, and an average maximum sound pressure level was calculated for each patient and recorded on a proforma.

Statistical Analysis

The data was recorded on an online Open Data Kit (ODK), exported to an Excel spreadsheet, and then analyzed using the Statistical Software for Social Sciences (SPSS) version 25. Quantitative variables, such as age and sound pressure level, were presented as mean and standard deviation. In contrast, categorical variables (gender, type of valve, etc.) were presented as frequencies and percentages. Pearson's Chi-square test was used to identify the association between sound pressure levels and valve sound-related complaints. The significance level was set at $p < 0.05$ at a 95% confidence level. Ethical clearance and approval were obtained from the Institutional Review Board of the Korle-Bu Teaching Hospital, Accra, Ghana, and the National Cardiothoracic Center, Accra.

RESULTS

Over the study period, a total of 39 patients had mechanical heart valve implantation at the center (Table 1). The youngest participant was 16 years old, while the oldest was 70.

Table 1: Sociodemographic characteristics

Age Range (Years)	*Male*	*Female*	*Total*
0-20	4	1	5
21-40	6	8	14
41-60	7	5	12
61-80	7	1	8
Total	24	15	39
Total %	62%	38%	

Abbreviation %: percentage

The mean age ± standard deviation was 43.82 ± 15.37 years. The male-to-female ratio was 1.6:1, with 62% (24) of participants being male and 38% (15) female (Table 1). The majority of patients (41%) had a pre-operative diagnosis of mitral regurgitation, 17.9% had aortic and mitral regurgitation, and only about 5% had mitral stenosis (Table 2).

Table 2: Pre-operative diagnoses

Variable	**Frequency (N=39)**	**Percent (%)**
Pre-operative Diagnosis		
AR	11	28.2
AR + MR	7	17.9
AS	3	7.7
MR	16	41.0
MS	2	5.1

Abbreviation: AR = aortic regurgitation; AS = aortic stenosis; MR = mitral regurgitation; MS = mitral stenosis

Thirty-one percent of the study participants were disturbed by their mechanical heart valve sounds. Most of the participants (89.8%) could hear the valve sounds, 94.9% did not experience sleep disturbance because of the valve sounds, 10.3% felt uncomfortable in social gatherings because of the valve sound, and 15.3% of the

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participants with partners claimed the sound disturbs their partners. Only 5 participants (12.8%) will want to replace the valve with a noiseless valve (Table 3).

Table 3: Valve-related Complaints

Variable	***Frequency (N=39)***	***Percent (100)***
Is your valve sound audible to you?		
Yes	35	89.8
No	4	10.2
Disturbance of your sleep		
Not disturbing	37	94.9
Sometimes	2	5.1
Uncomfortable in Social Gatherings		
No	33	84.6
Some of the time	4	10.3
Most of the time	1	2.6
All of the time	1	2.6
Sound affects partner		
No	26	84.7
Sometimes	4	15.3
No partner	9	N/A*
Replace Valve if possible		
No	34	87.2
Yes	5	12.8

N= number of participants, N/A Not applicable * Patients who didn't have partners were excluded from the calculation in this category

Table 4: Sound Pressure level measurement

Sound pressure level	***Minimum (dB)***	***Maximum (dB)***	***Mean (dB)***	***Standard deviation***
SPL EAR	15.7	25.4	20.47	1.78
SPL 0 cm	19.6	33.9	24.70	3.13
SPL 10 cm	17.2	24.6	20.43	1.91
SPL 50 cm	15.0	19.3	17.03	1.12
SPL 100 cm	13.3	17.7	15.37	0.97

Abbreviation: SPL, Sound pressure level, Number of participants =39, dB = decibel

Table 5: Comparison of Sound Pressure Level of Disturbed vs. Undisturbed Group

Variable	***Total(mean±SD)***	***Disturbed group (mean±SD)***	***Undisturbed group (mean±SD)***	***Sig***
Sound pressure level				
SPL EAR	20.47±1.78	20.63±2.03	20.10±1.00	0.40
SPL 0 cm	24.70±3.36	25.27±3.70	23.42±2.02	0.11
SPL 10 cm	20.43±1.91	20.58±1.78	20.08±2.23	0.45
SPL 50 cm	17.03±1.12	17.08±1.18	16.91±1.00	0.67
SPL 100 cm	15.37±0.97	15.47±0.98	15.14±1.00	0.32

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Abbreviation: Sd, Standard deviation; SPL, Sound pressure level, Number of participants =39

Table 6: Factors affecting disturbance

Variable	COR (C I)	Sig	AOR (C.I)	Sig
Age	1.01(0.96-1.05)	0.69	0.99(0.92-1.06)	0.77
BMI	0.97(0.82-1.12)	0.74	0.92(0.75-1.12)	0.42
Gender				0.78
Male	1			
Female	1.37(0.33-5.71)	0.66	1.27(0.14-4.28)	0.68
Type of surgery				
AVR	1			
DVR	2.8(6.12-12.97)	0.18	3.61(0.62-34.2)	0.13
MVR	1.67(0.24-14.19)	0.54	1.59(0.24-17.97)	0.50
Heart Rhythm				
Sinus	1			
AF	1.16(0.23-5,72)	0.84	1.46(0.23-9.08)	0.68
Audiometry				
Passed	1			
Failed	1.37(0.30-6.19)	0.63	1.32(0.28-5.56)	0.65

Abbreviation: COR Crude odds ratio, AOR Adjusted odds ratio, CI Confidence interval, AF Atrial fibrillation, AVR Aortic valve replacement, DVR double calve replacement, MVR Mitral valve replacement; Number of participants = 39

The mean sound pressure level ± standard deviation at the level of the chest was 24.7 decibel (dB) ± 3.13, at the level of the patient's ear 20.47 dB ± 1.78, and at 100cm from the patient 15.37 dB ±0.97 (Table 4).

There was no statistically significant difference between the sound pressure level of the mechanical heart valves at chest level, ear level, 10cm, 50cm, and 100cm between patients with disturbance secondary to the heart valve sound and those who do not experience disturbance. However, the SPL is slightly higher at the chest and ear levels in the group of patients that were disturbed by the valve sound (25.27±3.70dB versus 23.42±2.02dB at chest level and 20.63±2.03dB versus 20.10±1.00dB at ear level) (Table 5).

Female participants were 1.4 times more likely to experience disturbance from the valve sounds as compared to the male participants. Patients with single mechanical heart valves in the mitral position were 1.7 times more likely to have disturbance than those with a single mechanical valve in the aortic area. Those with more than one valve were 2.8 times more likely to be disturbed by the valve sounds compared to patients with a single valve in the aortic area. These findings were, however, not statistically significant (Table 6).

Discussion

Complications following mechanical heart valve surgery have been well documented in literature. These complications have influenced the type of valve implanted in patients with heart valve pathologies (mechanical versus biologic). However, mechanical heart valve sounds and related complaints as a complication of mechanical heart valves and the characteristics of these sounds have not been well documented in the literature, especially in the developing world. This study investigates the occurrence of valve sound-related complaints in patients in a developing country, characterized the sound pressure levels of mechanical heart valves implanted, and analyzed their relationship with valve sound-related complaints.

The participants' mean age was 43.82 years ± 15.37, which is similar to the median age of occurrence of rheumatic heart disease (the commonest valve pathology in the environment) in developing countries.[1] The predominant valve pathology was mitral regurgitation (41%), while the least common was mitral stenosis (5%). This is slightly different from other studies that found mitral regurgitation to be the most common pathology (59%) but found aortic stenosis the least common in developing countries (9%).[1] The possible reasons why aortic stenosis is not the least common in this study may be explained by the increasing life expectancy and adoption of western lifestyle and diet now seen in developing countries causing a slight increase in the incidence of aortic stenosis in the study population.

The majority of the participants (35, 89.8%) could hear their mechanical heart valve sounds, but only 5% of the participants had sleep disturbance as a result. Thirteen percent felt uncomfortable in social gatherings because of the sounds, and 15% of those with partners

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complained that the valve sounds disturbed their partners. About 13% of participants would want the valve replaced with a quieter valve. Some similar studies found that 63% of patients with a St. Jude Medical (SJM™) valve could hear the valve sound, 8.6% had sleep disturbance, and 11% wanted a quieter valve.[18] Others found that 15.4% of patients with an Advancing The System (ATS™) valve and 64.9% of patients with an SJM™ valve could hear the valve sounds. None of the patients with an ATS™ valve experienced sleep disturbance. In contrast, only 7% experienced sleep disturbance in the SJM group, a finding similar to that in this study.[14] None of the ATS group wanted the valve changed to a quieter valve, but about 5.3% of the SJM group wanted their valve changed to a quieter valve which is lower than the finding in this study.[14] The difference in the sound perception and complaints has been linked to the different sound pressure levels of the various models and designs of the mechanical heart valves by several researchers[7,15–17], some postulating that the open pivot design of the ATS (now Medtronic) valve and the presence of only a closing sound in this valve cause less noise.[16] Additionally, the response of the patient to the valve sounds may depend on various physiologic and psychologic factors which are difficult to evaluate.[14]

This study found mechanical heart valve sound-related complaints in 31% of the participants who had mechanical heart valves implanted 2 to 3 years before the study period. This prevalence is similar to the findings of some researchers who found that the valve sounds were somewhat disturbing in 36% of their patients two years after surgery.[13] Golczyk et al. found the prevalence of disturbance in their patients with SJM™ and ATS™ valves to be 30% and up to 80% in patients with the Sorin valves, six months after surgery.[9] All the participants in this study had Medtronic mechanical valves implanted, so it is not surprising that the prevalence is very similar to the ATS™ (now Medtronic) group in the previously mentioned study. The difference in the structural design of the different kinds of valves examined in the various studies may account for the varied prevalence of these complaints. Also, participants' characteristics, including age, gender, heart rhythm, body mass index (BMI), location of the valve, and the number of valves, may also account for the variation in the prevalence of complaints among the different studies.

The mean sound pressure level (SPL) at 0cm was 24.7dB ± 3.13, at 10cm 20.43dB ± 1.91, and at 100cm 15.37dB ± 0.97. Moritz et al. measured the SPL of four different types of mechanical heart valves, including three bi-leaflet valves and one tilting disc valve. In their findings, the SPL of the SJM valve was 41dB at 5cm, 40dB at 10cm, and 24 dB at 100cm, while that of the Bjork-Shiley Monostrut™ (BSM) was 40dB at 5cm, 41dB at 10cm, and 31dB at 100cm. (Moritz). Limb et al. recorded a mean SPL of 36.1dB at a 10 cm distance in patients with a BSM™ tilting disc valve.[10] These findings are at variance with the findings in this study. This could result from the structural design differences of the valves used for the patients in this study compared to the valves used in the other studies. The open-pivot design of the ATS valves used in this study gives it superior closing mechanics with less noise emission. The absence of an opening sound also reduces the noise emission from these valves.[9,16] It could also be explained by the differences in methods and devices used to record the sound pressure levels in the different studies.

Various studies have described increased valve sound-related complaints in patients with louder valves, i.e., patients with higher SPL measurements.[9,14,18] This study did not find a statistically significant difference in the SPL measurements between patients disturbed by the sounds and patients who experienced no disturbance at the various distances recorded. Limb and colleagues had similar results with this study and concluded that the problems arising from mechanical heart valve sound depend on factors other than the loudness of the valve, it may depend on physiologic and psychologic factors that are difficult to assess.[10,14]

Other factors like age and gender were also found to have no statistical significance in terms of the occurrence of valve sound-related complaints. Females were, however, found to be 1.4 times more likely to have disturbance when compared to males. Other studies also considered similar factors but eventually concluded that valve design was the most crucial factor in sound perception and related complaints.[7,15]

Strengths and Limitations of the Study

The study examined a study population in Ghana, sub-Saharan Africa, contributing to a more diverse understanding of mechanical valve sounds in different settings and patient profile. The small sample size may, however, limit the ability to generalize the findings to a larger population. The perception of disturbance may be subjective and may be influenced by factors like individual sensitivity to noise and some psychological factors that have not been fully explored in this study.

Conclusion

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Most of the participants in this study could hear the sound coming from their mechanical valves and the prevalence of valve sound disturbance was 31% in the study population. Five participants wanted the valve replaced with a quieter valve. The sound pressure level of the mechanical valves in this study were significantly lower than those in other studies. There was no statistically significant association between the sound pressure level of the mechanical heart valves and the valve sound-related complaints.

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Authors' Contribution:

Moyijo Maishanu: Conception, design, acquisition, analysis and interpretation of data. Also, the drafting, revision, final approval of the version to be published. Also agree to be accountable for all aspects of the work.

Mark Tettey: Conception, and design of the work. Also, the critical revision and final approval of the version to be published. Also agree to be accountable for all aspects of the work.

Kow Entsua-Mensah: Design of the work. Also, the critical revision and final approval of the version to be published. Also agree to be accountable for all aspects of the work.

Abubakar Umar: Design of the work. Also, the critical revision and final approval of the version to be published. Also agree to be accountable for all aspects of the work.

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