

Outcome and Quality of Life of Patients following Valve Replacement Surgery: Predictors of Healthy Survival

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Abstract:

Key Words :
Valve replacement surgery, Quality of life, Predictors of survival

Background: In search of factors influencing the postoperative health-related quality of life after heart valve replacement, the present study was designed to see the effects of valve replacement on the long-term healthy survival. The aim of the study was to explore whether the Preoperative variables, such as clinical characteristics and test data could be used to predict the effects of valve replacement on functional status and quality of life in patients with heart valve malfunctions after surgical intervention.

Method: We retrospectively identified 200 patients who underwent heart valve replacement for stenosis between 2005 and 2012 in the department of Cardiac Surgery, BSMMU, Dhaka, Bangladesh and survived the surgery and initial 30 day postoperative period. Late follow-up between January 2013 and July 2015 was done and completed in 50% cases.

Results: Among 100 study population, 47 were male and the rest 53 were female, aged 22 to 65 years (mean 37.0 ± 7.4 years). The quality of life was assessed with the Medical Outcomes Study Short Form -36 (MOS SF-36) and the functional outcome was evaluated using New York Heart Association (NYHA) functional class scores, in addition to analysis of laboratory tests, like ECG, X-ray chest, echocardiography, prothrombin time. Evaluation of preoperative medical history revealed that there were hypertension in 71%, diabetes mellitus in 13%, and history of stroke in 09% patients. Prolonged length of stay in intensive care unit and in hospital (mean: 14.7 and 37.1 days respectively) was observed in 17% patients. Late postoperative survival rate was 86% at 1 year and 63% at the end of 5 years. Predictors of late morbidity and mortality were Preoperative or Perioperative complications, preoperative history of stroke, chronic obstructive pulmonary disease, postoperative renal dysfunction. The mean NYHA functional class for all late survivors improved from 3.6 ± 0.9 to 1.9 ± 0.7 . Late survival was worse for those who were in an advanced NYHA functional class before surgery. Patient in NYHA Functional class III and IV had a worse late survival rate than those in Class I or II. There was significant improvement in all 8 health domains of the SF-36 Questionnaire in the overall sample.

Conclusion: The present study indicated that the late survival rate and functional outcome after heart valve replacement in Bangladeshi population with major valvular dysfunction was satisfactory. It was also observed that the preoperative physical as well as mental health status were identified as the only risk factors for potential non-improving quality of healthy survival following heart valve replacement after correction for age, gender and type after surgery.

(*Cardiovasc. j.* 2017; 10(1): 21-30)

Introduction:

Regardless of type of valvular diseases with progression of the disease process, symptoms developed including dyspnea, angina pectoris, fatigue, syncope and palpitations. Once symptom of heart valve malfunction develops, severely restricts the performance of daily living and the quality of life of patients. Over time heart valve replacement has become a safe and routine surgical procedure, though replacement devices are still far from ideal.

Procedural success, faster recovery and favorable clinical outcomes in the short term have been reported¹⁻⁴. Currently, with decreasing early-postoperative morbidity & mortality after heart valve replacement, the quality of life of survivor in long run has become the point of focus⁵.

To date, there has been little information about factors influencing the quality of life of patients undergoing valve replacement surgery for major valvular malfunction⁶⁻⁸. It has been observed that

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regardless of the success of surgery, post surgery co-morbidity affects quality of life^{1,2}. Fragile patients undergoing heart valve replacement are at risk of developing depression, anxiety or post-traumatic stress disorder^{9,10} in addition to physical sickness. leading to lifelong physical and mental fragility¹¹. After returning home, the feeling vulnerability and worries about transition phases appear and fear of rejection can be dominant¹².

First priority of Clinicians is to relieve the symptoms and to improve the prognosis. However, as the part of health care system, their goal should also be to maximize function in everyday life and to achieve the highest level of quality of life within the specific limits imposed by disease. In this case, describing and understanding patients' perception of recovery after heart valve replacement is essential. Understanding the quality of life after heart valve replacement with prosthetic valves, either mechanical or biological, has become increasingly important. As heart valve replacement number increases, more patients, physicians and families are affected by subsequent quality of life, Quality of life is relatively new scientific measure to evaluate effectiveness or treatment strategies and the course of disease .

Thus, in the present study, we tried to explore whether the preoperative variables, such as clinical characteristics and test data could be used to predict the effects of valve replacement on functional status and quality of life in patients with heart valve malfunctions after surgical intervention.

Objectives:

General Objective:

In order to identify the predictors of healthy survival after heart valve replacement, the present study was designed to explore whether the preoperative variables, such as clinical characteristics and laboratory test data could be used to predict the effects of valve replacement on functional status and quality of life in patients with heart valve malfunctions after surgical intervention.

Specific objective:

1. The clinical history, preoperative laboratory test data, operative, preoperative and early post-operative history and findings were collected from patients' record sheets who underwent heart valve replacement, irrespective of types

of valve surgery for analysis of preoperative and operative variables retrospectively

2. Patients, underwent heart valve replacement surgery for either aortic or mitral stenosis in the department of Cardiac Surgery, BSMMU, Dhaka, who survived the surgery and left hospital in good health were contacted for follow-up and post-operative health status analysis
3. The quality of life of patients after heart valve replacement was assessed with the Medical Outcomes Study Short Form-36 (MOS SF-36) and the functional outcome was evaluated using New York Heart Association, (NYHA) functional class scores, in addition to analysis of laboratory tests for assessing healthy survival of patients in their post-operative lives
4. The results would be used for alerting the clinicians about the impact of preoperative variables in postoperative functional outcomes and quality of life in patients undergoing heart valve replacement

Methods:

We retrospectively identified 200 patients (136 men, 64 women) who underwent heart valve replacement for stenosis between 2005 and 2012 in the department of Cardiac Surgery, BSMMU, Dhaka, Bangladesh. This Study consisted preoperative testing with Postoperative follow-up. Preoperative demographic information, medical history, and perioperative events were retrieved from our hospital record sheets. Late follow-up information was obtained either through postal questionnaire or telephone interview and testing was done at our follow-up clinic between January 2013 and July 2015. The patients' preoperative medical histories like anemia, angina Pectoris, hypertension, diabetes mellitus, rheumatic diseases, stroke, chronic obstructive pulmonary diseases (COPD), chronic renal insufficiency were recorded. Operative and Perioperative information such as type of valves used. cross-clamp time. early postoperative complications. amount of blood transfusion, length of stay in intensive care unit (ICU) and in hospital was also recorded. Follow-up was completed in 50% patients. So. Final sample size was 100 (Male: Female=47:53), aged 22 to 65 years (mean 37 ±7.4 years). All patients underwent clinical and routine laboratory examination, such as chest X-rays, ECG,

echocardiography, hematology with prothrombin time (PT), at follow-up. In order to examine the quality of life of patients underwent heart valve replacement, the patients were asked about their Quality of life after operation using a questionnaire. Questionnaire was prepared to determine how patients respond physically as well as mentally after artificial valve replacement and how they were accepted by their environment. The functional status was determined in 100 late survivors using New York Heart Association (NYHA) functional class. Table No. I describe the New York Heart Association (NYHA) Functional Classification system. It placed patients in one of four categories based on how much they were limited during physical activity. The quality of life was assessed with Medical outcomes Study (MOS) Short Form (SF036) tool [13]. Eight dimensions of health were investigated: physical function, Physical health related to age-and role-specific activities (Role-Physical), bodily pain, general health, vitality, Social functioning, personal feelings of Performance in age-and role-specific activities (Role- Emotional), and mental health (Table No. II). Scores were compared with those expected from the general population of a similar age.

Heart valve replacement was done by a team headed by experienced cardiac surgeon using cardiopulmonary bypass with either mechanical or biological prosthetic valves. All continuous data were expressed as mean \pm SD or as a percentage as indicated. The survival analysis was made by the kaplan-Meier estimator. Univariable analysis of risk factors for the early and late death was performed, and factors found to trend toward significance ($P < 0.05$) were entered into multivariable analysis

At follow-up a thorough clinical examination was done for assessment of valve function and physical well being. Quality of life evaluation was performed over the telephone by the same observer and was delayed until 12 months postoperatively. To record major adverse events, such as death, restenosis, all patients were followed by clinic review or telephone contact with the patient or family.

Results:

Follow-up was completed in 50% (100 patients) cases. Of the 100 study patients, 47 were male and the rest 53 were female. Mean age was 35 ± 7.4 years

(range: 22-55 years) and 13 patients were older than 50 years.

Demographics of the study population

Almost 98% of Patients with mitral stenosis had suffered from chronic obstructive pulmonary diseases (COPD), and COPD was present in 37% patients with aortic stenosis. None of our patients had it history of hypertension, but 24% patients had diabetes mellitus. Other significant preoperative co-morbidity included: history of stroke, peripheral vascular diseases, and chronic renal insufficiency (Table 1). Majority of patients had predominant functional stenosis, with a mean peak gradient of 54 ± 17 mmHg and a calculated valve area of 0.6 ± 0.02 cm² in aortic stenosis sub-group. Preoperatively, atrial fibrillation was found in 91% cases of mitral stenosis. Angina Pectoris was a common complaint in almost all patients.

All patients had symptoms of heart failure: NYHF class was 3.6 ± 0.9 ; 83 patients were in class III and IV. All patients were on medical treatment for symptomatic stenosis and co morbidity. Mean ejection fraction (EF) preoperatively was 0.41 ± 0.1 , and EF was less than 0.35 in 15% Patients.

Predominantly, valve replacement with mechanical valves was done (87%) irrespective of the type of stenosis. More than 15% patients experienced renal dysfunction and almost 5% of patients required hemodialysis. More than 24 hours mechanical ventilation was needed in almost 31% cases. Atrial fibrillation was common, and a relatively high percentage of patients experienced bleeding complications. Aortic insufficiency also was a predictor of operative risk ($p < 0.05$). Among perioperative complications, renal dysfunction and stroke were risk factors for death within 30 days of surgery. About 11% patients experienced renal dysfunction defined as an increase in serum creatinine level to > 2.0 mg/dl, and among them 4% needed hemodialysis after surgery. The mean NYHA functional class for all late survivors improved from 3.6 ± 0.9 to 1.9 ± 0.7 . However, operative risk was not related to preoperative NYHA functional class. The mean length of stay in intensive care unit (ICU) was 6.2 ± 1.1 days (5 to 43 days) and in hospital was 14.7 ± 3.7 days (4 to 92 days). The length of stay in the ICU as well as in hospital was prolonged in 17% patients.

After returning home, about 20% patients died at the end of one year and 40% died at the end of 5 years. Analysis of preoperative medical history revealed that almost all these patients had preoperative history of stroke COPD, and chronic renal insufficiency. Preoperative renal dysfunction and stroke were-also predictive of late survival.

Functional Class

The average functional class improved from 3.6 ± 0.9 preoperatively to 1.9 ± 0.7 after surgery. The number of patients in class III and IV decreased from 79 to 41 following valve replacement (p<0.001). Late survival was worse for those who were in an advanced NYHA functional class before surgery. Patient in NYHA functional class III and IV had a worse late survival late than those in Class 1- II.

Quality of Life

Forty long-term survivors responded to postal questionnaires or telephone interviews or attended our follow-up clinic for follow-up regarding their quality of life in relation to their physical and mental health. Actually all late survivors scored higher than the general population, especially in four areas: physical functioning, role-physical, general health, and social functioning. The main predictors of impaired postoperative quality of life were female gender and older age, with significant inferior values for all SF-36 scales (Fig No. 2). Presence of postoperative risk factors for coronary artery disease, such as hypertension, diabetes mellitus, chronic renal insufficiency, significantly reduced postoperative quality of life (Fig No. 2). Again patients with COPD and impaired left ventricular

Table-I

New York Heart Association (NYHA) Functional Classification System. It Placed patients in one of four categories based on how much they were limited during physical activity.

Class	Patients Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation of dyspnea
II	Slight limitation of physical activity. Comfortable at rest. Ordinary Physical activity results in fatigue, palpitation, or dyspnea
III	Marked limitation of physical activity, comfortable at rest. Less than ordinary activity causes fatigue, Palpitation or dyspnea
IV	Unable to carry on physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases

Table-II

Eight dimensions of health were investigated using the medical outcomes study (MOS) short form (MOS SF 36) tool for assessing the quality of life after surgery.

Dimension	
Physical functioning (PF)	Represents levels & kinds of limitations in lifting, climbing stairs, bending, kneeling, or walking moderate distance
Role-Physical (R-P)	The degree in physical health for which a person performs activities typical for a specific age & social responsibility, such as a job, community activities, and volunteer work
Bodily pain (BP)	The intensity, duration, and frequency of bodily pain & limitations in usual activities due to pain.
General Health (GH)	The beliefs & evaluations of a person's overall health, including current, & prior health, outlook, resistance to illness
Vitality (VT)	Measure of feelings of energy, pep, fatigue, & tiredness
Social Functioning (SF)	Ability to develop, maintain, & nurture mature social relationships, including family, friends, & marital relationships
Role- Emotional (R-E)	Represents personal feelings of job performance on work or other activities
Mental Health (MH)	A Person's emotional, cognitive, & intellectual status

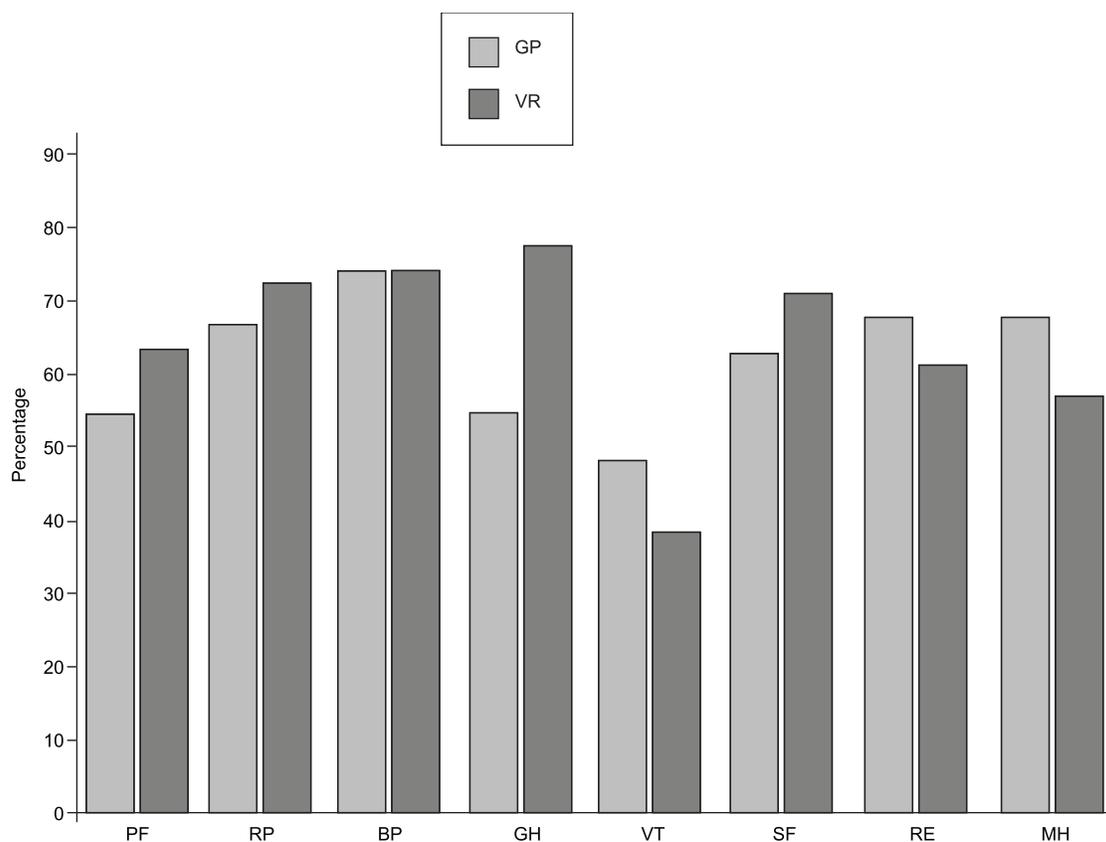
Table-III
Preoperative demographic characteristics of the study population

Parameters	Aortic Stenosis	Mitral Stenosis	Total Population
n (male/ female)	33 (20/13)	67 (27/ 40)	100 (47/53)
Age (years):	38.0 ± 7.4 (24 -64)/	35.0 ± 7.4 (23-63)/	37.0 ± 7.4 (22-65)
Male/Female: Mean ± SD (range)	39.0 ± 9.3 (22-65)	34.0 ± 9.3 (22-64)	
Valve aperture (sq-cm): mean ± SD (range)	0.7 ± 0.06 (0.5-1.2)	1.4±0.9 (1.2-2.1)	1.0 ± 0.9 (0.5-2.1)
Peak Pressure gradient (mmHg): mean ± SD (range)	55 ± 7.9 (40-75)	13.2±1.5 (12-15)	34.2±8.5 (12-75)
Wall Thickness (mm): Mean ±SD (range)	14.5±2.7(11-18)	6.5±1.3(5-8)	11.5±1.3(5-18)
EF:mean±SD(range)	0.45±0.05(0.3-0.5)	0.65±0.1(0.6-0.7)	0.55±0.13 (0.3-0.7)
EF less than 0.35(%)	15	0	15
Angina Pectoris (%)	99	97	98
DM (%)	8	18	13
History of stroke (%)	03	15	09
Active (%)	07	05	06
Inactive (%)	93	95	94
COPD (%)	37	98	68
Chronic renal insufficiency (%)	13	11	12
Atrial fibrillation (%)	04	91	48
Peripheral vascular Diseases	02	12	07

Table-IV
Operative and early postoperative characteristic

Parameters	
CPB time (min):mean ±SD (range)	130±52.9 (80-180)
Cross-clamp time (min):mean ±SD (range)	45±12.9(35-55)
Mechanical valve used : (%)	87
Biological valve used: (%)	13
ICU Stay (day): mean ±SD (range)	6.2±1.1(3-10)
Total hospital stay (day): mean ±SD (range)	14.7±3.7(10-31)
prolonged stay in ICU & hospital (%)	17
Respiratory tract infection:	17
Wound infection:	5
Renal dysfunction:	15.6
Bleeding disorder:	33
Reoperation for bleeding :	7
Low-output syndrome:	23
Arrhythmia	49
Stroke:	5
Atrial fibrillation	87

Results of MOS for Patients VS General Population



PF (Physical Functioning); RP (Role-Physical); BP (Bodily Pain); GH (General Health); VT (Vitality); SF (Social Functioning) RE (Role-Emotional); and MH (Mental Health)

Fig.-1: Results of MOS SF-36 for patients compared to that of general population with definitions of 8 dominions of health concepts

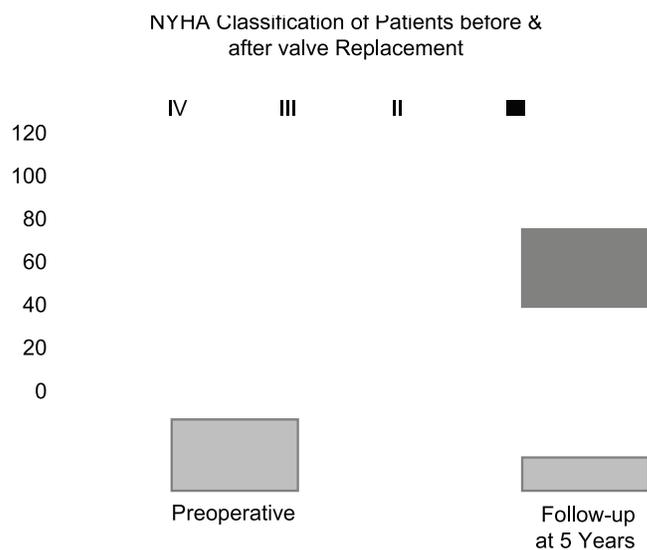


Fig.-2: NYHA classification of Patients before and after valve replacement

Appendix II*Medical Outcomes Study: 36-Item Short Form Survey Tool
RAND 36-Item Health Survey 1.0 Questionnaire Items***Questionnaire**

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
2. Compared to one year ago, how would you rate your health in general now	
Much better now than one year ago	1
Somewhat better now than one yea ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. does your health now limit you in these activities? If so, how much?

(Circle one number on each line)

	Yes, Limited a lot	Yes, Limited a little	No, not Limited at Work
3. Vigorous activities, Such as running, lifting heavy objects, participating in Strenuous Sports/exercise	1	2	3
4. Moderate activities, such as moving a table Pushing a vacuum cleaner, bowling, or playing off			
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking more than a mile	1	2	3
10. Walking Several block	1	2	3
11. Walking one block	1	2	3
12. Bathing or dressing yourself	1	2	3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number on each line)

13. Cut down the amount of time you s	1	2
14. Accomplished less than you would like	1	2
15. Were limited in the kind of work of other activities	1	2
16. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious?) (Circle one number)

	Yes	No
17. Cut down the amount of time you spent on work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as carefully as usual	1	2

20. During the past 4 weeks to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or group.

(Circle one number)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

21. How much bodily pain have you had during the past 4 weeks? (Circle one Number)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home & housework)? (Circle one number)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

These questions are about how you feel and how have been with you during the past 4 weeks. for each question, Please give the one answer that comes to the way you have been feeling. How much of the time during the past 4 weeks..... (Circle one Number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of Pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm & peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted & blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a Happy Person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the past 4 Weeks, how much of the time has your physical health or emotional Problems interfered with you social activities (like visiting with friends, relatives, etc.)?

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

function (EF<0.35) showed markedly inferior values on all eight scales.

Mental health

None of the late survivors forget their grave experience in relation to the disease process and treatment procedure. Almost all of them, especially mechanical valve recipients complained of anxiety and fear of bleeding and recurrence of their heart diseases. Although most of the late survivors were physically capable of doing physical activity. However, about 35% patients said that they were not fit for any professional activity.

Discussion:

In the present study, the functional status and the quality of life in late survivors who underwent heart valve replacement were assessed in order to identify predictors of healthy survival following surgery for major valvular malfunction. Survival rates at one and five years postoperatively were satisfactory, and there were significant improvement in NYHA functional class among long-term survivors. Moreover, the quality of life as evaluated with the MOS SF-36 survey was comparable to that is expected among general population comparable age and gender.

Almost similar 5-year survival rates of 55% to 60% have been reported by several researchers^{14,15}. Consistent with our study, Dahlberg [3] reported an equally limited 5-year survival of their patients. Again, Braum et al⁴ in their study, observed similar survival, clinical benefit and stable results after a mean follow-up of 4.3 years compared to 80% survival rate at 1 year in our patient population. Geldorp et al.¹⁶ observed 95% survival rate at 1 year. Although data on the functional outcome and the quality of life after valve replacement are Scarce. Khan et al.¹⁷ have reported a clear improvement in NYHA functional class in their cases. Krane et al [1] have observed a considerable improvement in the quality of life assessed with SF-36 questionnaire within 3 months after valve implantation. Additionally, it has been suggested that timely reconstructive surgery of diseased heart valve can benefit from superior survival and better future postoperative quality of Life². The present study identified the presence of preoperative stroke and COPD as predictors of late death. This finding, is in consistent with others¹⁸.

MOH SF-36 tool analysis clearly showed improvement in the quality of life patients in the present study

compared to that of apparently healthy general population. In some dominions, our patients showed better results. The patient, thus, can return to normal activities. maintain self esteem and keep normal relationships at work, in the community and at home. More importantly, our patients did not feel rejected by their surroundings after heart valve replacement. Mechanical valve recipients were permanently remained on their heart disease by valve sounds, blood sampling for anticoagulation control, and life-style and professional limitations, due to bleeding risks probably leading to an impaired health perception. Additionally the fear of the constant risk of bleeding and thrombolism may have a negative effect on the mental health of these patients.

Conclusion:

Successful heart valve replacement offers improved quality of life in symptomatic patients with severe stenosis. The beneficial effect is most evident in the physical components, but also general health perception, and social functioning aspects improved in long run. Preoperative health status is identified as a significant factor of potential non-improvement of quality survival following heart valve replacement.

Study limitations:

The present study was not randomized nor a prospective one. Additionally, there was no information of quality of life using SF-36 form before the valve replacement.

Conflict of Interest - None.

Acknowledgement:

Ministry of Science & Technology of Bangladesh has partly financed for this research work. I give thanks to our Ministry of Science and Technology for their support.

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