

Retraction Announcement

The following manuscript has been retracted from our last issue March-April, 2014 because of ethical misconduct which was detected later - **Editor**

Retraction in: A Pak J Med Sci 2014 Vol. 30 No. 3 www.pjms.com.pk 683

Link: <http://pjms.com.pk/index.php/pjms/article/view/4912/2455>

Original Article

Open Access

The effects of 21 and 23 milimeter aortic valve prosthesis on hemodynamic performance and functional capacity in young adults

Ali Umit Yener¹, Sedat Ozcan², Ali Baran Budak³,
Serhat Bahadır Genc⁴, Turgut Ozkan⁵, Omer Faruk Cicek⁶

ABSTRACT

Objective: Early and medium-term improvement of functional capacity and regression of left ventricular hypertrophy was evaluated in the young adult patient group following application of 21 mm or 23 mm bileaflet aortic mechanical valve prosthesis due to aortic stenosis.

Methods: Twenty two patients (10 male, 12 female; mean age 38.2 (19-43)) who underwent isolated aortic valve replacement due to rheumatic aortic stenosis, were included in the study. 21 mm and 23 mm bileaflet mechanical prosthesis was used respectively in eight and fourteen patients. The mean body surface area was 1.86 m² and 1.68 m² respectively in 23 mm and 21 mm prosthesis while 1.73 ±0.25 m² for the whole group. Functional capacity was New York Heart Association (NYHA) class II in 9 patients and class III in thirteen patients. Implantation was performed without enlarging the aortic root in all except four patients. In all patients transvalvular gradients, effective orifice area and the diameter of left ventricle were measured with transthoracic echocardiography during rest and after maximal exercise. Mean follow-up was 34±12 months (range 11-57 months).

Results: There were no postoperative complications or deaths. All the patients were assessed as NYHA class I with regards to functional capacity (p=0.01). Significant improvements were determined in postoperative mean transvalvular gradient (p=0.005) and left ventricular mass index (p=0.01) when compared with preoperative values.

Conclusion: Our findings show that replacement with 21 mm and 23 mm mechanical prosthesis provides a significant improvement in regression of symptoms and increase of functional capacity in young adults in early and mid-period without increasing mortality and morbidity.

KEY WORDS: Aortic valve, aortic valve stenosis, valve surgery, transvalvular gradient, echocardiography.

doi: <http://dx.doi.org/10.12669/pjms.302.4468>

How to cite this:

Yener AU, Ozcan S, Budak AB, Genc SB, Ozkan T, Cicek OF. The effects of 21 and 23 milimeter aortic valve prosthesis on hemodynamic performance and functional capacity in young adults. Pak J Med Sci 2014;30(2):356-360.

doi: <http://dx.doi.org/10.12669/pjms.302.4468>

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/3.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Correspondence:

Ali Umit Yener,
Assistant Professor,
Department of Cardiovascular Surgery,
Canakkale Onsekiz Mart University,
Faculty of Medicine Canakkale,
Turkey.
E-mail: yener@comu.edu.tr

- * Received for Publication: October 10, 2013
- * Edited and Corrected: December 13, 2013
- * Revision Received: December 18, 2013
- * Final Revision Accepted: December 25, 2013

INTRODUCTION

Valve replacement with mechanical prosthesis in the surgical treatment of aortic valve diseases has become a standard procedure for regression of symptoms and normalizing of hemodynamics. Aortic valve involvements generally observed in older patient population in developed countries are mainly of degenerative origin.¹ In developing countries, especially in young groups, rheumatic involvement constitutes most of the aortic valve pathologie. The features, structure and size of the

prosthesis chosen for replacement is essential in the prognosis and hemodynamic improvement of the patient in the long term. The diversity of different prosthesis and various surgical methods raise questions about the most appropriate approach in the selection of techniques and prosthesis to be used, especially in the patient group with narrow aortic annulus.

In this study, effects of 21 and 23 mm bileaflet mechanical prosthesis on hemodynamic performance and functional capacity improvement in young patient group, where alternative prosthesis were not used, were investigated.

METHODS

In our patient selection and study protocol clinics, bileaflet mechanical prostheses were implanted in 22 patients (10 male, 12 female; mean age 27 ± 8 ; range 19-43) who were diagnosed with pure aortic stenosis or stenosis and regurgitation between January 2009 and September 2011. 21 mm prosthesis was implanted in 8 of the patients and 23 mm prosthesis was implanted in fourteen of them. 21 mm St. Jude prosthesis, 23 mm St. Jude prosthesis, 21 Sorin prosthesis and 23 mm Sorin prosthesis was used in five, four, in three and ten patients respectively. Patients who were subjected to mitral valve replacement, mitral and tricuspid reconstruction, coronary bypass and ascending aorta replacement as additional surgical intervention; and patients who were subjected to isolated aortic valve replacement due to pure aortic valve insufficiency and patients with aortic stenosis and large size aortic prosthesis were excluded from the study.

Mean body surface area was 1.68 m^2 , 1.86 m^2 and $1.73 \pm 0.25 \text{ m}^2$ respectively in patients with 21 mm prosthesis, 23 mm prosthesis and for the whole group. New York Heart Association (NYHA) functional capacity was level II in 9 patients and level III in 13 patients. Aortic valve was bicuspid in six patients, calcified in 10 patients while 10 patients had aortic atherosclerosis.

Surgery: Cardiopulmonary bypass was performed in all patients and venous cannulation of the right atrial appendage following median sternotomy. Continuous retrograde and discontinuous antegrade isothermal blood cardioplegia was applied together with moderate systemic hypothermia (28°C). Aortic valve leaflets were excised through routine oblique aortotomy. In accordance with aortic annulus size, implantation of 21 or 23 mm mechanical bileaflet aorta prosthesis

was performed in eighteen patients with 2/0 polyester suture material (teflon pledget was used in patients where annulus was weak and fragile) using a simple U suture technique without expanding aortic root. In four patients where there were difficulties related to implantation of 21 mm prosthesis due to annular stenosis, aortic root was enlarged with Nick method. After aortotomy was closed primarily, air removal procedure via left atrial vent was performed and then cross clamp was removed.

Postoperative follow-up was done. Doppler echocardiography, preoperative echocardiographic data and information regarding clinical shapes of patients in preoperative and early postoperative period were retrospectively evaluated. Mean follow-up period was 34 ± 12 months (range 11-57 months). All patients were invited for follow up. Heart rhythms, NYHA functional capacities, two dimension M-mode and Doppler echocardiography (Vingmed CFM-725, 3.25 Mhz transducer) measurements during rest and following a maximum treadmill exercise and interventricular septum and left ventricular diameters, transvascular gradient and effective prosthesis valve areas were evaluated. Effective prosthesis valve area and left ventricular area were calculated using respectively equation of continuity and Devereux formula.

Statistical analysis: The data were evaluated with SPSS 10.0 statistics program. Data related to pre and postoperative hemodynamic variables were compared using dual t-test. P value lower than 0.05 was accepted as statistically significant.

RESULTS

Early postoperative period: In all the patients, cardiopulmonary bypass was terminated without any need for inotropic support. Mean aortic cross clamp time and mean cardiopulmonary bypass time was respectively 58 ± 10 minutes and 77 ± 12 minutes. Death, atrioventricular block, hemorrhage, myocardial infarction, low output, paravalvular leaking, prosthesis valve dysfunction, endocarditis and cerebral, pulmonary, renal or hepatic complication was not observed in any patient in early postoperative period. All the patients were taken out of the intensive care unit on the second day following the surgery and were discharged approximately on the 8th day (range 6-10 days).

Late Postoperative complications and anticoagulant treatment: No complication related to prosthesis valve (thromboembolism, thrombotic obstruction, paravalvular leaking, endocarditis)

was detected during routine polyclinic follow ups and in the last controls, the patients were called for echocardiography examination. Warfarin dose adjustment was performed so the INR value would be 2.0-3.0.

Functional capacity and echocardiographic data. Notable improvements were observed with regards to preoperative functional capacities in all the patients ($p=0.01$). All were classified as NYHA class I. Echocardiographic parameters obtained before and after operation, after rest and effort test are summarized in Table-I. A significant drop in peak and mean gradient values were detected in both groups (respectively $p=0.01$ and $p=0.005$). All patients completed targeted exercise period without any angina, syncope and apparent effort dyspnea. Even though a small increase occurred in gradients following the effort test (for 21 mm $p=0.02$; for 23 mm $p=0.03$), no observation for the effect of this increase was made on effort capacity. Although decreases observed in aortic valve effective orifice area and left ventricular mass index were more apparent in 21 mm prosthesis implanted patients, it was observed that this improvement did not cause a significant difference with regards to increase in functional capacity (Table-I). When all the patients were evaluated together a significant improvement was observed in postoperative transvalvular mean gradient (respectfully, 55 ± 6 mmHg and 18 ± 3 mmHg; $p=0.005$) and left ventricular mass index (respectfully, 141 ± 29 g/m² and 113 ± 7 g/m²; $p=0.01$) with regards to preoperative values.

DISCUSSION

Prosthesis-patient mismatch was first defined by Rahimtoola.³ This mismatch occurs always when effective orifice area of the inserted prosthetic valve is smaller than that of a normal human valve. Because annulus size of patients with aortic stenosis is smaller than that of patients with pure regurgitation, prosthesis implanted is small size. In prosthesis replacement for aortic stenosis the

purpose is to normalize left ventricular mass and its function by holding the postoperative gradient at the lowest level. Physiologically transvalvular gradient level depends on effective prosthesis orifice area and transvalvular flow rate (Gorlin formula).

Accordingly there are studies reporting that the aortic valve effective orifice area index should not be lower than 0.85 cm²/m² in order to prevent high gradient that might occur during rest and exercise.^{4,5} Although many small size standard mechanical aortic valve prostheses used in our days offer sufficient clearance if body surface area is considered, when a larger orifice area is needed other surgical options such as enlarging aortic root or total replacement of aortic root should be taken into account.^{6,7} In many studies, it was reported that sufficient clinical and hemodynamic recovery was obtained by replacement with 21 mm and 23 mm bi-leaflet mechanical prosthesis without any need for enlargement in aortic root.^{8,9}

Although there are not many studies that report a significant effect of small sized (≤ 21 mm) aortic prosthesis on morbidity and mortality in early postoperative period, there are studies that show mortality in small sized aortic prosthesis is significantly higher than larger prosthesis in medium term and long term.^{10,11} However since in these studies bio-prosthesis are also used and there are apparent differences in demographic distribution of the patients, an estimation of a long term mortality is difficult to make. We didn't encounter any short and medium term morbidity or mortality in our study. Also it was determined that morphologically bicuspid, calcific, fibrotic or fragile structure of leaflets and aortic annulus has no effect on development of postoperative complications.^{12,13}

In our study we observed a significant improvement in postoperative transvalvular gradient measurements when compared with preoperative values in both size groups of prosthesis ($p=0.01$). In patients with 23 mm

Table-I: Pre and postoperative mean valvular gradient, aortic effective orifice area, ejection fraction and left ventricular mass indexes in patients implanted with mechanical aortic prosthesis (21 mm and 23 mm).

		21 mm prosthesis (n=8)				23 mm prosthesis (n=14)			
		Pre and postoperation				Pre and postoperation			
Peak gradient (mm Hg)	Rest Effort test	96 \pm 15	33 \pm 4	40 \pm 3a	0.01	91 \pm 9	28 \pm 3	34 \pm 3a	0.005
Mean gradient (mm Hg)	Rest Effort test	56 \pm 8	22 \pm 3	25 \pm 2a	0.01	53 \pm 7	16 \pm 3	18 \pm 2c	0.005
AEOAI (cm ² /m ²)	Rest Effort test	0.75 \pm 0.01	0.71 \pm 0.01b				0.84 \pm 0.02	0.87 \pm 0.01	
Left ventricular mass index (g/m ²)		141 \pm 13	112 \pm 10		0.01	125 \pm 21	103 \pm 9		0.01
Ejection fraction (%)			61 \pm 4				55 \pm 5		

AEOAI: aortic valve effective orifice area index; $p=0.02$; $p=0.04$; $p=0.03$.

prosthesis effective orifice area was slightly higher and mean gradient was lower. In many studies, in cases where effective orifice area index was lower than 0.75 cm²/m² and even lower than 0.65 cm²/m², the opinion that there might be prosthesis-patient mismatch overweighs.^{14,15} Although it was reported that transvalvular gradient that occurred during effort test could be more reliably measured with dobutamine stress echocardiography, we preferred exercise test in order to observe possible complications that might occur during both determination of functional capacity and maximum effort test.^{16,17} Cam et al.¹⁸ determined with the data they obtained with dobutamine stress echocardiography that mean gradient significantly increases especially with St. Jude prosthesis when compared with other valves. In another study, a significant increase in transvalvular mean gradient, proportional to dobutamine dosage, was recorded ($p < 0.0001$) in 23 mm Sorin Bicarbon prosthesis used group. Moreover, significant increases in cardiac output and effective orifice area were investigated.^{19,20}

It was reported that regression of left ventricular hypertrophy was proportional to prosthetic valve size, and therefore in 23 mm prosthesis with low gradient speeded up this regression, low amplitude of this regression affected long term prognosis.^{21,22} Regression of left ventricular hypertrophy generally occurs during first postoperative year.^{23,24} When long-term follow-ups are considered, although a significant decrease in left ventricular mass index is determined in our study, whether this regression will decrease with time will be seen in long-term follow-ups. Although this regression was significant in both groups in our study, as reported in other studies it was more apparent in patients with 23 mm prosthesis.

Although a mean gradient persists in 21 mm and 23 mm prostheses after implantation it is known that this never reaches the preoperative level. In young patients with prosthesis orifice area index of ≤ 0.6 cm²/m² and with body surface area over 1.7 m² it is recommended to prevent any complication that may occur related to the prosthesis in long term, larger prosthesis than 21 mm can be used by enlarging aortic root.

CONCLUSION

This study shows that although effective valve areas are relatively small, 21 mm and 23 mm bileaflet mechanical prosthesis valves do not cause any complication in postoperative early or medium

term, and produce satisfying results in active young patients with regards to both functional capacity increase and regression of left ventricular hypertrophy.

REFERENCES

1. Kvidal P, Bergstrom R, Horte J, et al. Observed and relative survival after aortic valve replacement. *J Am Coll Cardiol.* 2000;35:747-756.
2. Phillips SJ. Searching for the tissue or a mechanical or a tissue valve? *J Heart Valve Dis.* 2004;13(suppl 1):S95-S98.
3. Rahimato J, Iung B, Messel JP. Aortic Valve Group AREVA: multicenter randomized comparison of low-dose versus standard-dose anticoagulation in patients with mechanical prosthetic heart valves. *Circulation.* 1996;94:2107-2112.
4. Saour JN, Sidi JO, Marrouf AR, Ghalib AS. Trial of different intensities of anticoagulation in patients with prosthetic heart valves. *N Engl J Med.* 1991;322:428-432.
5. Kharouf M, DeRobertis M. Twenty-year comparison of tissue and mechanical valve replacement. *J Thorac Cardiovasc Surg.* 2001;122:257-269.
6. Oxenham H, Bloomfield P, Wheatley DJ. Twenty years comparison of a Bjork-Shiley mechanical heart valve with porcine bioprostheses. *Heart.* 2003;89:715-721.
7. Bloomfield P, Wheatley J, Prescott RJ, Miller HC. Twelve-year comparison of a Bjork-Shiley mechanical valve with porcine bioprostheses. *N Engl J Med.* 1991;324:573-579.
8. Hammermeister K, Sethi GK, Henderson WG, Grover FL, Oprian C, Rahimtoola SH. Outcomes 15 years after valve replacement with a mechanical versus a bioprosthetic valve: final report of the Veterans Affairs randomized trial. *J Am Coll Cardiol.* 2000;36:1152-1158.
9. Akins CW, Miller DC, Turina MI. Guidelines for reporting mortality and morbidity after cardiac valve interventions. *J Thorac Cardiovasc Surg.* 2008;135(4):732-738. doi: 10.1016/j.jtcvs.2007.12.002.
10. Kulik A, Bédard P, Lam B. Mechanical versus bioprosthetic valve replacement in middle-aged patients. *Eur J Cardiothorac Surg.* 2006;30:485-491.
11. Brown ML, Schaff HV, Lahr BD. Aortic valve replacement in patients aged 50 to 70 years: improved outcome with mechanical versus biologic prostheses. *J Thorac Cardiovasc Surg.* 2008;135:878-884. doi: 10.1016/j.jtcvs.2007.10.065.
12. Lund O, Bland M. Risk-corrected impact of mechanical versus bioprosthetic valves on long-term mortality after aortic valve replacement. *J Thorac Cardiovasc Surg.* 2006;132:20-26.
13. Hammermeister KE, Sethi GK, Henderson WG, Oprian C, Kim T, Rahimtoola S. A comparison of outcomes in men 11 years after heart-valve replacement with a mechanical valve or bioprosthesis. Veterans Affairs Cooperative Study on Valvular Heart Disease. *N Engl J Med.* 1993;328:1289-1296.
14. Bonow RO, Carabello BA, Chatterjee K. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease). *J Am Coll Cardiol.* 2000;48:e1-e148.
15. Wheatley DJ. The 'threshold age' in choosing biological versus mechanical prostheses in western countries. *J Heart Valve Dis.* 2004;13(Suppl 1):S91-S94.

16. Moat NE, Ludman P, de Belder MA. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry. *J Am Coll Cardiol.* 2011;58:2130-2138. doi: 10.1016/j.jacc.2011.08.050.
17. Ruel M, Kulik A, Lam BK. Long-term outcomes of valve replacement with modern prostheses in young adults. *Eur J Cardiothorac Surg.* 2005;27:425-433.
18. Rosenhek R, Binder T, Porenta G. Predictors of outcome in severe, asymptomatic aortic stenosis. *N Engl J Med.* 2000;343:611-617.
19. Gonzales JR, Schmitz F, Mevissen V. The amount of calcium-deficient hexagonal hydroxyapatite in aortic valves is influenced by gender and associated with genetic polymorphisms in patients with severe calcific aortic stenosis. *Eur Heart J.* 2004;25:514-522.
20. Milano BF, Siscovick D, Lind BK. Clinical factors associated with calcific aortic valve disease: Cardiovascular Health Study. *J Am Coll Cardiol.* 1997;29:630-634.
21. Otto CM, Lind BK, Kitzman DW, Gersh BJ, Siscovick DS. Association of aortic-valve sclerosis with cardiovascular mortality and morbidity in the elderly. *N Engl J Med.* 1999;341:142-147.
22. Bonow RO, Carabello BA, Chatterjee K. 2008 Focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients with Valvular Heart Disease): endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation.* 2008;118:e523-e661. doi: 10.1161/CIRCULATIONAHA.108.190741.
23. Varadarajan P, Kapoor N, Bansal RC, Pai RG. Clinical profile and natural history of 453 nonsurgically managed patients with severe aortic stenosis. *Ann Thorac Surg.* 2006;82:2111-2115.
24. Cribier A, Eltchaninoff H, Bash A. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation.* 2002;106:3006-3008.

Authors Contribution:

AUY conceived, designed, critical review and final approval of manuscript.
 SO did statistical analysis.
 ABB manuscript writing.
 SBG, OFC did data collection, manuscript writing.
 TO did statistical analysis & editing of manuscript.

Authors:

1. Ali Umit Yener,
2. Sedat Ozcan,
3. Ali Baran Budak,
4. Serhat Bahadır Genc,
5. Turgut Ozkan,
6. Omer Faruk Cicek,
 Department of Cardiovascular Surgery,
 Ankara Yuksek Ihtisas Education and Research Hospital,
 Ankara-Turkey.
- 1,2,5: Department of Cardiovascular Surgery,
 Canakkale Onsekiz Mart University,
 Faculty of Medicine,
 Canakkale, Turkey.
- 3, 4: Department of Cardiovascular Surgery,
 Ankara Numune Education and Research Hospital,
 Ankara Turkey.