e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(10); 461-464

Original Research Article

The outcome of New Miltonia Mechanical Bileaflet Valve Implantation in Severe Mitral Stenosis: A Case Series of Rheumatic Heart Disease

Krishnakant Sahu[1], Nishant Chandel[2], Namita Shrivastava[3]

[1,2]Department of Cardiovascular and Thoracic Surgery, Pt JNM Medical College, Raipur
[3]Department of Physiology, Pt JNM Medical College, Raipur

Received: 25-07-2024 / Revised: 23-08-2024 / Accepted: 26-09-2024
Corresponding Author: Dr. Krishnakant Sahu
Conflict of interest: Nil

Abstract:

The most common heart valve affected by rheumatic heart disease (RHD) is the Mitral Valve. The bileaflet mechanical heart valves have demonstrated their superiority over previous designs in surgical management of RHD. It is better in terms of lower transvalvular gradients, a more physiologic flow pattern distribution, and, possibly, a lower thrombogenic potential. In 2018, the new MILTONIA mechanical bileaflet valve manufactured by Meril Life Sciences Pvt. Ltd. was approved for clinical use by the Indian authorities. The main advantage of this model over other leaflet models was the possibility of rotation once implanted, utilizing a new sewing ring design. We have performed mitral valve replacement in three continuous cases of RHD induced severe mitral valve stenosis using the MILTONIA mechanical bileaflet valve. The results of the procedure have been very satisfactory with none of the patients showing any valve-related complications like thrombosis, endocarditis and anticoagulation-related bleeding in a follow up period of 3 years. The authors believe that the use of the Miltonia valve is very safe and effective. A study with a larger patient population and longer follow-up is warranted to assess the device further.

Introduction

The most common heart valve affected by rheumatic heart disease (RHD) is the Mitral Valve. [1] Management of advanced RHD involves one or a combination of medical management and surgical and non-surgical interventions, with surgical procedures being valve repair, open valvuloplasty, or replacement. In India, even younger patients require surgical valve replacement due to severe RHD [3]. However, not all valves are suitable for repair, and repaired valves may be associated with an increased need for early reoperation [2]. Prosthetic valves can be mechanical or bioprosthetic. During the last 16 years, the bileaflet mechanical heart valves have demonstrated their superiority over previous designs. It is better in terms of lower transvalvular gradients, a more physiologic flow pattern distribution, and, possibly, a lower thrombogenic potential. [4]

In 2018, the new MILTONIA mechanical bileaflet valve manufactured by Meril Life Sciences Pvt. Ltd. was approved for clinical use by the Indian authorities. The main advantage of this model over other leaflet models was the possibility of rotation once implanted, utilizing a new sewing ring design. We performed the successful implantation of the new MILTONIA mechanical bileaflet valves in three cases. Herein, we are reporting our experience regarding the short-term performance of this valve in three patients.

Case 1

A 65-year-old male patient, a known smoker with a past medical history of cough, fever, chest pain, complained of dyspnea (NYHA CLASS II), and associated with palpitations for one month came to Department of Cardiovascular and thoracic surgery, Pt JNM Medical College, Raipur. His heart rate was 90 beats /minute, and his blood pressure was 130/80mm/Hg. On clinical examination, Mitral's first heart sound was slightly accentuated, but the pulmonic sound was typical. Grade–II diastolic murmur was heard over the mitral area opening snap was absent. Lungs were clear, and the chest radiograph showed slight cardiomegaly.

All baseline preoperative laboratory investigations were within normal limits except his serum creatinine was 2.1mg/dl. USG abdomen was suggestive of bilateral renal parenchymal disease with chronic kidney disease (Stage I). Pre-operative electrocardiography revealed atrial fibrillation with Controlled heart rate. His preoperative echocardiography findings were severe Mitral stenosis (MVA 0.75cm$^{2)}$ with a peak gradient of 19 mm/Hg and a mean gradient of 13 mm/Hg. The left

ventricular ejection fraction was 71.7%. The coronary angiography finding was normal coronaries. She was planned for Mitral valve replacement with Miltonia bi leaflet mechanical prosthesis.

He was planned for Mitral valve replacement with a new Miltonia mechanical mitral valve prosthesis. He underwent mitral valve replacement under general anaesthesia. Midline sternotomy was performed and CPB was established with bi caval venous drainage cannula and aortic return was maintained with central aortic cannulation.

Topical cooling along with mild hypothermia was achieved up to 32 ^{0}C. Cross clamp was applied, and cardioplegic arrest was accomplished with antegrade cold del Nido cardioplegia. The left atrium opened, and after proper assessment of the Mitral Valve, the diseased mitral Valve was excised, and a 29 mm-sized Miltonia mechanical mitral valve was implanted with a Semi-continuous technique considering Posterior mitral leaflet preservation. The Patient was weaned off CPB support without any ionotropic support and shifted to post-operative recovery after completion of surgery. The post-operative period was uneventful. His post-operative serum creatinine was 2.3 and it remained stable throughout his recovery time. Post-operative Echocardiography revealed normal functioning mitral valve prosthesis with no paravalvular leak. Prosthetic mitral valve PHT was 51 milliseconds. The peak gradient across the prosthetic Valve was 12 mm/Hg, and the mean gradient was 4 mm/Hg. The Patient was discharged on the 7th postoperative day. He is doing good in his 6-month follow-up on oral anticoagulation with a target INR of 2.5 to 3.5.

Case 2

A 32-year-old female who complained of dyspnea (NYHA CLASS III) and was associated with palpitations for three years, came to our hospital. She had already a diagnosed case of Rheumatic heart disease with severe Mitral stenosis in another hospital. She was referred for mitral valve replacement. Her heart rate was 70 beats /minute, and her blood pressure was 114/80mm/Hg. A Grade –-II mid-diastolic murmur with presystolic accentuation was heard over the mitral area on clinical examination. Bilateral lung fields were clear, and the chest radiograph showed increased bronchovascular marking with left atrial enlargement. All findings were within the standard limit on Laboratory investigation, except she is suffering from sickle cell trait disease.

The Echocardiography showed the stenotic mitral valve with an orifice area of 0.84cm^2. The Peak gradient and mean gradient across the mitral Valve are 22mm/Hg and 14 mm/Hg, respectively. The left ventricular ejection fraction was 68.7%. She underwent mitral valve replacement under general anaesthesia. After median sternotomy, CPB was established as per the conventional procedure. The cross-clamp was applied, and cardioplegic arrest was accomplished with warm St. Thomas blood cardioplegia under normothermia. The left atrium was opened, and the diseased mitral Valve was excised and replaced with a Miltonia 27 mm sized bi-leaflet mechanical valve along with posterior mitral leaflet and total Chordal preservation. The Patient was weaned off CPB support without ionotropic support and shifted to post-operative recovery after completion of surgery. Fast-track extubation was performed.

Post-operative 2-D Echocardiography showed normal functioning mitral valve prosthesis with a peak gradient across mitral valve prosthesis was 9mm/Hg and a mean gradient was 4mm/Hg. The post-operative period was uneventful, and the Patient was discharged on the 5th postoperative day. She is doing good in her 6-month follow-up on oral anticoagulation with a target INR of 2.5 to 3.5.

Case 3

Forty-five-year-old female complained of dyspnea which aggravated on exertion (NYHA CLASS III) admitted to our hospital. She had a history of hypothyroidism on regular medication. Electrocardiography revealed atrial fibrillation. 2-D echocardiography impression was rheumatic heart disease and severe mitral stenosis. The mitral valve area was 0.87 cm^2. Heavy specks of calcium were present on the thickened Posterior mitral leaflet and anterior mitral leaflet tip along with sub-valvular crowding. The peak gradient across the mitral Valve was 33 mm/Hg, and the mean gradient was 23 mm/Hg. The left ventricular ejection fraction was 52.5%. The coronary angiography did not reveal any coronary artery obstructions. She was planned for Mitral valve replacement with Miltonia bi-leaflet mechanical prosthesis.

She underwent minimally invasive mitral valve replacement under general anaesthesia. A small right anterolateral thoracotomy was performed, CPB was established through the femoral and internal jugular vein, and aortic return was maintained with femoral arterial cannulation. Topical cooling along with mild hypothermia was achieved up to 32 ^{0}C. Cross clamp was applied, and cardioplegic arrest was accomplished with antegrade cold del Nido cardioplegia.

The left atrium was opened, and after proper assessment of the Mitral Valve, the diseased mitral Valve was excised implantation of a Miltonia 29 mm sized mechanical bileaftlet mitral valve with an interrupted suturing technique. The Patient was weaned off CPB support without any complications and shifted to post-operative recovery after completion of surgery. Post-operative 2-D

echocardiography impression was normal functioning mitral valve prosthesis, peak gradient across mitral valve prosthesis was 12mm/Hg, and the mean gradient was 4mm/Hg. She was discharged on 5 th postoperative day. She is doing good in her six-monthly follow-up on oral anticoagulation with a target INR of 2.5 to 3.5.

Discussion

A valve design based on two occluders, as opposed to a single occluder, should provide, in theory, at least, more excellent functional safety. However, it entails the use of a double hinge mechanism. Clinical experience with the St. Jude Medical valve (St. Jude Medical Inc., St. Paul, Minn.) has shown a low rate of structural failure and thrombotic complications. [5,6,7,8]

No case report is available to implant this new Miltonia mechanical bi-leaflet valve in the literature. MILTONIA mechanical leaflet valve is manufactured by Meril Life Science Pvt. In 2018, the Indian authorities approved the use of the product for clinical use. Ltd. Its main advantage over other leaflet models was the possibility of rotation once implanted, utilizing a new sewing ring design.

The MILTONIA Mechanical Bi-Leaflet Heart Valve consists of an orifice ring and two mirror-image leaflets (Figure 1). The leaflets are made up of pyrolytic carbon coated over graphite. Radiopacity is achieved by impregnating the graphite substrate with tungsten. Pyrolytic carbon comprises the entire orifice ring. Each leaflet's plane forms a nominal angle of 85° with respect to the orifice ring's plane when fully open.

Double velour polyester fabric is used for the valve sewing ring. The titanium stiffening ring is mounted on the orifice ring and secured with a lock wire and two titanium lock rings. In situ rotation of the sewing ring is possible with this sewing cuff attachment. To assist with the uniform placement of sutures around the valve annulus, four markers are located in the mitral sewing ring. Through its open-pivot design, the device ensures sufficient blood washing to reduce thrombosis risks. To minimize damage to blood cells, this design reduces shear stress on the cells.

In addition, the open hing mechanism drastically reduces the noise of the valve movement, thereby improving the quality of the Patient's and their family life. The effective orifice area (EOA) of the Miltonia valve is larger, size-for-size, than other Valves on the market and virtually eliminates patient-prosthesis mismatch (PPM). Considerably larger EOAs and excellent patient prosthesis match result in a valve with exceptional hemodynamic performance. In the present study, patients were evaluated for valve-related mortality, valve thrombosis, thromboembolism, endocarditis, bleeding events, or reoperation at 06-month follow-up in three different subsets of patients. In case 1, we have performed standard mitral valve replacement in severe mitral valve stenosis with stage I chronic kidney disease patients. We showed no adverse events even after six months of use. The Patient was free from valve-related complications like thrombosis, endocarditis anticoagulation-related bleeding. The Patient is showing significant improvement in NYHA classification. A significant change in gradient across the valve was noted compared to its preoperative status. The author did not find any difficulty during its implantation or handling.

In Case 2, a Patient with mitral valve stenosis, with sickle cell anemia can be safely operated with the implantation of a Miltonia bi leaflet mechanical valve. We have used the normothermic CPB approach to avoid any sickling-related complications. No adverse event was noted in her post-operative and follow-up period with significant improvement in functional class.

In case 3, we have performed minimally invasive Mitral valve replacement without any difficulty with the use of the Miltonia valve. This also shows a significant decrease in gradient across the valve with improvement in the functional class of the patient.

Conclusion

The author believes that the use of the Miltonia valve is very safe and effective. The clinical safety and performance of the Miltonia mechanical bileaflet Mitral valve prosthesis were favourable at three years. Moreover, a study with a larger patient population and longer follow-up is warranted to assess the device further.

References

1. Russell EA, Walsh WF, Reid CM, et al. Outcomes after mitral valve surgery for rheumatic heart disease. Heart Asia. 2017; 9(2):e010916. Published 2017 Jun 19. doi: 10.1136/heartasia-2017-010916
2. Bakir I, Onan B, Onan IS, et al. Is rheumatic mitral valve repair still a feasible alternative?: indications, technique, and results. Tex Heart I J 2013; 40:163–9.
3. Talwar S, Sharma AK, Kumar AS. Tissue heart valve implantation in India; indications, results and impact on quality of life. Indian J Thorac Cardiovasc Surg. 2008; 24:10–4
4. Schoen FJ. Valvular heart disease: cardiac valve replacement. In: Schoen FJ, ed. Interventional and surgical cardiovascular pathology: clinical correlations and basic principles. Philadelphia: WB Saunders, 1989:109-71.
5. Duncan JM, Cooley DA, Reul GJ, et al. Durability and low thrombogenicity of the St. Jude

Medical valve at 5-year follow-up. Ann Thorac Surg 1986; 42:500-5.
6. Kratz JM, Crawford FA, Sade RM, Crumbley A J, Stroud MR. St. Jude prosthesis for aortic and mitral valve replacement: a ten-year experience. Ann Thorac Surg 1993; 56:462-8.
7. Khan S, Chaux A, Matloff J, et al. The St. Jude Medical valve: experience with 1000 cases. J Thorac Cardiovasc Surg 1994; 108:1010-20.
8. Aoyagi S, Oryoji A, Nishi Y, Tanaka K, Kosuga K, Oishi K. Long-term results of valve replacement with the St. Jude Medical valve. J Thorac Cardiovasc Surg 1994; 108:1021-9.