Minimally Invasive Aortic Valve Surgery (MIAVR) Using St. Jude Medical Trifecta Aortic Bioprosthesis – An Assessment of Midterm Haemodynamic Function

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BACKGROUND
The St. Jude Medical Trifecta aortic valve represents the next generation of supra-annular bioprostheses.

OBJECTIVE
The objective of this prospective, single-center, observational study was to evaluate the midterm hemodynamic performance of the Trifecta aortic valve bioprosthesis following implantation using a minimally invasive approach.

METHODS
- A consecutive series of patients undergoing aortic valve replacement with the Trifecta bioprosthesis using MIAVR (J sternotomy) were included in the study.

RESULTS
A total of 99 consecutive patients with a mean age of 73.2 ± 5.7 years underwent aortic valve replacement with the Trifecta valve.

- The mean post-operative pressure gradients are shown in Graph 1.
- All valves were well seated on echocardiographic assessment.
- There was one case each of mild to moderate and moderate to severe paravalvular leak. A total of 14 patients experienced trivial regurgitation.

SUMMARY OF KEY FINDINGS
- The Trifecta valve demonstrated excellent hemodynamic performance in the 19, 21, 23, 25 and 27 mm sizes when implanted using a minimally invasive approach.
- Post-operative mean gradients were in the single digits for all valve sizes in the study.

CONCLUSION
Results of early experience indicate that the hemodynamic performance of the Trifecta valve compares favorably to that of other currently available supra-annular aortic bioprostheses.
REFERENCE


Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Trifecta Valve is indicated as a replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic heart valve. Adverse events potentially associated with the use of bioprosthetic heart valves include: angina, cardiac arrhythmias, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, leak (transvalvular or perivalvular), myocardial infarction, nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other), prosthesis regurgitation, stroke, structural deterioration (calcification, leaflet tear, perforation, or other), thromboembolism and valve thrombosis. It is possible that these complications could lead to reoperation, explantation, permanent disability or death. Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism. Please see the Instructions for Use (IFU) for a full description of indications, contraindications, side effects, precautions, warnings and Instructions for Use.

Product referenced is approved for CE Mark.

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