On-X vs. SJM Bileaflet Mechanical Valve In Mitral Position: Early Postoperative Hemodynamic Function And Clinical Events

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Abstract

Objective: To compare the early postoperative hemodynamic function and major clinical events in patients receiving SJM valve & On-X valve in mitral position.

Methods: A prospective, controlled, randomized comparative study incuded 60 patients who were scheduled for elective MVR. Patients were grouped into **Group A** (n= 30) received On-X mechanical valve and **Group B** (n=30) received SJM mecahanical valve. Preoperative, intraoperative, and postoperative data were collected, analyzed and compared between the two groups. Echocardiographic and clinical assessments were performed in the immediate postoperative period and at 6 months.

Results: There were no hospital mortalities in either group; preoperative data were similar in both groups. There was no statistical significance (P>0.05) between the two groups regarding aortic cross clamp time, total bypass time, need for inotropic support, duration of mechanical ventilation, ICU stay or total hospital stay. As regards the postoperative complications; there were 6 patients (20%) in group A (2 re-exploration for bleeding 6.7%, 2 rhythm disturbance 6.7%, 2 wound infection 6.7%), compared to 5 patients (16.7%) in group b (2 re-exploration for bleeding 6.7%, 1 rhythm disturbance 3.3%, 1 wound infection 3.3%,1 bleeding event 3.3%). In 6-month follow-up there was no statistical significance regarding PPG and MPG, in group A (10.1±1.3 and 5.0±0.7 respectively) and in group B (10.2±2.3 and 5.2±1.3 respectively). Effective orifice area (EOA) was in group A (2.0±0.3) and (1.9±0.2) in group B. Nevertheless, indexed EOA was significantly higher in group A (1.1±0.1) than in group B (1.0±0.1) (*P* value 0.034). MV EOA in group A was (1.79±0.28, 2.05±0.30 and 2.37±0.26) for (25, 27/29, 31/33) valve sizes, respectively. It was higher than group B (1.53±0.13, 1.92±0.24, 2.13±0.25 and 2.05±0.16) for (25, 27, 29, and 31) valve sizes, respectively. In group A, 13 patients (43.3%) had no PPM, 16 (53.3%) had moderate PPM while only one (3.3%) had severe PPM, that was lower than in group B, 9 patients (30.0%) had no PPM, 20 (66.7%) had moderate PPM and only one (3.3%) had severe PPM.

Conclusion: On-X mitral valve has comparable results with St.Jude mitral valve regarding hemodynamic function and early postoperative complications, with slightly higher EOA especially in small valve sizes and lower incidence of PPM.

Keywords: Valve surgery, Bileaflet mechanical valve, On-X valve, St.Jude valve, early results

Table Of Contents

List Of Tables

List Of Figures

List Of Abbreviations

ABG	Arterial Blood Gases
ACT	Activated Clotting Time
AF	Atrial Fibrillation
AML	Anterior Mitral Leaflet
AV	Atrioventricular
BSA	Body Surface Area
CAD	Coronary Artery Disease
CBC	Complete Blood Count
CPB	Cardiopulmonary Bypass
CT	Computerized Tomography
ECG	ElectroCardioGram
EDD	End Diastolic Dimension
EF	Ejection Fraction
EOA	Effective Orifice Area
ESD	End Systolic Dimension
FDA	Food and Drug Administration
FS	Fractional Shortening
HF	Heart Failure
HS	Highly Significant
ICU	Intensive Care Unit
IEOA	Indexed Effective Orifice Area
INR	International Normalized Ratio
LA	Left Atrium
LAD	Left Atrium Diameter
LV	Left Ventricle
MHV	Mechanical Heart Valve
MPG	Mean Pressure Gradient

MR	Mitral Regurgitation
MRI	Magnetic Resonance Imaging
MS	Mitral Stenosis
MV	Mitral Valve
MVA	Mitral Valve Area
MVD	Mitral Valve disease
MVR	Mitral Valve Replacement
NS	Not Significant
NYHA	New York Heart Association
PASP	Pulmonary Artery Systolic Pressure
PML	Posterior Mitral Leaflet
PPG	Peak Pressure Gradient
PPM	Patient Prosthesis Mismatch
PS	Pressure Support
PVE	Prosthetic Valve Endocarditis
RCT	Randomized Controlled Trial
SD	Standard Deviation
SJM	St. Jude Medical
SPSS	Statistical Package For Social Science
SVD	Structural Valve Deterioration
TEE	Trans Esophageal Echocardiography
TIA	Transient Ischemic Attack
TR	Tricuspid Regurgitation

Introduction

The introduction of heart valve replacement surgery nearly five decades ago revolutionized the treatment of aortic and mitral valve disease, since then, additional bileaflet devices with numerous design modifications have been developed and continue to be used today [(1)].Because of the inherent drawbacks of anticoagulation required in patients with mechanical valves, design modifications have focused not only on improved hemodynamic performance but also on minimizing the risks of valve-related thrombosis. It is important to comment that the ideal mechanical valve should mimic a native valve enough to minimize or eliminate the need for anticoagulant therapy while maintaining long-term durability that is unmatched by biological valves [(2)].

The On-X prosthesis has a bileaflet design with a larger opening angle (90 degrees) compared with the other prostheses. The On-X valve is constructed of pure pyrolytic carbon, and therefore does not require silicon additives used in the other designs to gain sufficient durability. The avoidance of silicon additive in the pyrolytic carbon results in a smoother polished leaflet surface, theoretically reducing its thrombogenicity. The rapid closure of leaflets within the elongated cylinder housing significantly reduces the closing volume of the On-X valve. This has allowed the design of intentionally large regurgitant wash jets at the hinge points of the valve, while maintaining a small overall regurgitant fraction. These features may offer a significant advantage with regards to anticoagulation compared with the other models. The sewing ring of this valve sits in a supra-annular position, whereas the cylindrical housing component is seated within the annulus [(3)].

This design allows the incorporation of hydrodynamically efficient features such as a flared inlet and elongated housing that allows improved hemodynamics, more laminar flow, and less hemolysis. This cylindrical housing design may also mitigate tissue ingrowth, which can occasionally impinge upon the leaflets in the other bileaflet models [(4)].

Aim Of The Work

To compare the early postoperative hemodynamic function and major clinical events in patients receiving SJM valve & On-X valve in mitral position.

Anatomy Of The Mitral Valve

The mitral valve is a highly complex structure, the normal functioning of which requires the coordinated interaction of its anatomic elements, namely the mitral leaflets, annulus, chordae tendineae, and papillary muscles [(5)].

The mitral valve requires all its components, together with the adjacent atrial and ventricular musculature, in order to work properly [(6)].

The annulus

The mitral annulus is a pliable junctional zone of fibrous and muscular tissue joining the left atrium and ventricle that anchors the hinge portion of the anterior and posterior mitral leaflets. The annulus is more D shaped than circular the shape portrayed by prosthetic valves. The straight border accommodates the aortic valve allowing it to be wedged between the ventricular septum and the mitral valve **(Fig. 1)** [(7)].

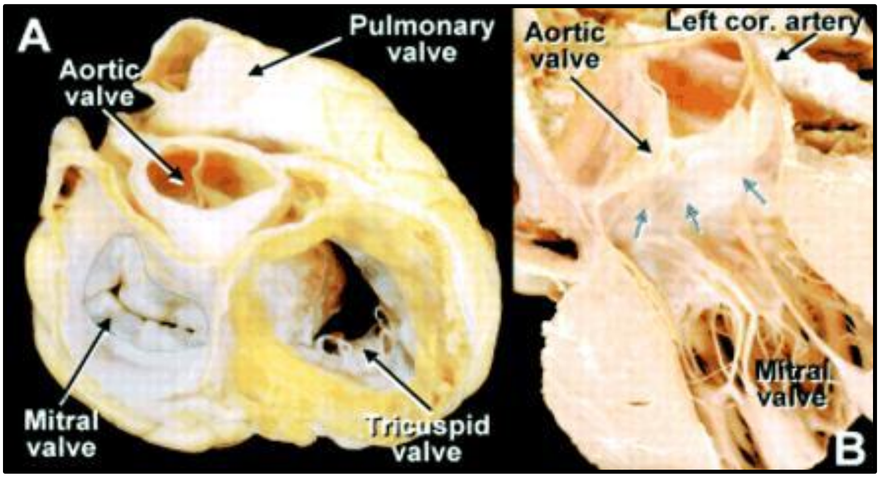

Fig. (1): (A) View of the base of the heart in anatomical orientation shows the spatial relations of the four cardiac valves. The left heart valves are close together whereas the right heart valves are separated by myocardium. Dotted line marks the limit of atrial myocardium around the mitral orifice. (B) This dissection of the heart viewed from the anterior aspect shows the close relation between aortic and mitral valves in situ. Fibrous continuity between the valves (blue arrows) is related to the non- and left coronary sinuses of the aorta [(7)].

In this region the aortic valve is in fibrous continuity with one of the two leaflets of the mitral valve. The annulus has two major collagenous structures formed by expansions of fibrous tissues at either extreme of the area of continuity: (1) **the right fibrous trigone**, which is part of the central fibrous body and is located at the intersection of the atrioventricular membranous septum, the mitral and tricuspid valves, and the aortic root; and (2) **the left fibrous trigone** at the junction of the mitral valve and left coronary cusp of the aortic valve. **(Fig. 2), (Fig. 3).** The atrioventricular conduction bundle passes through the right fibrous trigone [6].

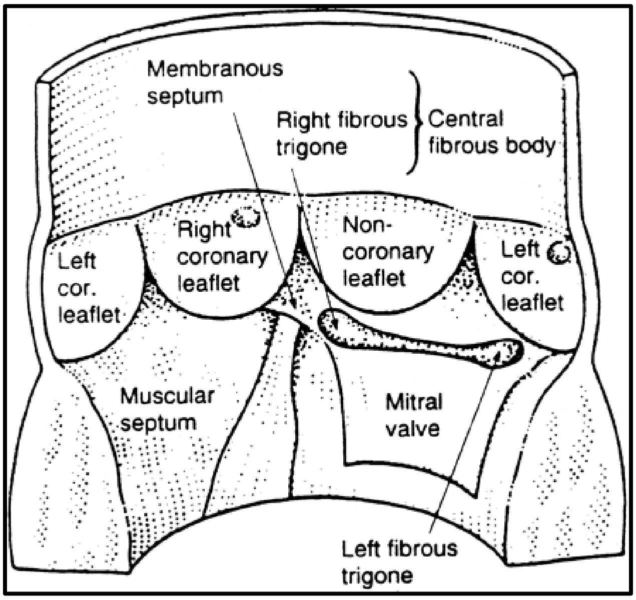

Fig. (2): Diagram from a pathological perspective with division of the septum illustrating the fibrous continuity between the mitral and aortic valves [7].

Fine tendon-like collagen bundles, the fila of Henle, extend out circumferentially from each fibrous trigone a variable distance towards the corresponding side of the mitral orifice. The posterior one half to two thirds of the annulus, which subtends the posterior leaflet, is primarily muscular with little or no fibrous tissue. This muscle is arranged mainly perpendicularly to the annulus, but a less prominent group of muscle fibers is arranged parallel to the annulus [9].

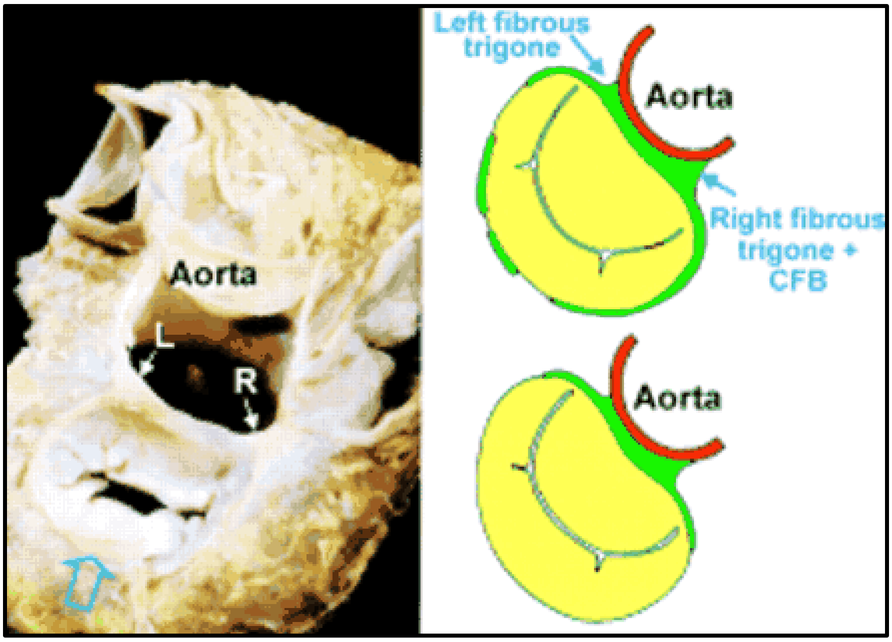

Fig. (3): A dissection showing the left (L) and right (R) fibrous trigones revealed by removing the left and non-coronary aortic sinuses. The trigones are expansions of fibrous tissue at either end of the area of aortic–mitral valvar continuity. The right fibrous trigone together with the membranous septum forms the central fibrous body. They show the variation in completeness of the so-called valvar annulus (green areas) [4].

The mitral leaflets

The mitral valve has two major leaflets, the much larger anterior (or aortic) leaflet and the smaller posterior (or mural) leaflet.

The anterior (aortic) mitral leaflet*:* is a semicircular or triangular struct*ure*. The central portions of the leaflets on the atrial surface are termed the *rough zone*, with the remainder of the free edge leaflet surface being the *bare*, *membranous*, *smooth*, or *clear zone*. The ratio of the height of the rough zone to the height of the clear zone is 0.6 for the anterior leaflet and 1.4 for the posterior leaflet, as the clear zone on the posterior scallop is only about 2 mm high on its ventricular surface [10].