



# Randomized Trial of Conventional Mechanical Prostheses to Evaluate the Incidence of Thromboembolic-Related Complications: Results of PROSE Trial NCT000639782

**OBJECTIVE:** The PROSE (Prospective Randomized Trial of On-X and SJM Evaluation) trial was to investigate if the incidence of thromboembolic related complications was reduced with the current generation mechanical prosthesis (On-X Prosthetic Heart Valve – On-X) compared with a previous generation prosthesis (St. Jude Mechanical – SJM).

**METHODS:** The study was conducted in 28 worldwide centers with 855 subjects randomized from 2003 to 2016. The protocol, preoperative demographics, and patient risk factors were published in the Journal of Cardiothoracic Surgery in 2021. The preoperative demographics included age, gender, etiology, New York Heart Association (NYHA) class, primary rhythm, primary valve lesion, BSA and BMI. The evaluation incorporated 24 patient risk factors.

**RESULTS:** The overall freedom evaluation showed no difference at 5 years between the prostheses for thromboembolism (TE) – On-X  $96.8 \pm 0.9$  % and SJM  $95.8 \pm 1.1$  % ( $p=0.606$ ) or for valve thrombosis (VT) – On-X  $98.8 \pm 0.5$  % and SJM  $98.9 \pm 0.5$  % ( $p=0.919$ ). There were also no differences in mortalities. VT was different by valve position at 5 years: aortic –  $96.6 \pm 0.3$  % and mitral –  $97.8 \pm 0.8$  % ( $p=0.0217$ ). There were several differences between Developing(D) and Western(W) world populations. The freedom relations at 5-years were: all-cause mortality -  $88.4 \pm 1.6$  % for D and  $92.9 \pm 1.3$  % for W ( $p=0.0055$ ); valve related mortality & sudden death -  $93.3 \pm 1.3$  % for D and  $96.8 \pm 0.9$  % for W ( $p=0.0106$ ); TE -  $98.1 \pm 0.7$  % for D and  $94.7 \pm 1.1$  % for W

( $p=0.0201$ ); VT -  $97.9 \pm 0.7$  % for D and  $99.8 \pm 0.2$  % for W ( $p=0.0137$ ); TE for mitral valve was  $97.7 \pm 0.9$  % for D and  $92.4 \pm 3.6$  % for W ( $p=0.0072$ ); all-cause mortality for mitral valve patients was  $88.4 \pm 1.9$  % for D and  $100.00$  % for W ( $p=0.0306$ ). The linearized event rates were not different for the prostheses: TE – On-X  $0.5\%/ptyr$  and SJM  $0.5\%/ptyr$  ( $p=0.992$ ) and VT On-X  $0.2\%/ptyr$  and SJM  $0.3\%/ptyr$  ( $p=0.778$ ). VT was differentiated by position: aortic – 2 ( $0.1\%/ptyr$ ) and mitral – 8 ( $0.5\%/ptyr$ ) - $p=0.007$ . VT for the W world was 1( $0.04\%/ptyr$ ) and for the D world was 9 ( $0.5\%/ptyr$ )- $p=0.005$ . In the mitral position there were no VT cases in the W world while there were 8 ( $0.6\%/ptyr$ ) in the D world ( $p=0.217$ ). The risk assessment was conducted with the following parameters – age, BMI, CHF, COPD, CVA, NYHA and rhythm. Risk factor assessment showed VT to occur in younger patients in the mitral position. NYHA status showed improvement in higher than 70 percent in all groups. Cardiac rhythm improved significantly with reduction of atrial fibrillation in all groups.

**CONCLUSION:** The On-X and SJM performed equally well in the study with no differences found. The only differentiation occurred with valve thrombosis in the mitral position occurring in the Developing world more than the Western world and occurring in a younger population possibly due to anticoagulation compliance issues.

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