

Edwards-Sapien Positioning during Transcatheter Aortic-Valve Implantation: A Multi-Center Study

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Background: Accurate valve implantation during transcatheter aortic-valve implantation (TAVI) is crucial in order to avoid complications. A novel imaging modality capable of real-time positioning assistance has recently been introduced (CardioOp-THV, C-THV, Paieon Inc). The aim of the study was to evaluate the exact location of Edwards-Sapien valves before and after deployment.

Methods: We used the CardioOp THV system for evaluating Edwards-Sapien TAVI cases from 4 medical centers between February 2009 and October 2010. We have evaluated the prosthetic valve position in relation to the native valve annulus (the target line) in several stages: before and after angiographic aortic contrast injection and after valve implantation. Valve position was analyzed as the extent of valve that is below the target-line in relation to the total prosthetic valve length.

Results: The study group consisted of 62 patients, 62% women, of mean age 82.9 ± 8 years. The valves implanted were Edwards-Sapien (58%) and Edwards-Sapien XT (42%). Valve size was 23mm in 52% and 26mm in 48% of cases. The procedure was transfemoral in 66% and transapical in 33% of cases. In the total group of patients, the location of the valve before aortic contrast injection, after injection and after implantation was $32 \pm 21.5\%$, $39 \pm 14.7\%$ and $14.6 \pm 16.8\%$ into the left-ventricle, accordingly ($p < 0.0001$ between the first and second groups vs. the last group). The final valve location was further sub-analyzed: 23mm valve, $18 \pm 18\%$ vs. 26mm valve $13 \pm 14\%$ ($p = 0.09$); transfemoral approach, $16 \pm 17\%$ vs. transapical approach, $12 \pm 17\%$ ($p = \text{NS}$). Patient age below 85 years $14 \pm 18\%$ vs. equal or above 85 years $15 \pm 15\%$ ($p = \text{NS}$).

Conclusions: During Edwards-Sapien TAVI there is a significant change in valve position. The final position tends to be more aortic immediately after implantation. This result remained in different sub groups evaluated. Future evaluation should explore the possible correlation between final valve location and clinical results.