

## Prospective evaluation of commissural alignment of balloon-expandable transcatheter heart valves utilizing pre- and post-procedure computed-tomography

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**Background:** Previous studies suggested that bioprosthetic valve commissural alignment may improve device performance and clinical outcomes in patients undergoing transcatheter aortic valve implantation (TAVI). However, no cath-lab method for correct commissural alignment of balloon-expandable valves was described to-date. Our aim is to evaluate the impact of a predefined patient specific crimped SAPIEN 3 orientation on its final implant orientation in relation to original valve commissures and overlap with coronary arteries as demonstrated by cardiac computed tomography (CT) in tricuspid aortic valve stenosis patients.

**Methods and results:** A prospective study of patients undergoing TAVI with SAPIEN 3 (Edwards Lifesciences), including post procedure cardiac CT. Patients were divided to 2 groups, a planned group in which the SAPIEN 3 was crimped before implantation in a pre-defined position, and a control group with conventional valve deployment. All patients underwent pre and post TAVI cardiac CT, which were evaluated by cardiac imaging

experts that were blinded to the method of valve deployment. Twenty-eight patients were prospectively evaluated before and after TAVI with SAPIEN 3. All patients had elevated risk for open-heart surgery (age  $77.6 \pm 7.9$  years, 68% male, STS PROM  $4.4\% \pm 3.4\%$ ). Fifteen patients were included in the active alignment group vs. thirteen patients in the control. Patients in the active alignment group had a trend for more correct commissural alignment (73.3% vs. 38.5%,  $p=0.06$ ). There was no statistically significant difference in patient characteristics, echocardiographic measures or in anatomical CT features between the active commissural alignment and control groups.

**Conclusion:** This is probably the first study that shows that patient-specific initial crimped orientation of balloon-expandable TAVI may improve our ability to have correct commissural alignment of the implanted valve. Our prospective study continues to recruit patients and updated study results will be presented.