Safety and feasibility of single suture-mediated closure system in patients undergoing TAVI with 14-F expandable sheath

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BACKGROUNDS

Vascular complications are an important limitation of transfemoral TAVI as have been associated with bleeding, transfusions, and mortality. Management of the vascular access site is therefore a key component of the overall success of the procedure.

AIM OF THE STUDY

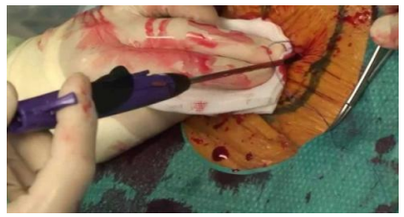
Aim of this study was to analyze feasibility, efficacy, and safety of using a single Perclose ProGlide Suture-Mediated Closure System technique vs. using a single Prostar XL Percutaneous Vascular Surgical System for access site closure after transfemoral TAVI performed with 23 and 26 mm sizes last generation balloon-expandable bioprosthesis which are compatible with the new 14-F expandable sheath technology.

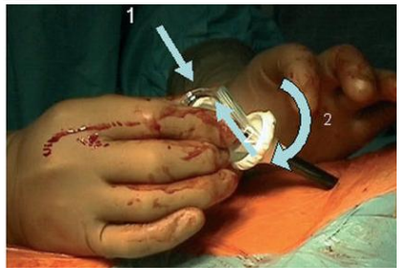
METHODS

We enrolled 89 consecutive patients (37 men, mean age 81.3 ± 5.1 years) admitted from February 2014 to June 2015 to "Montevergine" Clinic (AV), "Santa Maria" Clinic (BA) and Policlinico University Hospital (BA), Italy, to perform TAVI (Logistic EuroSCORE 20%, mean 21.6 ± 15.4%; STS score mortality 10%, mean 20.9 ± 14.9%).

After full evaluation by Multi-Detector Computed Tomography, all of them were implanted with 23 and 26 mm Edwards SAPIEN 3™ bioprosthesis. Patients were 2:1 randomly assigned to receive single ProGlide (n = 62) or single Prostar XL (n = 27). Both percutaneous closure devices were deployed in a preclose technique prior to insertion of the 14-F expandable sheath, always with vascular surgery stand-by.

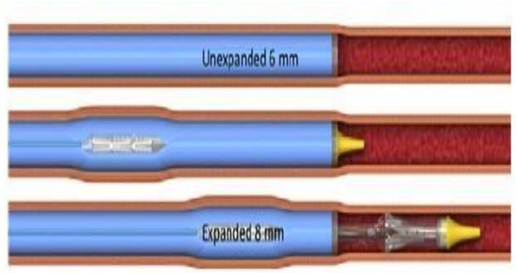
The percutaneous closure device success as well as access-related vascular and bleeding complications have been accurately detected and evaluated until the patient discharge, according to Valve Academy Research Consurtium-2 and Bleeding Academic Research Consortium definitions.

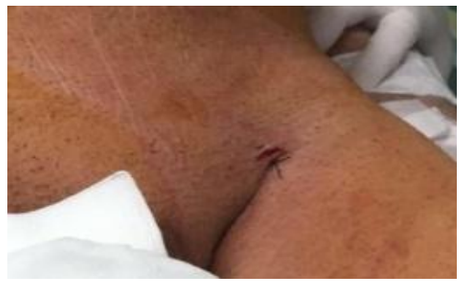




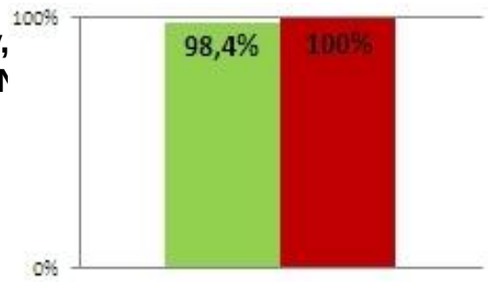
RESULTS

Single-ProGlide and Prostar XL groups showed the same overall device success rate (98.4% vs. 100%; p = 0.511), independently from heparinization dose and dual-antiplatelet therapy, and also similar access-related vascular complication rate (12.9% vs. 18.5%; p = 0.490). All the access-related vascular complications observed in our population were VARC-2 minor. In addition, according to VARC-2 and BARC criteria, also the rate of bleeding are not significantly different between the two groups (11.3% vs. 14.8%; p = 0.642). Both the percutaneous closure devices have <u>similar impact also on the hospital length of stay</u> (6.0 ± 2.6 vs. 5.4 ± 1.7 days; p = 0.252).

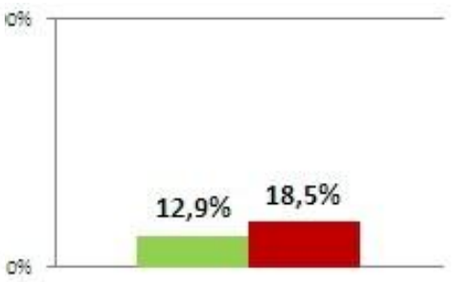




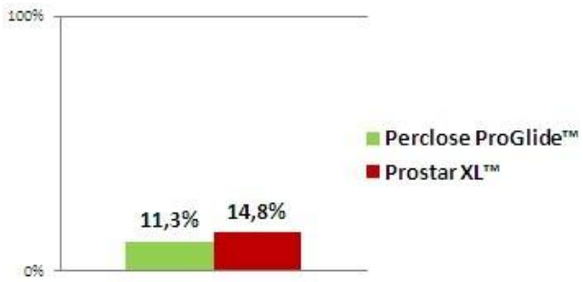
device success (p = 0,511)



vascular complications (p = 0,490)



heamorragic complications (p = 0,642)



CONCLUSIONS

This small study suggests that single-Perclose ProGlide technique may offer a simple, effective and safe method for closure of the arterial access site after transfemoral TAVI with 14-F expandable sheath comparable to conventional single Prostar XL strategy.