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Acute and 30 day results of a multi-center study on a novel apical closure device for transapical transcatheter aortic valve implantation - The STASIS trial

Hendrik Treede[1], *Lenard Conradi*[1], *Thomas Walther*[2], *Joerg Kempfert*[2], *Sabine Bleiziffer*[3], *Walther Eichinger*[4], *Oliver Heyn*[5], *Hermann Reichenspurner*[1], *Ruediger Lange*[3].

[1]*University Heart Center Hamburg, Hamburg, Germany,* [2]*Kerckhoff Clinic, Bad Nauheim, Germany,* [3]*German Heart Center Munich, Munich, Germany,* [4]*Bigenhausen Hospital, Munich, Germany,* [5]*Bogenhausen Hospital, Munich, Germany.*

OBJECTIVE: Transapical access for transcatheter aortic valve implantation (TA-TAVI) has become a routine procedure for patients at high surgical risk as an alternative to transfemoral access. In contrast to transfemoral TAVI, transapical access has seen little standardization of technique due to the absence of automated preclosure and carries a risk for bleeding complications. Here we describe the use of a novel device designed to facilitate safe and reliable, automated transmyocardial access and closure during structural heart interventions such as TA TAVI.
METHODS: TA-TAVI was performed in 30 patients in 4 German centers through mini-thoracotomies using the Permaseal closure device (STASIS trial). All patients received Edwards Sapien 3 or Sapien XT valves. The closure device consists of 8 polyethylene anchors connected by a braided polyester pre-tied suture allowing for sheath sizes up to 30 Fr. Anchors are mechanically deployed into the myocardial tissue near the anatomical apex using an over the wire system. After removal of the TAVI sheath, hemostasis is achieved by suture tying and approximation of the anchors without need for fast pacing. All patients were prospectively followed for 30 days.
RESULTS: The Permaseal apical closure device was successfully deployed in all patients. In 27 of 28 patients (96%) hemostasis was achieved with no or only one pledgeted suture after sheath removal. In 1 patient additional sutures had to be applied to resolve ongoing bleeding from the apical access site. Two patients, one roll-in patient and one protocol deviation were excluded from the efficacy analysis. Four patients (15.4%) required transfusion either peri-procedurally or prior to discharge. No patients suffered strokes, myocardial infarctions or died during 30 d follow-up. Mean operation time was 86 ± 22,5 min and mean length of stay in the hospital 9.5±3.2 days.
CONCLUSIONS: The Permaseal device allows for minimally invasive reproducible access and closure of the left ventricular apex for TA TAVI. The device complies with the beating heart and shows no interference with wall motion while leaving only little foreign material behind. It may help to reduce OR time, abate blood loss, and simplify transapical access for TAVI.

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