

for implantations in aortic position. Histological analyses showed a debris capture rate of 93% in any or both filters. Finding debris in the proximal filter was more common (100%) than in the distal filter (86%). Acute thrombus was the most common type of debris, captured in 64% of the filters. In 28%, valve and arterial wall tissue and calcification were also found, with the percentage of debris higher in the proximal filter. Organized thrombus was found in 7%; foreign material was also found in 7% of all cases, but only in the distal filter.

CONCLUSIONS Histopathological analyses showed high overall debris capture rates, with higher prevalence of thrombus over valve and arterial wall tissue, calcification and foreign material. Procedural stroke rate was 0%. Further investigation (especially histopathological) is needed to investigate the characterization of the debris and to differentiate between valve-in-valve procedures in the aortic and mitral position.

CATEGORIES ENDOVASCULAR: Stroke and Stroke Prevention

TCT-688

Acute, 30 and 90-day results of the STASIS trial: a multi-center study on a novel apical closure device for transapical transcatheter aortic valve implantation

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BACKGROUND Transapical access for transcatheter aortic valve implantation (TA-TAVI) has become a routine procedure for patients at high surgical risk and is a valid alternative 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 A total of 34 patients in 1 Dutch and 4 German centers underwent transapical TAVI 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 polypropylene anchors connected by a braided polyester pre-tied suture allowing for the passage of sheaths 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 advancement of the pre-tied suture, and approximation of the anchors without the need for fast pacing. All patients were prospectively followed for 30 and 90 days.

RESULTS The Permaseal apical closure device was successfully deployed in all patients. Hemostasis was achieved with no or only one additional pledgeted suture after sheath removal and anchor approximation by closing of the pre-tied suture in 94.1% of patients. In 2 patients additional sutures were 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. Three patients (8.8%) required transfusion of more than 2 units either peri-procedure or prior to discharge. Mean operation time was 86 ± 22.5 min and mean length of stay in the hospital was 9.5 ± 3.2 days. Pulsatile bleeding was not reported and re-intervention was not required for any patient following the surgical procedure, at hospital discharge, 30-day follow-up or 90-day follow-up. No patients died during 30 day follow-up, however one patient died on day 37 from complications related to hip replacement surgery. No patients suffered strokes or myocardial infarctions during the 90 day follow-up period.

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. This access and closure approach may help to reduce OR time, abate blood loss, and simplify transapical access for TAVI.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Clinical Trial, Closure device, Transapical TAVI

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Chronic anemia is a strong predictor of long-term outcomes in patients undergoing TAVI (POL-TAVI Registry)

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BACKGROUND POL-TAVI is an on-going all-comer registry enrolling all TAVI procedures in Poland since 2009. Within the registry baseline clinical, imaging and procedural data as well as in-hospital, early (30 days) and long-term (6 and 12 months) outcomes are prospectively registered and reported yearly. Aim of the study was to evaluate the outcomes of TAVI patients presenting with chronic anemia.

METHODS The registry enrolled 381 patients treated in 2013 (43.6% males, mean age of 78.75 ± 7.4 years, logistic EuroScore 20.2 ± 14.5 , STS 8.52 ± 8.3). Anemia was diagnosed based on WHO definition (Hb < 13 g/dL for men and < 12 g/dL for women).

RESULTS There were 184 (47.5%) patients with anemia. In comparison to patients without anemia they were significantly older (79.7 ± 7.2 vs. 77.9 ± 7.4 , $p < 0.03$). Both groups had comparable Log EuroScore (21.1 ± 14.5 vs. 19.5 ± 14.5 , $p = 0.16$), NYHA and CCS class. Patients with anemia have more often creatinine level > 200 $\mu\text{mol/l}$ (10.87 vs. 3.6% , $p < 0.01$) and lower GFR (50.3 ± 19.9 vs. 59.4 ± 19.2 mL/min, $p < 0.001$) on admission. The groups did not differ in the frequency of chronic dialysis prior to AV as well as acute kidney injury post TAVI (14.67% vs. 9.33% , $p = 0.11$). Patients with anemia required more blood transfusion post TAVI (49.18% vs. 27.2% , $p < 0.001$). A trend to higher mortality in a group of patients with anemia on admission could be observed at 1 month (12.20 vs. 8.9% , $p = 0.36$), 6 months (21.97 vs. 13.9% , $p = 0.11$) which became significant at 12 months (34.31 vs. 17.43% , $p < 0.01$). In logistic regression analysis presence of anemia was an independent predictor of death at 1 year [OR 95% CI 2.47 ($1.32; 4.77$), $p = 0.0048$] similarly to drop in Hb level during hospitalization [OR 95% CI 0.82 ($0.67; 0.99$), $p = 0.039$ for decrease of by 1 g/dL]. The need of transfusion increased the risk of death 3.2 times (OR 95% CI 3.23 ($1.70; 6.32$), $p < 0.002$).

CONCLUSIONS Chronic anemia is present in almost 48% of patients undergoing TAVI and associated with 2.5-fold higher mortality in 12 months follow-up. Significant drop in hemoglobin levels and need of blood transfusion also significantly increased the short and long term mortality.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS TAVI

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Prognostic Value of Body Surface Area on Clinical Outcomes after Transcatheter Aortic Valve Replacement

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BACKGROUND An inverse association between body mass index (BMI) and mortality in patients after Transcatheter Aortic Valve Replacement (TAVR) has been reported. This 'obesity paradox' is controversial, however, because not all TAVR series have demonstrated such a relationship between BMI and mortality. Body surface area (BSA) might be a more suitable marker to identify patients at risk for mortality following TAVR, but little is currently known about its prognostic value.

METHODS This prospective, observational study consisted of 917 consecutive patients undergoing TAVR at our center from 2011-2014. The association between BSA and mortality (at 30-days and 1-year) was assessed using restricted cubic spline functions in a propensity-adjusted (by Society of Thoracic Surgeons' risk factors) logistic and Cox proportional model, respectively.

RESULTS Mean follow-up time was 141 days. Throughout the study period, 152 (16.5%) patients died; 72 (7.9%) patients died within 30