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 Permeasapal 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 Permeasal apical closure device was successfully deployed in all patients. Hemostasis was achieved with no or only one additional pledged 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-procedurally 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 a problem 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 infarction during the 90 day follow-up period. In total, no patients developed no re-intervention at 30 days.

CONCLUSIONS
The Permeasal 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

TCT-669
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 EuroScore2 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 > 150 µmol/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 were more similar in the frequency of chronic diuresis prior to AVA 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. 17,48%, p=0.01). In logistic regression analysis presence of anemia was an independent predictor of death at 1 year [OR 95% CI 1,24,7,1 (1,24,7,1) p<0.001]. 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 > 150 µmol/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 were more similar in the frequency of chronic diuresis prior to AVA 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. 17,48%, p=0.01).

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

TCT-690
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 undergoing 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