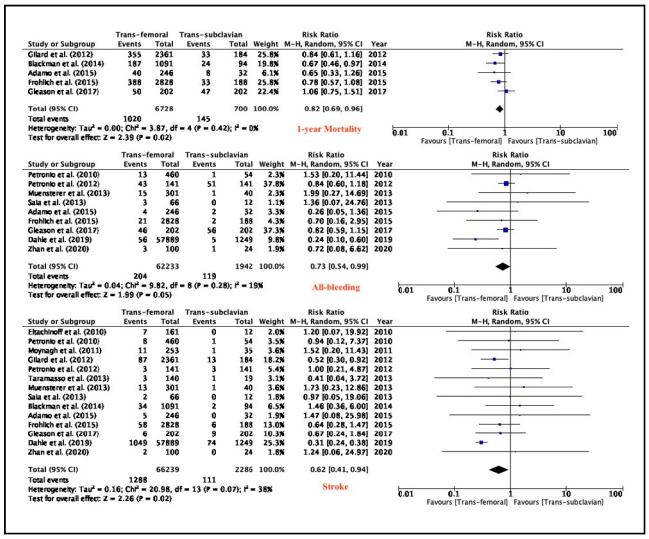

CRT-700.12

TAVR Vascular Access Closure Using the Tri-Suture Technique

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BACKGROUND Despite pre-procedure CT, careful puncture techniques and advances in TAVR delivery system, vascular access complications remain high when compared to other TAVR related complications. We assessed outcomes in consecutive patients treated with TAVR using a novel Tri-Suture technique for vascular access closure.

METHODS AND RESULTS The Tri-Suture technique involves pre-closure of the TAVR TF access site with one 6F ProGlide (x1 suture) and one 10F Prostar (x2 sutures) closure devices. TAVR was then completed using standard methods and access site haemostasis achieved using the 3 sutures. All data were prospectively collected and retrospectively analysed. All patients were deemed high or surgically inoperable risk by the Heart Team. A total of 105 consecutive patients (mean age: 83yrs; Male: 42%) underwent percutaneous transfemoral TAVR (local anaesthesia and transfemoral: 100%). Mean vessel diameter was 5.5mm (range: 4.8 - 8.9mm). Access site calcification was observed in 32% of patients and mean TF vessel depth was 5.5cm. Ultrasound guided puncture was used in 33% of patients. A total of 72.8% of patients requiring a 27, 29 or 34mm self-expanding device. The Tri-Suture technique for pre-closure was successfully deployed in 100% of patients. The ProGlide device was successfully deployed in all patients at 1st attempt; The Prostar device required repositioning in 4 patients due to calcification restricting suture retrieval. All TAVR devices were inserted sheathless successfully, with a procedural success of 100%. Haemostasis post TAVR was achieved successfully in all patients without complication. There were no procedural related death, major vascular complication or bleeding. Minor vascular complication was observed in 4 patients at day 2 (small subcutaneous haematoma) - all were commenced on warfarin or a DOAC therapy whilst on subcutaneous low molecular weight heparin at day 1 post procedure. Non disabling stroke was observed in 1 patient. Median discharge was 1 day post TAVI. At 30days, no death, additional stroke or vascular complication were observed.

CONCLUSIONS Pre-closure of the TAVR TF access site with the Tri-Suture technique using x1 ProGlide and X1 Prostar appears safe, with no procedural or late major vascular complications observed. Larger series are required to assess this technique further.

CRT-700.15

Real-World 1-Year Experience of Standard Cerebral Embolic Protection Device in Routine TAVR Practice With Sentinel or TriGuard 3 Device

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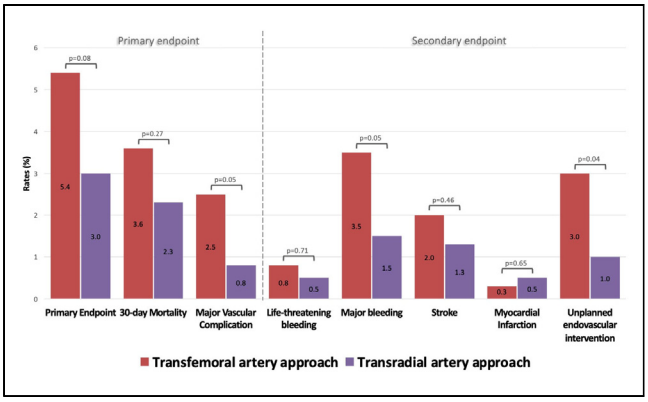
BACKGROUND Neurological events are still a matter of concern when performing transcatheter aortic valve replacement (TAVR). Currently there are 2 CE approved devices (Sentinel and TriGuard 3). We evaluated it's use in daily practice where the aim was to use CEP in 100% of all cases. From July 28th 2021 to November 18th 2021, 165 consecutive subjects undergoing TF-TAVR were evaluated. Primary endpoint was absence of neurological symptoms (Stroke or TIA) within 72 hours after TAVR. Secondary endpoints were: protection device related safety outcomes and causes of non-successful implantation of the device.

RESULTS The primary in hospital endpoint was met in 98.18% (n=133) cases (three TIA - 2 without CEP and 1 in TriGuard arm). The secondary outcome of protection device related safety was met in 95.7% (n=132), presenting 7 patients with vascular complications (4 femoral dissections treated conservatively and 3 pseudo aneurysms after closure with Angio-Seal 8 Fr), all with good resolution, all of them in the TriGuard arm. A total of 110 (66.6%) TriGuard 3 devices were used and 13 Sentinel (7.8%), 42 patients didn't receive a device (25.45%) for the next reasons: in twelve patients (7.17%) the tortuous anatomy did not allow the adequate placement of the device, in five (3.03%) it was impossible to advance the device because peripheral vascular disease, in three cases the left femoral approach was used to protect the left main and finally in 22 cases (13.3) the device was not placed because lack of time in the cath lab.

CONCLUSIONS The use of cerebral protection device during TF-TAVR is an easy and safe way to prevent cerebral embolic lesions with a low risk of complications. Although 100% use was intended, due to various reasons this was only 74.5% in our first year of experience.



CRT-700.18

Early Single-Center Experience With Meril's Myval Transcatheter Heart Valve

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BACKGROUND TAVR has emerged as a revolutionary treatment for patients with symptomatic and severe AS, irrespective of surgical-risk profile. Novel transcatheter heart valves (THV) with a lower profile, ease of use and expected longer durability are being developed to target younger and low-risk population. Myval is a 14Fr-balloon expandable THV with a skirt to minimize the occurrence of paravalvular leak (PVL), and has been recently approved for commercial use in Brazil. We sought to report our initial experience with this novel device.

METHODS Single-center, single arm, open label prospective registry encompassing all consecutive patients referred to TAVR in our Institution between December 2020 and November 2021. Indication for TAVR was according to current international guidelines. Clinical and echocardiographic outcomes were defined accordingly to VARC-III criteria.

RESULTS A total of 39 patients were enrolled so far. Mean age was 79.5 years, 42% were female and mean STS score was 4%. Pre-procedures mean gradient and aortic valve area were 53.3 mmHg and 0.7cm^2, respectively. All procedures were performed under minimalist approach using percutaneous, femoral access. Two patients were treated for bicuspid aortic stenosis and four patients underwent a valve-in-valve procedure. Procedure success was achieved in 100% of the cases, and post-procedure echocardiogram revealed a mean residual gradient of 5 mmHg, with PVL greater than mild in a single case. Permanent pacemaker was required in only 2 patients, and mean hospital stay was 3.1 days. At 30-days, there were two deaths, one due to COVID in a patient who presented major access bleeding requiring prolonged hospital stay, and another one a cardiovascular death.

CONCLUSION In our initial experience with the Myval THV, valve performance and 30-day clinical results were encouraging. Low rates of complications were observed, comparable to the best last-generation THV. At the time of the meeting, three-month clinical and echocardiographic FU will be available.

CRT-700.19

Five-Year Outcomes of Transcatheter Versus Surgical Aortic Valve Replacement in Low- to Intermediate-Risk Patients

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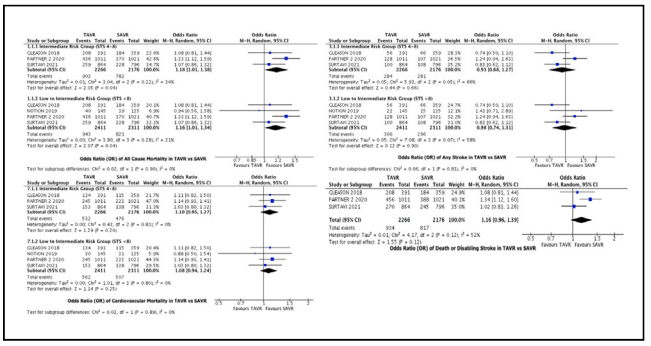
BACKGROUND Transcatheter aortic valve replacement (TAVR) is an alternate to surgical aortic valve replacement (SAVR) in patients with aortic stenosis (AS). In patients with low to intermediate surgical risk, while SAVR remains the procedure of choice, TAVR has shown promising results.

OBJECTIVES This meta-analysis of randomized controlled trials (RCTs) compared the outcomes of TAVR versus SAVR in low to intermediate surgical risk candidates at five year follow up.

METHODS Electronic databases were searched from inception to November 4, 2021. RCTs comparing TAVR versus SAVR in low to intermediate-risk patients (Society of Thoracic Surgeons Predicted Risk of Mortality [STS-PROM] score <8%) were included. Primary outcome was all-cause mortality at 5 years. Random-effects models were used to calculate pooled odds ratio (OR) and corresponding 95% confidence intervals (CI)

RESULTS The meta-analysis included 4 RCTs that randomized 4722 patients (2411 to TAVR and 2311 to SAVR). Patients had a mean age of 89.9 and mean STS score of 5.1 in TAVR versus 5.2 in SAVR. All-cause mortality at five years was lower in SAVR compared to TAVR (OR 1.16; 95% CI: 1.01-1.34, I^2=21%, P=0.28). There was no difference in the risk of any stroke at five years (OR 0.98; 95% CI: 0.74-1.31. I^2=58%, P=0.07). The need for valve reintervention at five years was higher in TAVR (OR 2.50; 95% CI: 1.55-4.03, I^2=0%, P=0.55). There was no difference in the composite outcome of death or disabling stroke, endocarditis, or cardiovascular mortality.

CONCLUSIONS The findings of this meta-analysis show encouraging results of TAVR at five year follow up with non-inferiority of TAVR for cardiovascular mortality, death, or disabling stroke. While there is inferiority of TAVR in all-cause mortality, the difference between the two groups is minimal.



CRT-700.20

Foldax TRIA TAVI: A Novel-Polymer Transcatheter Aortic Valve: Pilot Chronic Ovine Model Study

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BACKGROUND Indication expansion in young patients requires enhanced hemodynamics and durability with greater life expectancy. TRIA TAVI uses a unique polymer, 1/3 thickness of bioprosthetic tissue, specifically formulated for no need for lifetime anticoagulation. This is studied in the TRIA surgical aortic valve (EFS) and the surgical mitral valve study (EFS). This analysis assesses the TRIA TAVI in a chronic ovine model.

METHODS TRIA TAVI (Fig 1) was implanted in 4 animals (A) with surgical annuloplasty rings (method to simulate a calcified annulus). 27mm TRIA TAVI devices (for perimeter derived annuli of 21mm-24mm) were delivered transfemorally. Target deployment, with commissural alignment, was first cell of the TAVI device at annular ring.

RESULTS A2 and A3 had suboptimal deliveries resulting in immediate explantation. Both had an annulus significantly smaller than the indicated range (21-24mm) resulting in inability to fully expand the implant and severe PVL (A2). The study device in A3 was placed too low in the annulus resulting in migration to the left ventricle.

A1, A4 were successful and followed to 30 and 90 days. A1 had a small annulus (19mm), resulting in mild acute PVL and mild central AI due to inability to achieve full frame expansion. PVL completely resolved at 5 days. Mean gradient was 15mmHg post-implant and 9mmHg at 5 days. Mean gradient was 12mmHg at 30 days with trace AI. Histology showed no fibrin, pannus, or calcification on polymer surfaces. No valve thrombosis, leaflet tears or tissue ingrowth was present. The sealing skirt was well integrated by fibrocellular tissue.

A4 was implanted with a 27mm device in a 23mm inner diameter annular ring. The mean gradient was 6 mmHg immediately and at 31 day follow up. 90-day follow up will be available at time of presentation.

CONCLUSIONS This pilot chronic ovine study, TRIA TAVI demonstrated satisfactory deployment, function and good hemodynamic results. There was no pannus, calcification or thrombosis on leaflet surfaces. These results warrant continued GLP and clinical study.

Figure 1: TRIA TAVI Implanted in Ovine Model