



HOT TOPICS IN CARDIOLOGIA 2024

27 e 28 Novembre 2024

Villa Doria D'Angri - Via F. Petrarca 80,
Napoli

Press Review: Interventistica
strutturale



Dott. Fulvio La Rocca

Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

EARLY TAVR Trial Investigators*

Aortic Stenosis (EARLY TAVR) trial is a prospective, multicenter, open-label, randomized, controlled trial in which TAVR with transfemoral placement of a balloon-expandable valve (SAPIEN 3 or SAPIEN 3 Ultra, Edwards Lifesciences) was compared with clinical surveillance among patients with asymptomatic severe aortic stenosis and indications for clinical surveillance according to current guidelines.³ The protocol (avail-

Patients were assessed for a minimum of 2 years during the period of data collection for this

The primary end point was a composite of death from any cause, stroke, or unplanned hospitalization for cardiovascular causes. Any aortic-valve

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EARLY-TAVR TRIAL

Dr. P. Genereux et al

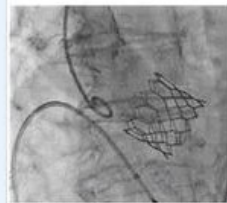
Dr. Luigi Biasco

Source: PCRONline.com



901 asymptomatic, elderly, low risk AS patients randomized 1:1 to balloon expandable (BEV) TAVI or clinical surveillance

Primary Outcome: composite of all-cause deaths, strokes or unplanned hospitalizations for CV causes



BEV
TAVI

26.8%



Clinical
surveillance

45.3%

Hazard Ratio 0.50 (95% CI 0.40-0.63; $p < 0.001$)



TAVI is superior to a clinical surveillance strategy for the composite of death, strokes or unplanned hospitalizations for CV causes.

Primary outcome difference was predominantly driven by early (<6 M) hospitalizations for CV causes. These events were mainly related to deferred TAVI procedures due to development of symptoms.

Among patients with asymptomatic severe aortic stenosis, a strategy of early TAVR was superior to guideline-recommended clinical surveillance in reducing the composite end point of death, stroke, or unplanned hospitalization for cardiovascular causes.

Comparison of strategies for vascular ACCESS closure after transcatheter aortic valve implantation: the ACCESS-TAVI randomized trial

Brief title: The ACCESS-TAVI Trial

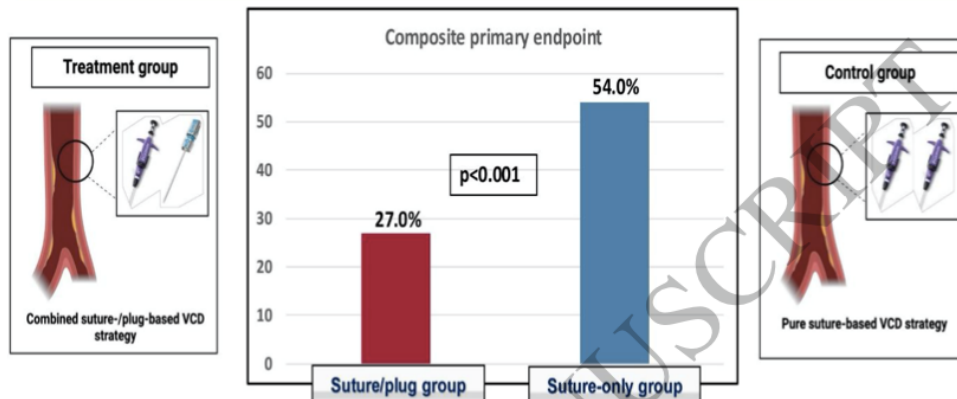
prospective, randomized controlled trial conducted at four sites in Germany. The trial was designed to compare a strategy of a combined suture- and plug-based VCD strategy (suture/plug-group) using a combination of one ProGlide™/ProStyle™ (Abbott Vascular) and one Angio-Seal® (Terumo) versus a suture-based VCD strategy (suture-only group) using two ProGlides™/ProStyles™ to achieve hemostasis following TF-TAVI.

The primary endpoint was a composite of major or minor access site-related vascular complications according to VARC-3 criteria during index hospitalization for TF-TAVI.¹⁴

Comparison of strategies for vascular ACCESS closure after transcatheter aortic valve implantation: the ACCESS-TAVI randomized trial

Brief title: The ACCESS-TAVI Trial

Comparison of Strategies for Vascular ACCESS Closure after Transcatheter Aortic Valve Implantation: The ACCESS-TAVI Randomized Trial



Individual components of primary endpoint

3.5%	Major access site-related vascular complications	6.7%
23.5%	Minor access site-related vascular complications	47.3%

Conclusions

With regard to the composite of major or minor access-related vascular complications, a combined suture-/plug-based VCD strategy was superior to a suture-based VCD strategy for vascular access closure in patients undergoing transfemoral TAVI.

Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

OPTION Trial I

tion (OPTION) trial was designed to determine whether left atrial appendage closure can safely decrease the risk of bleeding associated with oral anticoagulants while maintaining a low risk of stroke among patients with atrial fibrillation who have undergone catheter ablation and are at moderate or high risk for stroke.

Follow-up visits occurred at 3, 12, 24, and 36 months after randomization. Clinical informa-

The primary safety end point was non-procedure-related **bleeding** — a combination of major bleeding (as defined by the International Society on Thrombosis and Haemostasis [ISTH]) and clinically relevant nonmajor bleeding (bleeding that required medical intervention, led to hospitalization or increased level of care, or prompted a face-to-face evaluation) — through 36 months (Table S5).^{10,11} The primary efficacy end point was a composite of **death from any cause, stroke, or systemic embolism** at 36 months after randomization.

Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

OPTION Trial I

AHA 2024
November 14-18, 2024
Chicago


OPTION trial

#AHA 2024

PCR
online

 @Sticchi_Alex

Source: PCRONline.com

 **1600** patients at high risk for stroke undergoing ablation for atrial fibrillation (AF) randomized to Left Atrial Appendage Closure (LAAC) vs Oral Anticoagulation (OAC).

Primary **Efficacy** Endpoint: composite of death from any cause, stroke or systemic embolism at 36 months.

Primary **Safety** Endpoint: non-procedural bleeding (ISTH major bleeding and clinically relevant non-major bleeding).

 <p>LAAC WATCHMAN FLX device (Boston Scientific)</p>	 <p>OAC</p>
Efficacy 5.3%	Efficacy 5.8%
Safety 8.5%	Safety 18.1%

HR 0.91; P<0.001 for noninferiority; HR 0.44; P<0.001 for superiority

The OPTION trial affirms that LAAC is a strong, safe alternative to long-term OAC for post-ablation AF patients, particularly those at high risk of bleeding, providing comparable stroke prevention with a significantly reduced bleeding risk. Further studies with longer follow-up are needed to confirm its benefits.

The results of this trial showed that among patients at moderate-to-high risk for stroke who underwent catheter-based ablation for atrial fibrillation, left atrial appendage closure was associated with a lower risk of non-procedure-related major or clinically relevant nonmajor bleeding than oral anticoagulation and was noninferior to oral anticoagulation with respect to a composite end point of death from any cause, stroke, or systemic embolism at 36 months.

Transcatheter Repair versus Mitral-Valve Surgery for Secondary Mitral Regurgitation

MATTERHORN Investigators*

emic Origin (MATTERHORN) trial to determine whether transcatheter edge-to-edge therapy is noninferior to mitral-valve surgery in patients with secondary mitral regurgitation who are at high surgical risk.

The primary efficacy end point was a composite of death from any cause, hospitalization for heart failure, mitral-valve reintervention, implantation of an assist device in the left ventricle, or stroke within 1 year after the procedure. Recurrence of

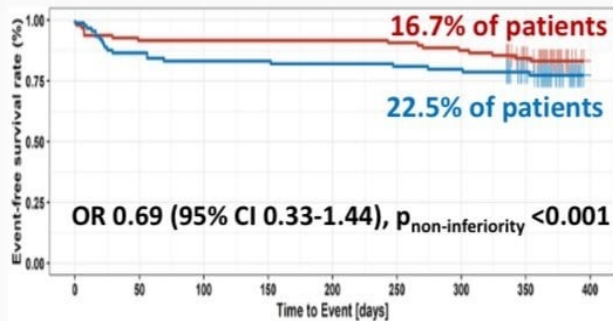
naire. The primary safety end point was a composite of the following major adverse events within 30 days after the procedure: death (from

Transcatheter Repair versus Mitral-Valve Surgery for Secondary Mitral Regurgitation

MATTERHORN Investigators*

Results

Primary efficacy endpoint

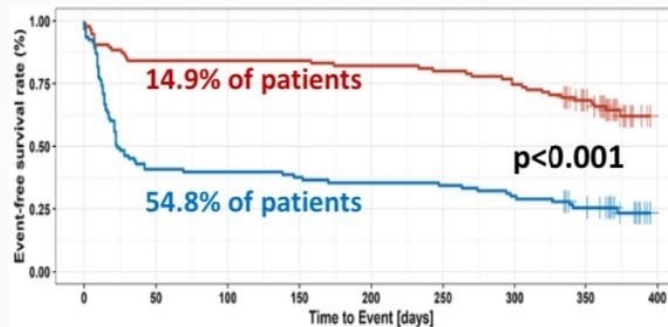


Number at risk: n (%)

TEER	96 (100)	88 (92)	88 (92)	88 (92)	88 (92)	87 (91)	84 (88)	71 (74)	0 (0)
Surgery	89 (100)	77 (87)	74 (83)	74 (83)	73 (82)	72 (81)	71 (80)	58 (65)	0 (0)

Combination of death, heart failure rehospitalization, mitral reintervention, assist device implantation, stroke

Primary safety endpoint



Number at risk: n (%)

TEER	95 (100)	80 (84)	80 (84)	80 (84)	78 (82)	76 (80)	71 (75)	57 (60)	0 (0)
surgical	93 (11)								

Major reinter infection surgery

Among patients with heart failure and secondary mitral regurgitation who were suitable candidates for isolated mitral-valve surgery according to current practice, transcatheter edge-to-edge repair was noninferior to surgery with respect to a composite of death, hospitalization for heart failure, reintervention, implantation of an assist device, or stroke at 1 year after the procedure.

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