CRT 21 Virtual

AorticLab Embrace Transcatheter Antiembolic Filter

Filippo Scalise

Filippo Scalise, MD

I have no relevant financial relationships

TAVR growth

NEWS • INTERVENTIONAL

US TAVR Cases Pass a Quarter Million, Surpassing Surgery: Key Trends

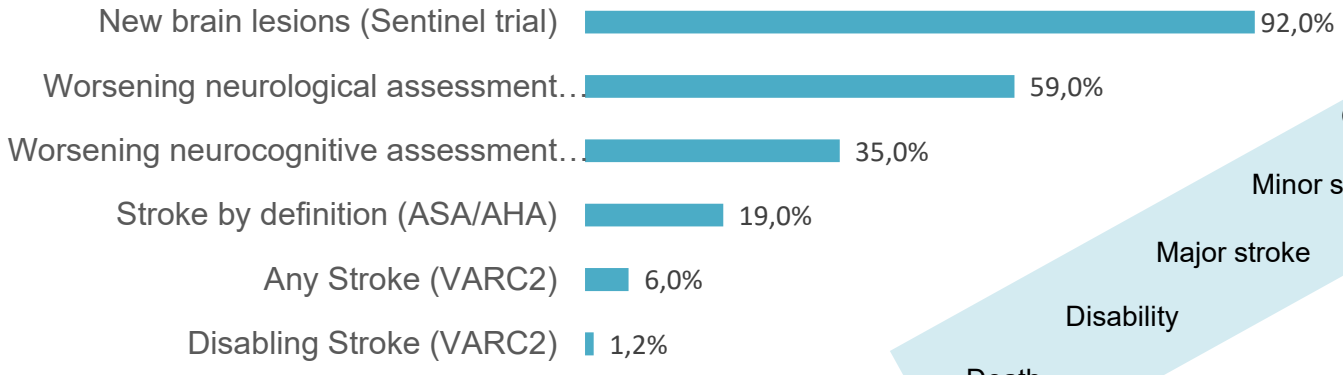
Nine years of TVT Registry data show deaths are down, but pacemakers, stroke, and racial/ethnic disparities merit attention.

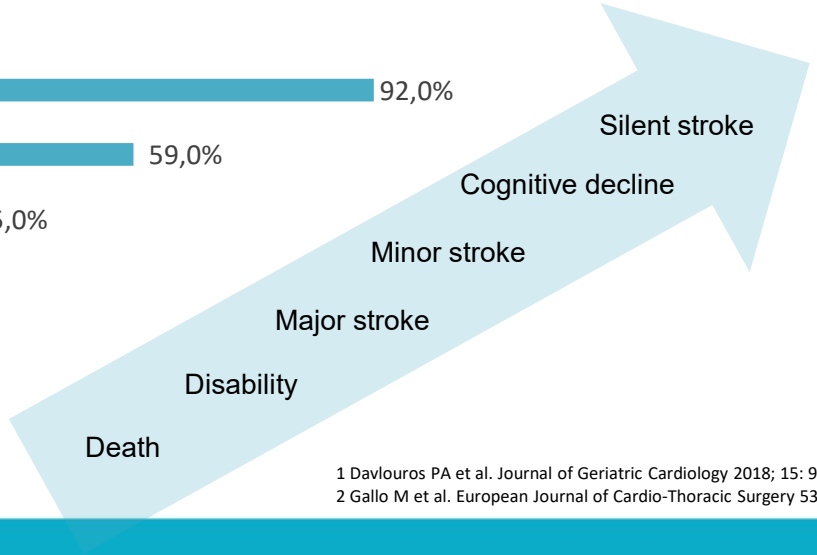
TAVR is growing fast, beating SAVR in numbers, but still presents subclinical results, as stroke, that need attention.

The TAVR procedure carries an inherent risk of stroke

Stroke is confined mainly in the periprocedural and 30-day period following TAVR and it is one of the most feared complications of TAVR because of its associated severe disability and high mortality[1]

During TAVR cerebrovascular accidents can occur at any time[2]



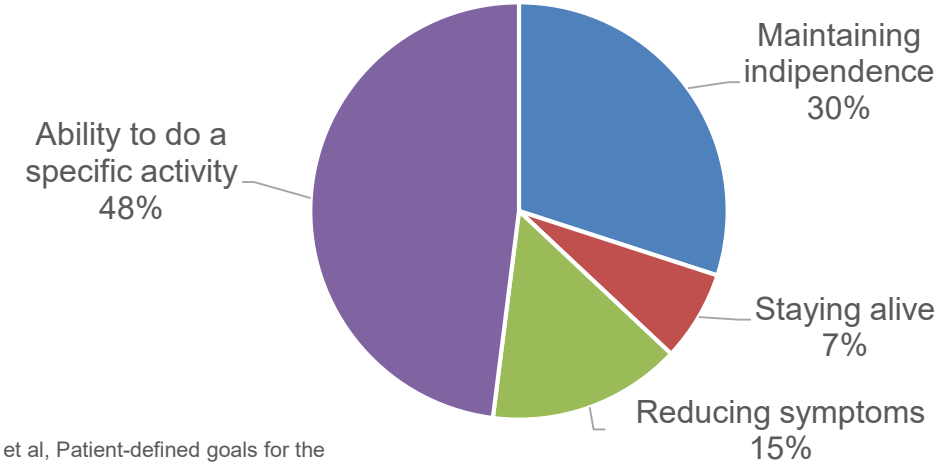


1 Davlouros PA et al. Journal of Geriatric Cardiology 2018; 15: 95-104;
2 Gallo M et al. European Journal of Cardio-Thoracic Surgery 53; 2018: 1118–26;

TAVR patients' goals

For TAVR patients is better to stay independent and active than alive.

Stroke is a major factor in these outcomes.



Source: Coylewright M., et al, Patient-defined goals for the treatment of severe aortic stenosis: a qualitative analysis

AorticLab solution

The transcatheter total body antiembolic system

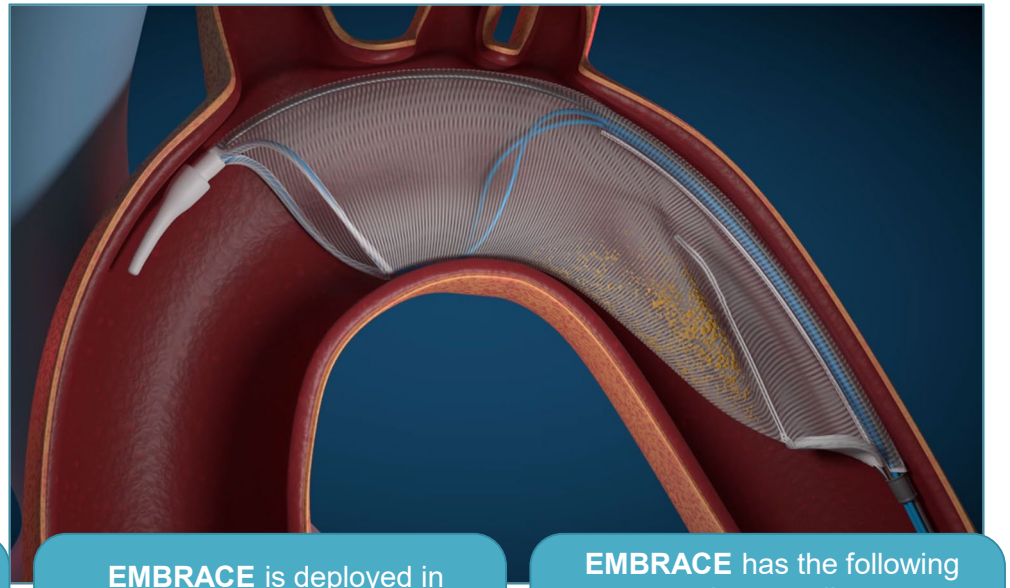

EMBRACE
WITH CATCH & FLOW TECHNOLOGY

EMBRACE – The transcatheter antiembolic filter

EMBRACE has been designed to protect cerebral and peripheral vessels

EMBRACE unique design is compatible with **ALL delivery systems**

EMBRACE will make TAVR procedures more safe in term of cerebral strokes, kidney and peripheral adverse events



Pigtail for TAVR procedures integrated in the **EMBRACE** delivery

EMBRACE is deployed in the ascending aorta in less than 5 minute and perfectly **fits with the aortic wall**

EMBRACE has the following unique quality:
≤ 70µm mesh pore
Compatibility with 12 Fr introducer for all sizes

EMBRACE In-Vitro test

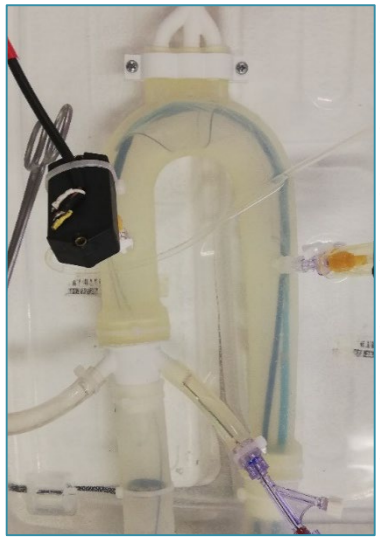
Debris capture ability test

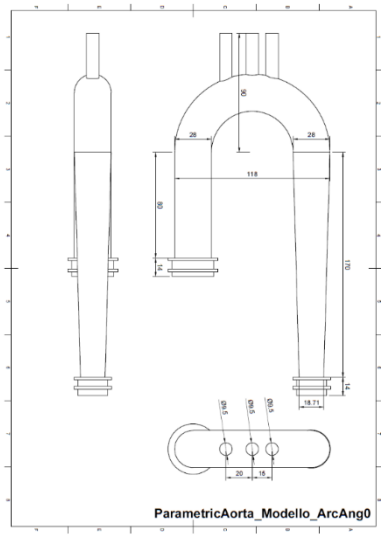
>150µm particles captured during
In-Vitro TAVR procedures

EMBRACE	Cerebral branches protection	Systemic protection
Mean±SD	99±1%	84±8%

Pressure drop

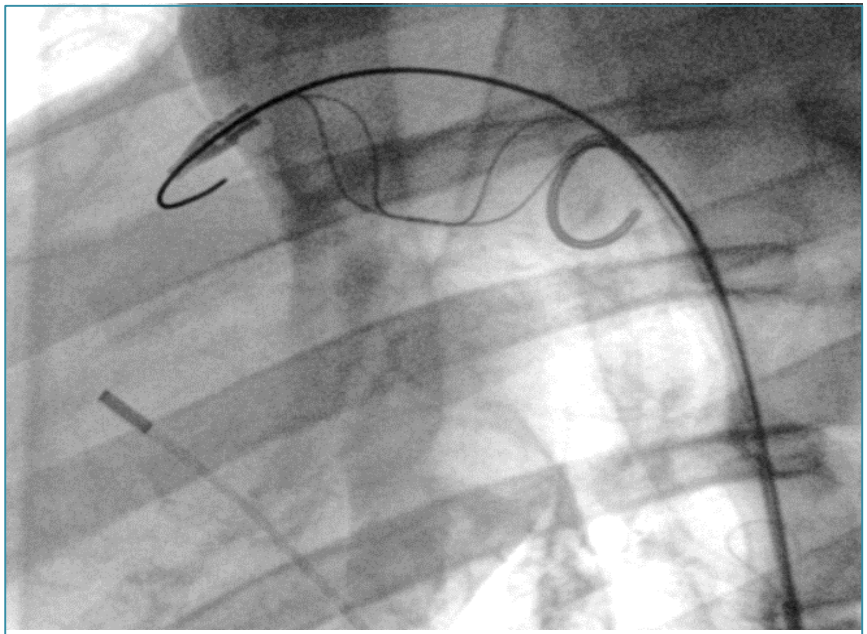
The Δp calculated through EMBRACE filter in the
In-Vitro test is **6.6 mmHg** @4,5 l/min cardiac output





EMBRACE Usability test

Cardiologists perform EMBRACE In-Vivo test



EMBRACE In-Vivo test positioning

Not simply another EPD…

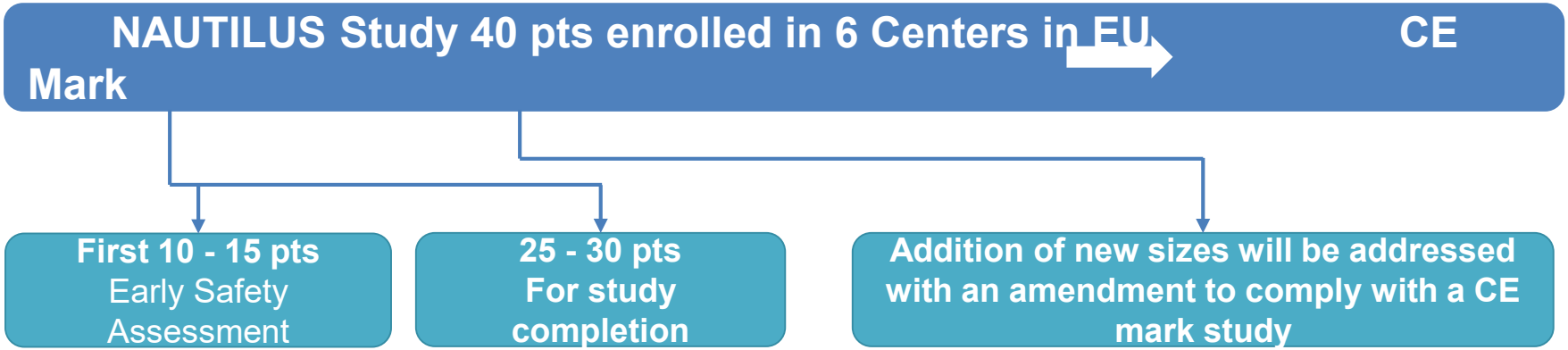
EPD	TAF	Sentinel	Triguard3	Protembo	Pointguard	Emblok	Emboliner	Captis
Cerebral protection		Not all branches covered						
Systemic protection								
Debris removal								
Stability								
Filter pore size (µm)	70	140	115x145	60	?	125	170	115x145

TAF procedural data*:

- **Timing device preparation:** within 3 minutes
- **Timing device deployment and positioning:** within 2 minutes
- **Timing device retrieve:** within 2 minutes

* Data from preclinical in-vivo tests

EMBRACE Clinical trial – Nautilus Study



Nautilus study endpoints

Performance Endpoints:	• **Technical Success** [Time Frame: immediately after procedure] defined as successful placement, insertion and removal of the EMBRACE System • **Debris capture** post-TAVR by the EMBRACE System with gross and histopathological evaluation including particle size and composition • **EMBRACE System Usability**, graded by the Investigator with a 5-point Likert scale
Clinical Benefit Endpoints:	• **Brain imaging (DW-MRI):** Acute cerebral embolic burden reduction after TAVR, defined as number and volume of new cerebral lesions in all cerebral territories assessed by DW-MRI [Timeframe: within 2-5 days after procedure vs. baseline]. • **Neurocognitive:** Neurocognitive protection assessed by NIHSS, Montreal Cognitive Assessment and mRS [Timeframe: 2-7 days and 30-days vs. baseline].

The essentials to remember

Stroke is one of the most feared complications of TAVR

Embolic protection devices act as a **mechanical barrier** to prevent emboli to reach cerebral vasculature

EMBRACE filter positioned in the aortic arch captures the debris released during the TAVR procedure with a dimension over 70µm

EMBRACE demonstrates to be quickly and easily deployed, compatible with different aortic arch geometries, stable during TAVR procedures and with a low thrombosis risk

Patients with lower risk profile and longer life expectancy, submitted to TAVR procedure, need to be protected from stroke