Interim 30-day safety outcomes in symptomatic and asymptomatic patients treated with the Roadsaver® dual-layer micromesh carotid artery stent

Evidence from a large multicentre European ROADSAVER study

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on behalf of the study investigators

Disclosure

Speaker name:

RALF LANGHOFF, MD

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

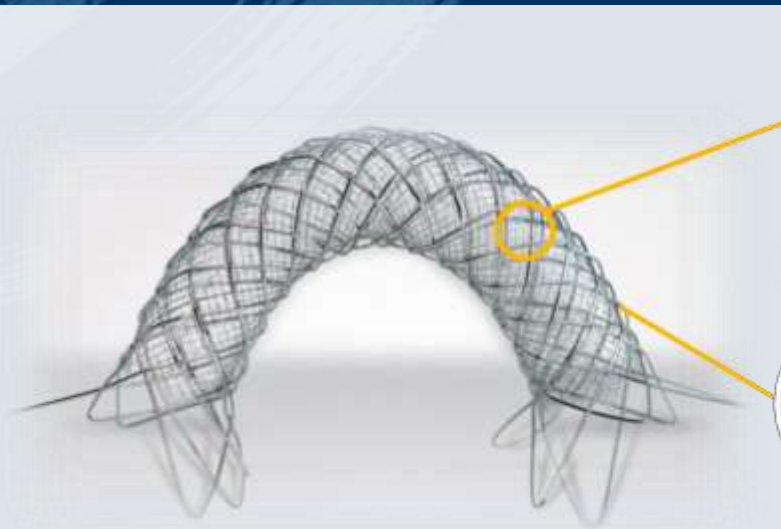
- [ ] I do not have any potential conflict of interest

Background and aim

- Peri- and early post-procedural **cerebral embolization** events related to the carotid artery stenting (CAS) warrant further attention in both **symptomatic** and **asymptomatic** patients.
- **Dual-layer micromesh stents (DLMS)** were **designed** to limit the embolization risk and provide **sustained cerebral protection** during and after CAS.
- The **ROADSAVER observational study** aims to further assess clinical performance of the **Roadsaver® DLMS in a large "real-world" European patient cohort** eligible for **elective CAS.**

Roadsaver® carotid artery stent

-Dual layer braided stent with micro-mesh technology-



Inner layer

- **Micro-mesh** with very small cell size (375-700 µm) limits plaque prolapse and embolic release

Outer layer

- **Conformability:** Braided Nitinol design allows for in-vivo stent tapering and conformability to ICA-CCA segments
- **Flexibility:** Closed cell stent with the flexibility of open cell stent, resulting in excellent vessel wall apposition in tortuous anatomy

Roadsaver® carotid artery stent

-Dual layer braided stent with micro-mesh technology-

Cell size comparison

Roadsaver　　Stent A　　Stent B

Stent C　　Stent D　　Stent E

ROADSAVER study

Design:

Prospective, single-arm, multi-center, **observational study,** with several predefined sub-analyses.

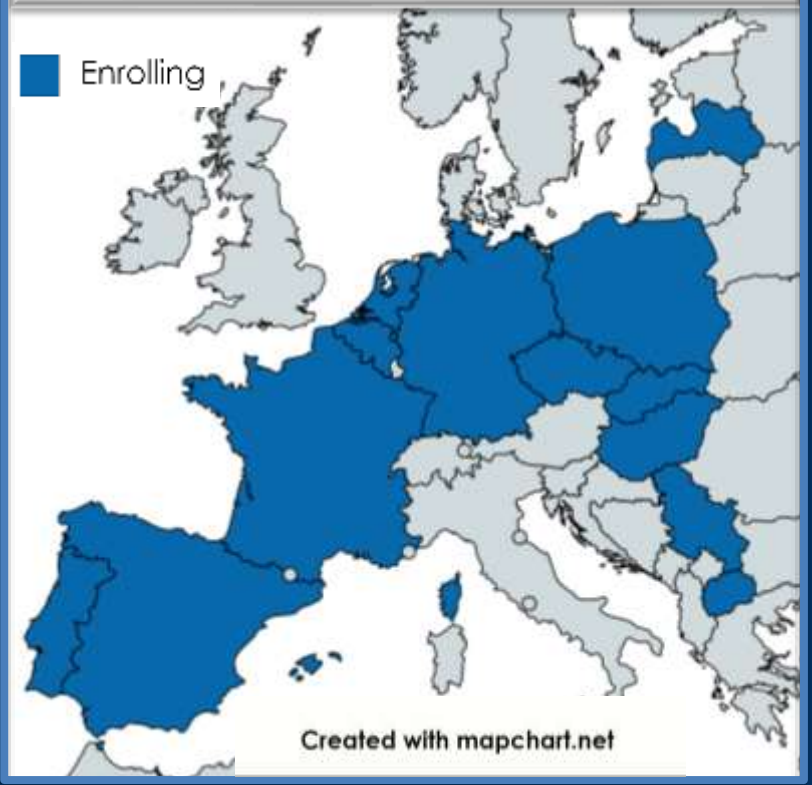
Population:

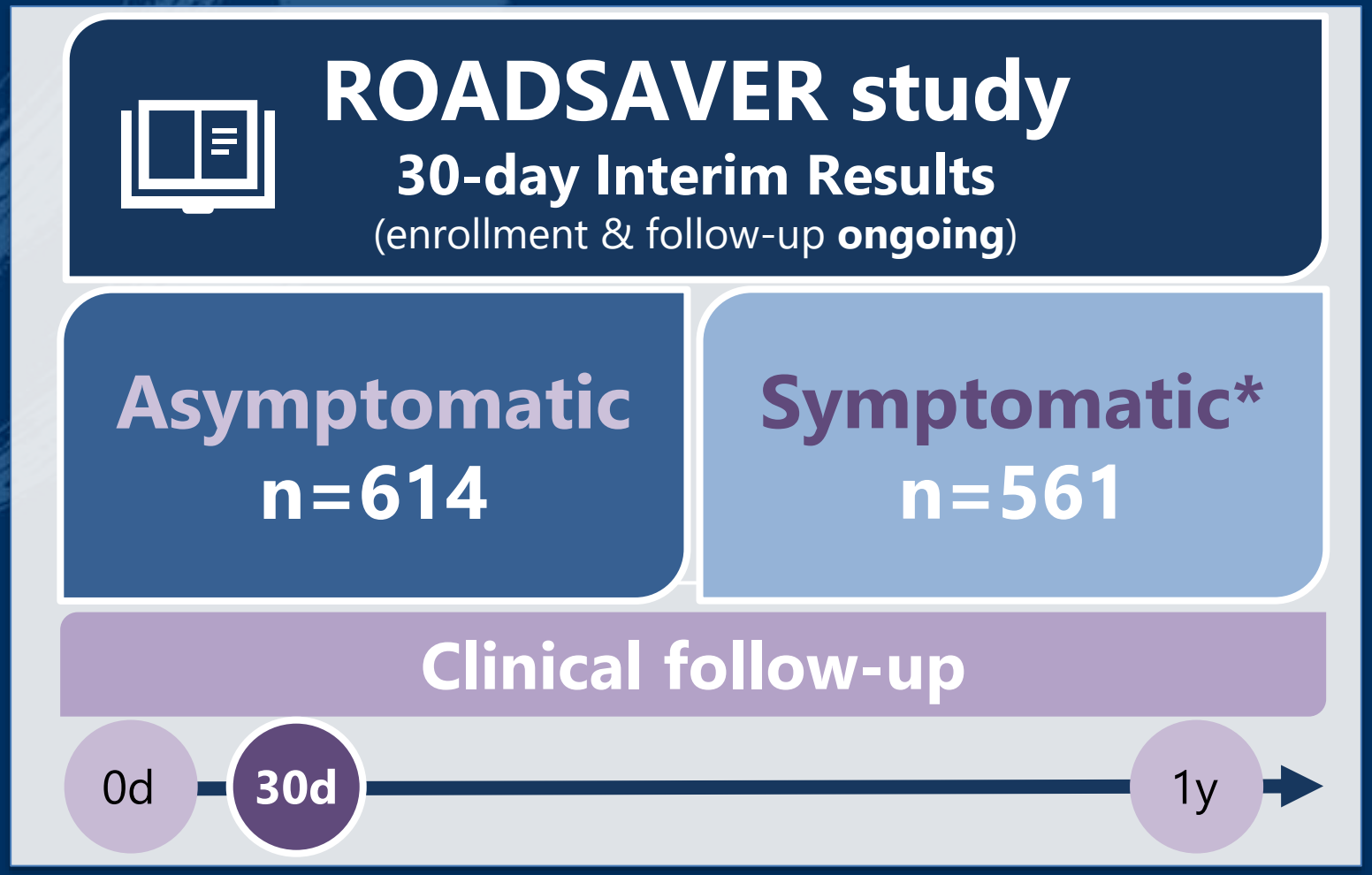
Planned enrolment of **2000** patients with **non-occlusive & non-thrombotic** carotid stenosis (minimal exclusion criteria) eligible for **elective** CAS treatment.

Primary endpoint:

The rate of **Major Adverse Events (MAE)** defined as cumulative incidence of **any death** or **stroke** up to **30 days** post-index procedure.

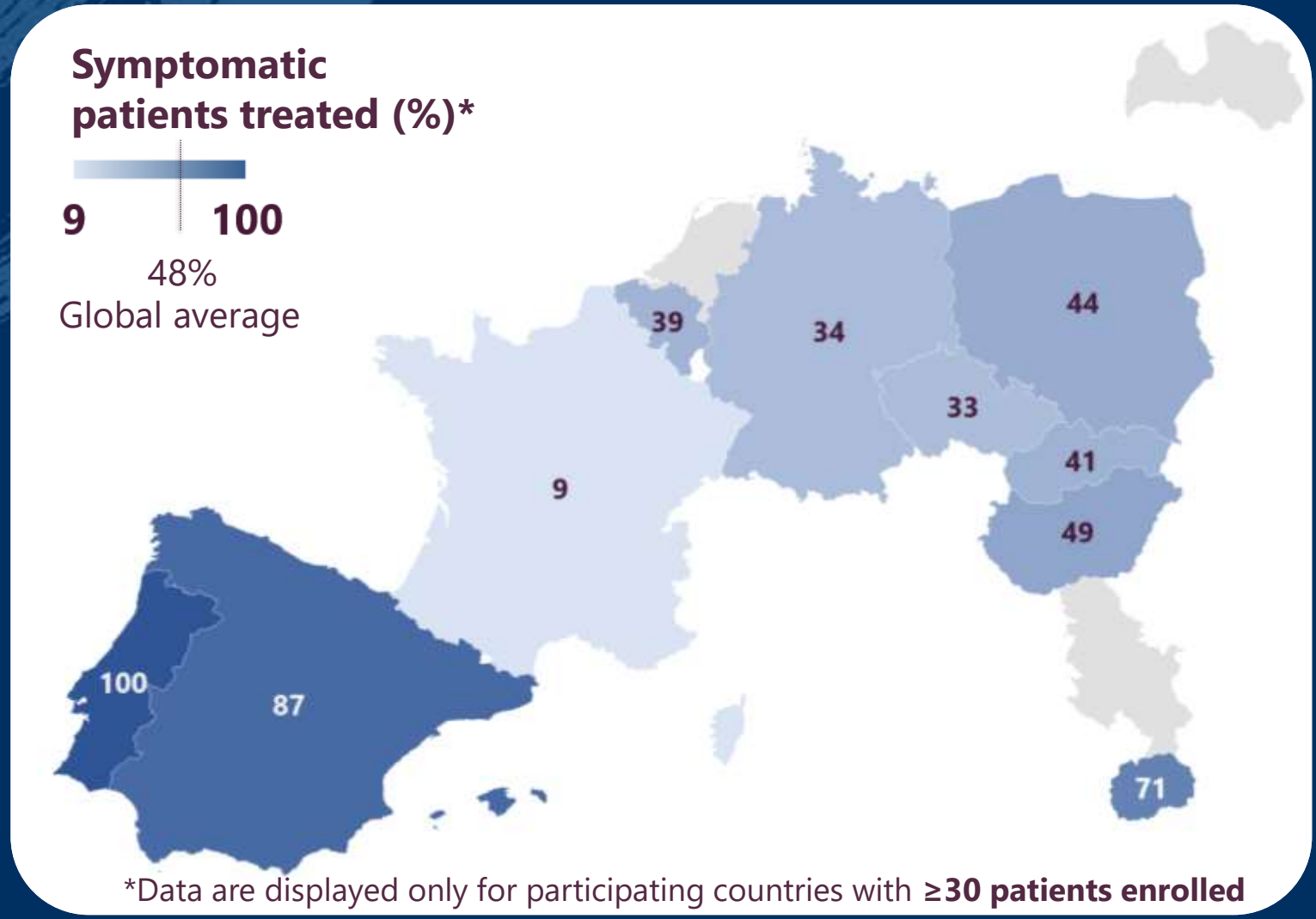
- **58 activated sites**
- **Across 13 countries**





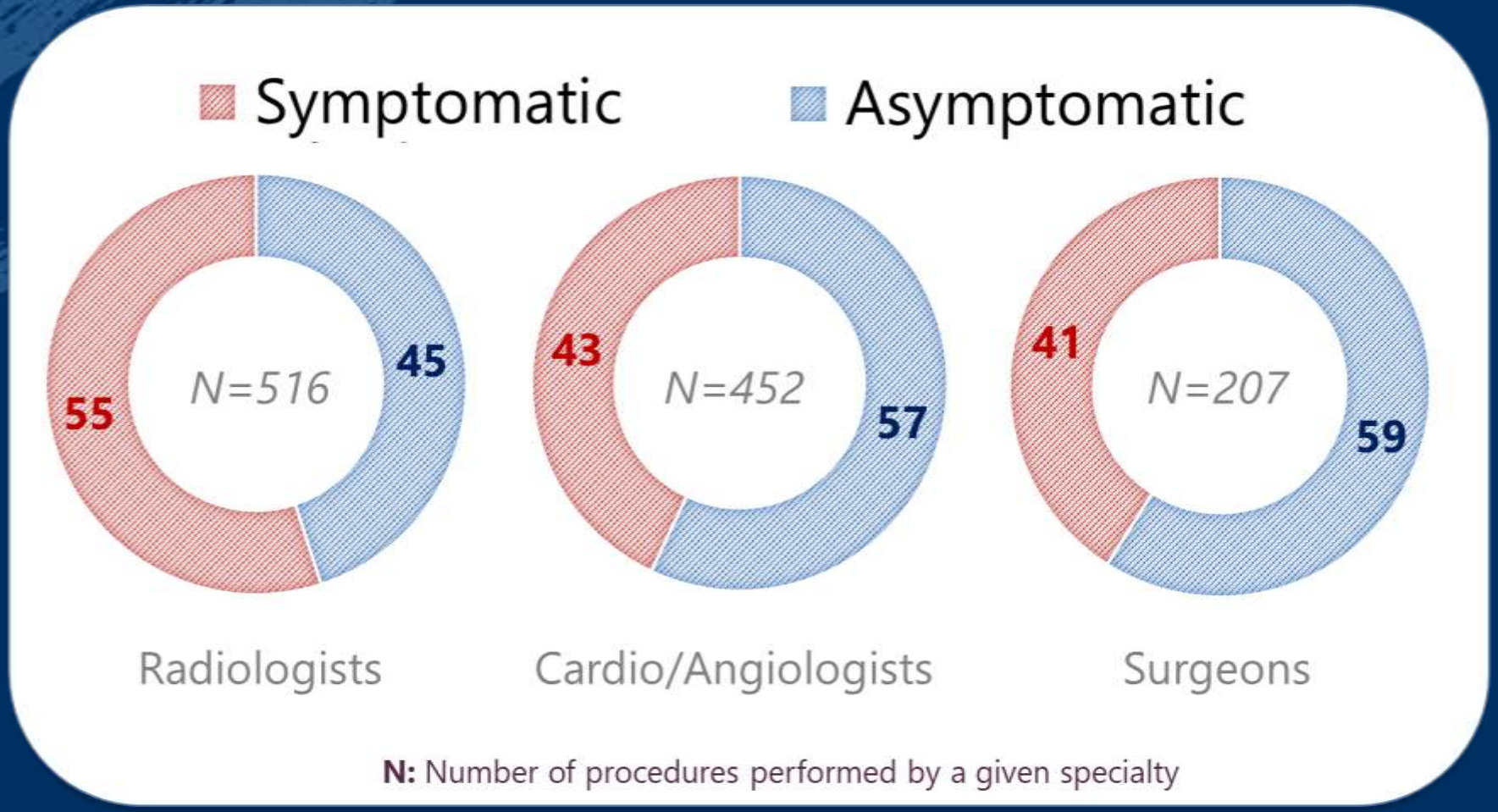
*Defined as having experienced amaurosis fugax ipsilateral to the carotid lesion, TIA or non-disabling stroke within 180 days of the procedure within the hemisphere supplied by the target vessel (for 67 patients excluded from the present analysis the symptomatic status was missing at the time of data extraction);
TIA: Transient Ischemic Attack

CAS indication per country



*Data are displayed only for participating countries with **≥30 patients enrolled**

CAS indication per physicians' specialty



N: Number of procedures performed by a given specialty

Baseline patient characteristics

mean±SD or %	Asymptomatic (n=614)	Symptomatic (n=561)	p-value
Age (years)	71.4±8.2	70.0±9.3	***0.006***
<65 years	21.5	28.9	***0.004***
<80 years	82.4	84.9	*0.26*
Gender (male)	72.0	68.3	*0.16*
Aortic arch			
Type I	47.2	56.3	***0.002***
Type II	37.8	33.3	*0.11*
Type III	9.1	6.6	*0.11*
Bovine	5.9	3.7	*0.09*

SD: standard deviation

Baseline patient characteristics

%	Asymptomatic (n=614)	Symptomatic (n=561)	p-value
Current smoker	23.8	28.2	*0.09*
Diabetes	32.6	31.8	*0.79*
Hypertension	90.0	85.9	***0.03***
Hyperlipidaemia	80.5	72.3	***0.001***
Peripheral vascular disease	31.2	24.7	***0.01***
Cardiovascular disease	47.3	28.0	***<0.0001***
Obesity	23.2	22.6	*0.81*
Previous stroke	16.8	51.9	***<0.0001***
Previous ischemic stroke	14.8	49.6	***<0.0001***
Previous TIA	7.7	30.3	***<0.0001***

Lesion characteristics

mean±SD or %	Asymptomatic n=614	Symptomatic n=561	p-value
Target lesion localisation			
Internal carotid artery (ICA)	89.8	89.3	*0.81*
Bifurcation	8.1	7.7	*0.76*
Lesion length (mm)	18.5±7.61	17.5±8.64	*0.05*
Lesion calcification	62.3	60.3	*0.50*
Lesion ulceration	27.3	28.4	*0.69*
Lesion concentricity	37.3	43.7	***0.03***
Target-vessel tortuosity	8.0	10.0	*0.23*
DS (%), pre-procedure	81.0±10.0	80.1±16.1	*0.22*
DS (%), post-procedure	7.5±11.0	6.0±9.0	***0.01***

DS: diameter stenosis as per **NASCET:** North American Symptomatic Carotid Endarterectomy Trial;
SD: standard deviation

30-day safety outcomes

% (N)	Asymptomatic n=614	Symptomatic n=561	p-value
Primary endpoint MAE (*i.e. any death or stroke*)	**1.5 (9)**	**2.7 (15)**	*0.14*
Any death	0.3 (2)	1.4 (8)	***0.04***
Stroke-related death	0.0 (0)	1.3 (7)	***0.01***
Cardiac & unknown death	0.3 (2)	0.2 (1)	*0.62*
Any stroke	1.1 (7)	2.5 (14)	*0.08*
Ipsilateral stroke	1.1 (7)	2.1 (12)	*0.18*
Ipsilateral ischemic stroke	1.0 (6)	2.1 (12)	*0.10*
Major ipsilateral ischemic stroke*	0.3 (2)	1.6 (9)	***0.02***

All deaths and strokes were adjudicated by an independent Clinical Event Committee (CEC)

***Defined as neurological event that persists for > 24 hours and results in a > 4 points increase in the NIHSS score compared to baseline or any subsequent lower score. **MAE:** Major Adverse Event; **N:** number of events

Conclusions

- The present 30-day interim analysis of the ROADSAVER study in patients with symptomatic and asymptomatic carotid artery disease demonstrated:
  - **Unequal patient selection** preferences across European countries and medical specialties.
  - **Low** and **comparable rate** of **any death or stroke** in symptomatic and asymptomatic patients.
  - **Higher rate of major stroke** and **stroke-related deaths** in symptomatic vs asymptomatic patients.
- Overall, the study confirms the **safety of CAS with Roadsaver® DLMS** in a **large, contemporary pan-European** patient cohort.