proximAl pRotection with the MO.ma device dUring caRotid stenting

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Speaker Disclosure for Robert M. Bersin, MD

The following relationships exist related to this presentation: None

Off label use of products will be discussed in this presentation: None

ARMOUR Study Overview

- Prospective multicenter (US and EU) single arm IDE trial to evaluate the safety and effectiveness of the MO.MA device for cerebral protection in *high surgical risk* CAS candidates with *any FDA approved carotid stent*
  - **Primary Endpoint:** Major adverse cardiac and cerebrovascular events (MACCE: MI, stroke, death) at 30 days
  - **Number of Investigational Sites:** 25 (20 US + 5 EU)
  - **Number of patients:** 225 study subjects (ITT) + 37 roll-in
  - Independent Clinical Event Committee, Data Safety Monitoring Board, Angio and DUS Core labs

Study Investigators and Core Laboratories

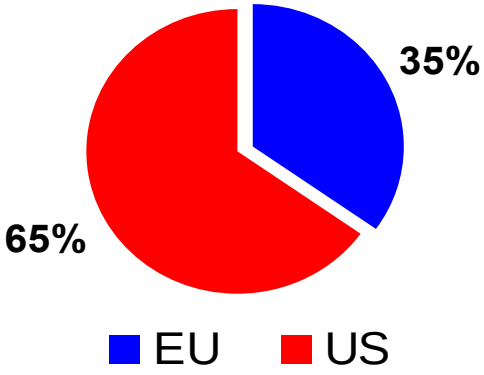
20 Sites US

Gary Ansel - Columbus, OH
Mike Bacharach - Sioux Falls, SD
Robert M.Bersin – Seattle, WA
Michael Dahn – Farmington, CT
Tony Das – Dallas, TX
Rajesh M. Dave – Harrisburg, PA
Bruce Gray – Greenville, SC
Richard Heuser – Phoenix, AZ
L. Nelson Hopkins - Buffalo, NY
Barry Katzen – Miami, FL
John R. Laird – Sacramento, CA
James R. Margolis – Miami, FL
Gregory J. Mishkel – Springfield, IL
Subbarao Myla – Newport Beach, CA
Issam D. Moussa - New York, NY
Stephen R. Ramee - New Orleans, LA
Kenneth Rosenfield – Boston, MA
Gary Roubin – New York, NY
Robert Safian - Royal Oak, MI
Lowell Satler – Washngton, DC

5 Sites EU

Alberto Cremonesi – Cotignola, Italy
Horst Sievert – Frankfurt, Germany
Dierk Scheinert – Leipzig, Germany
Paolo Rubino – Mercogliano, Italy
Dariusz Dudek – Kracow, Poland

225 Study Subjects



Core Laboratories

VasCore – Michael Jaff, DO
Brigham & Women's – Jeffrey Popma, MD

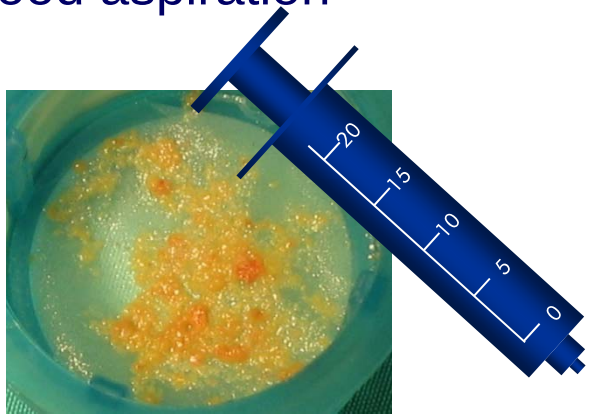
Principal Investigators

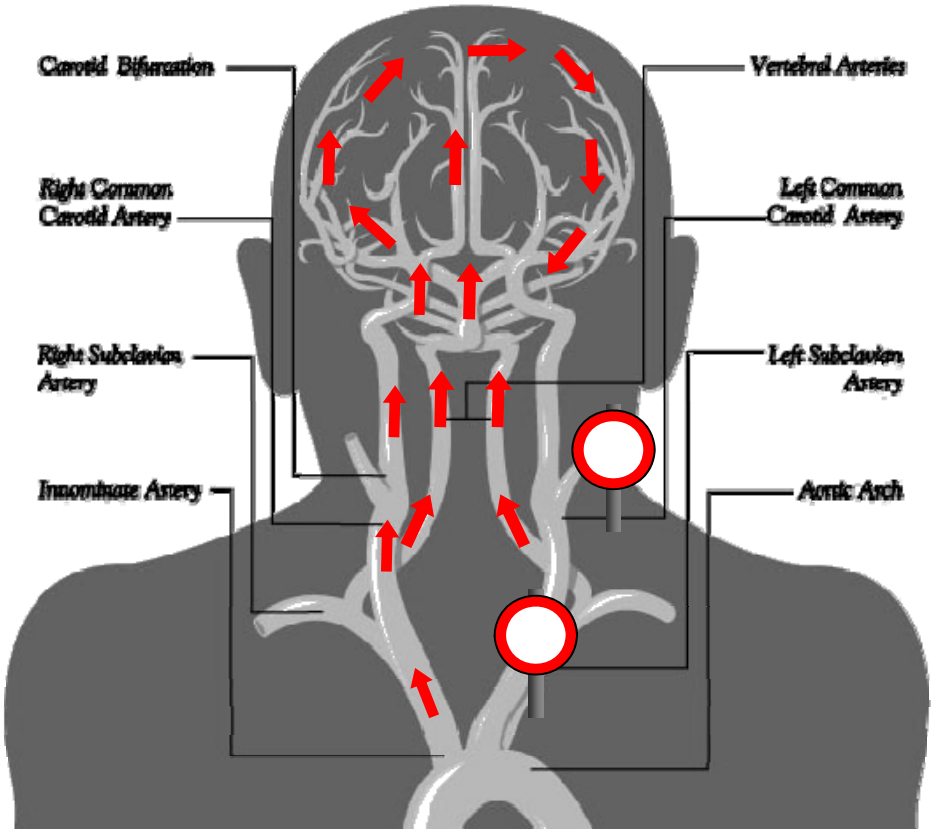
Gary Ansel, MD – Columbus, OH
L. Nelson Hopkins, MD – Buffalo, NY

MO.MA Overview

Proximal Flow Blockage Cerebral Protection Device

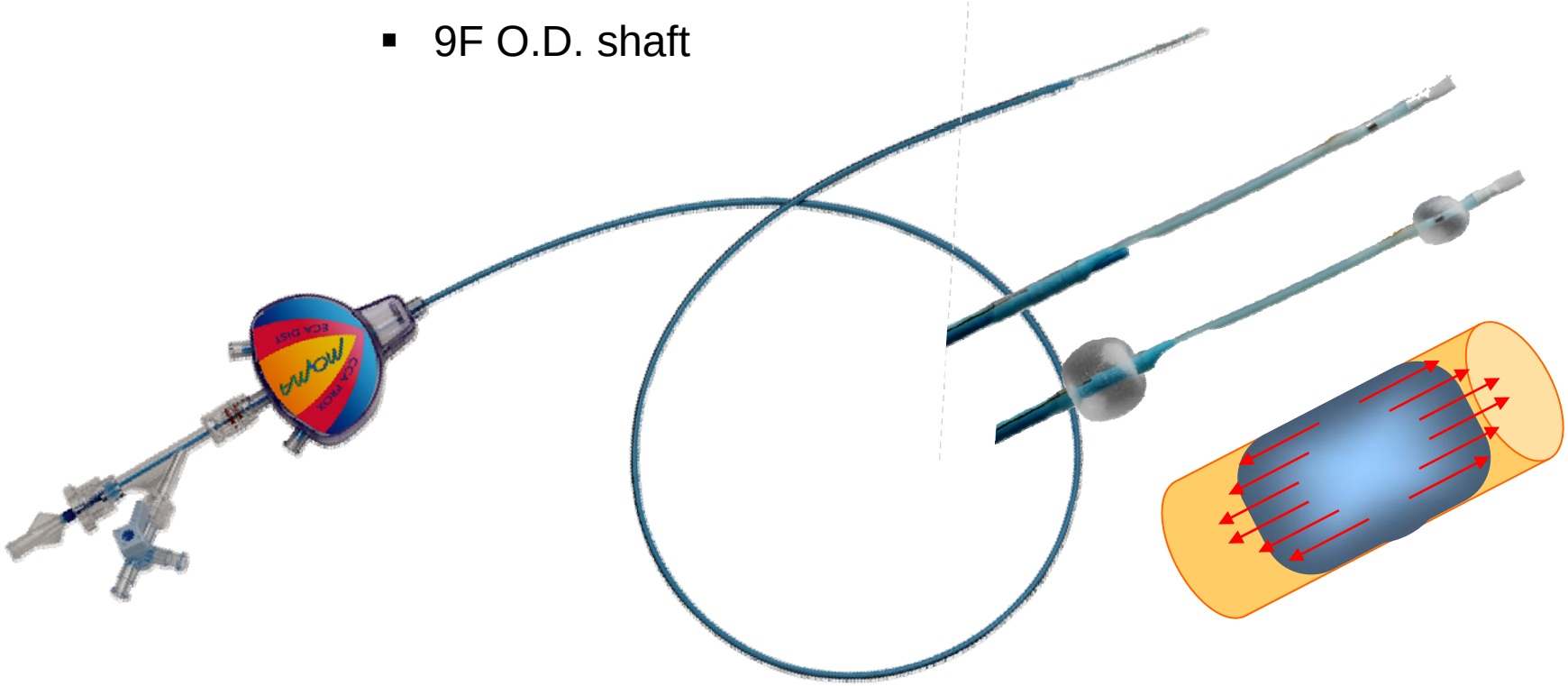
- **CCA clamping:** blockage of antegrade blood flow
- **ECA clamping:** blockage of retrograde blood flow
- **Debris removal:** syringe blood aspiration



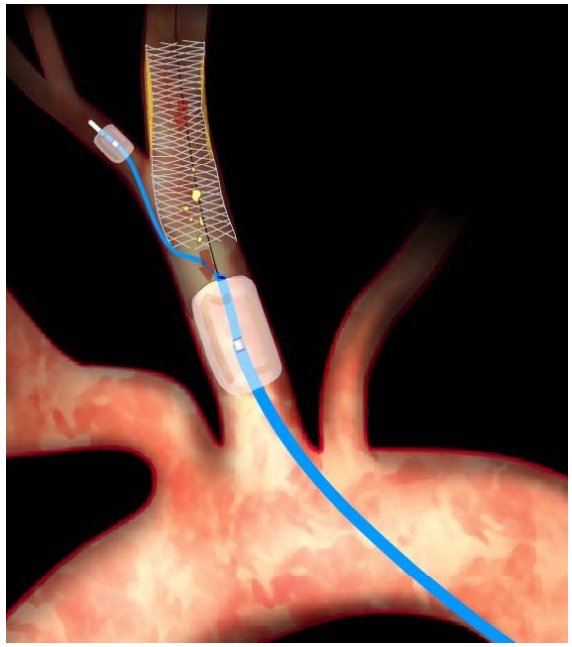


MOMA Overview

- Guiding Sheath integrating 2 compliant balloons
  - 6F I.D. fully usable Working Channel
  - 9F O.D. shaft



MO.MA Key Facts

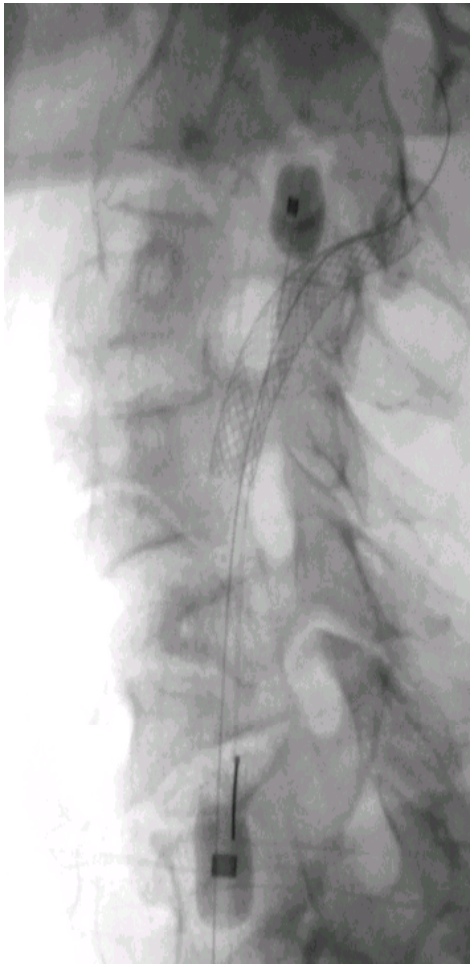


- Guiding sheath with 2 anchoring balloons
  - high system stability and back-up support
  - guide wire of choice to cross the lesion
- Lesion crossing under protection
- No need for suitable landing zone in the distal diseased ICA
- All type and size debris aspiration

Case Example

Procedural Steps

1. Mo.Ma device introduction
2. ECA balloon inflation
3. CCA balloon inflation
4. Guidewire to cross ICA lesion
5. PTA/Stent placement
6. Aspiration of blood and debris



Key Eligibility Criteria

ARMOUR

- Target lesion within the ICA and/or the carotid bifurcation
  - ≥ 80% DS for Asymptomatic subjects or
  - ≥ 50% DS for Symptomatic subjects

and

≥ 1 High Surgical Risk Criteria:

Clinical

- **Age > 75**
- **CCS Angina class 3-4 or UA**
- **CHF Class III-IV**
- **LVEF < 35%**
- **MI < 6 weeks**
- **Coronary artery disease with >2 vessel disease in major vessel & history of angina**
- **Severe pulmonary disease**
- **Permanent contralateral cranial nerve injury**

Anatomical

- **High cervical lesion**
- **Tandem lesions > 70%**
- **Hostile neck**
- **CEA restenosis**
- **Cervical immobility due to fusion or arthritis**
- **Bilateral carotid stenosis, both requiring treatment**

Key Exclusion Criteria

- Key Exclusion Criteria
  - TIA or amaurosis fugax within 48 hours
  - MI within 72 hours
  - CABG or vascular surgery within 30 days
  - Stroke or retinal artery occlusion within 30 days
  - Total occlusion of the target carotid artery
  - CCA ostial stenosis requiring treatment
  - Aortic arch anatomical anomalies precluding safe placement of the device

Baseline Demographics

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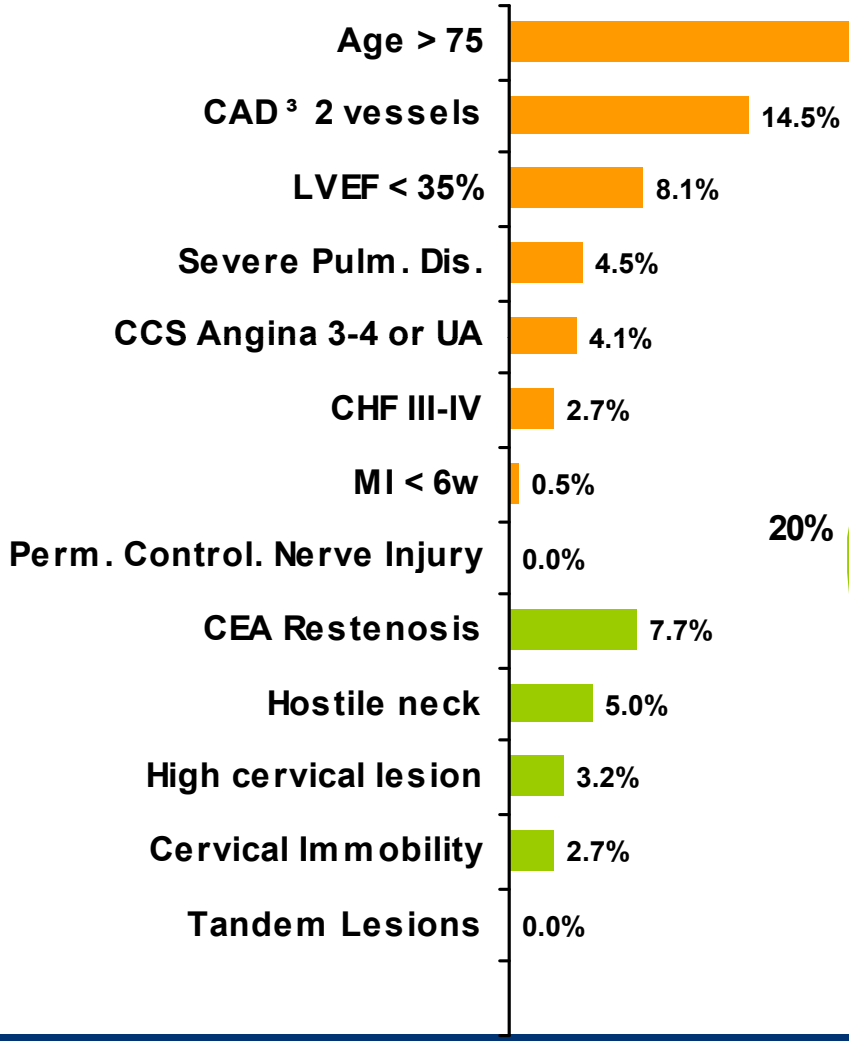
Demographics and Clinical

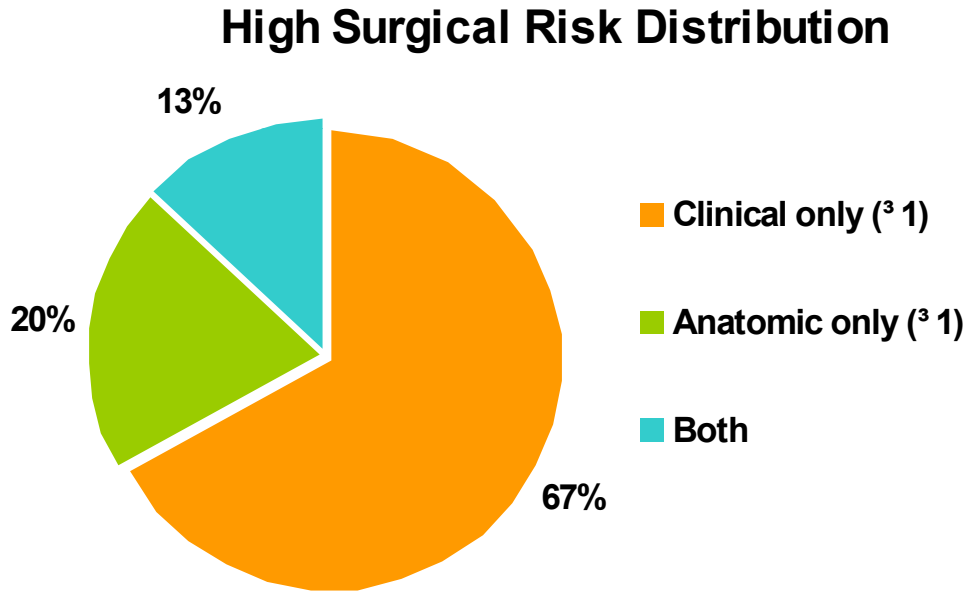
Nr of Patients (ITT)	220
Male gender	66.7%
Age (mean ± SD)	74.66±8.54
Octogenarians	28.88%
Age > 75y	56.1%
Symptomatic	15.1%
Diabetes	37.1%
Current Smokers	15.1%
Hypertension	87.1%

Lesion and Anatomy

Lesion length (mm)	13.37±5.57
%DS	72.15±10.50
Eccentric lesion	43.3%
Severe calcification	67.4%
Ulceration	7.8%
Right ICA (%)	54.0%
Aortic Arch	Type I = 64% Type II = 29.3% Type III = 6.7% Bovine = 16%

High Surgical Risk Distribution (ITT)

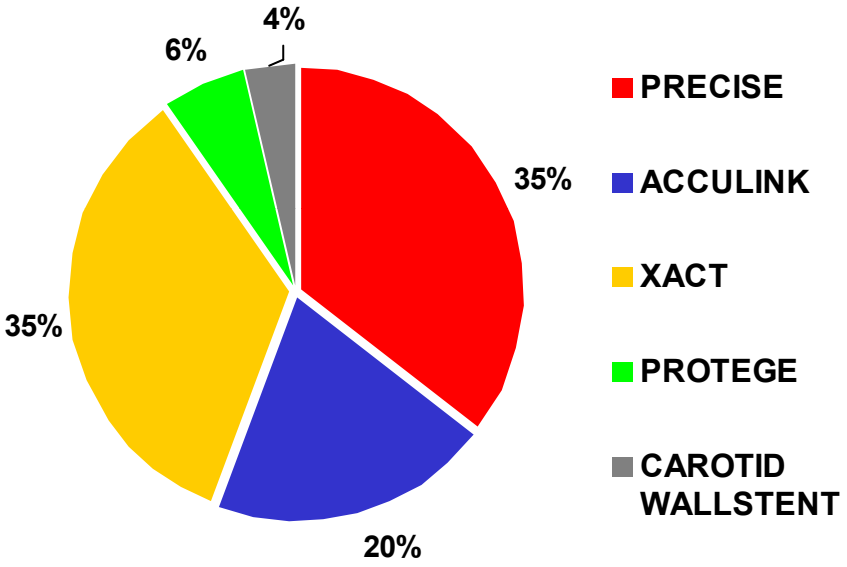




Lesion, Procedural Characteristics (ITT)

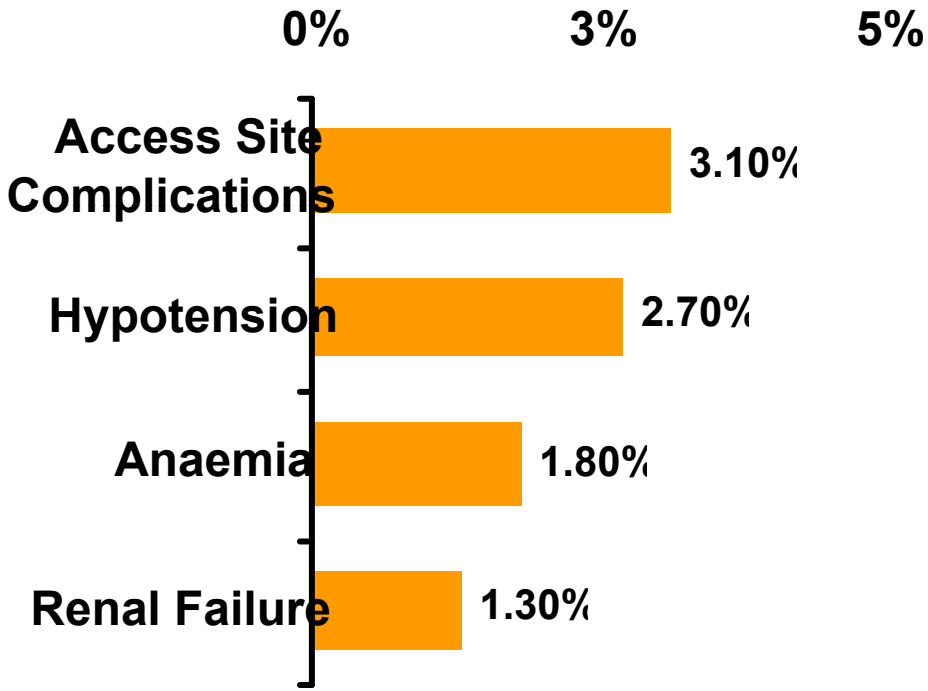
Procedural time (min)	38.35±21.20
Clamping time (min)	6.71±3.82
Collected debris	44%
Back Pressure (mm Hg)	55.38±24.19
Lesion pre-dilatation	57.1%
Stent post-dilatation	97.4%
Device Success [1]	98.2%
Technical Success [2]	94.6%
Procedural Success [3]	93.2%

Carotid Stent Distribution



1. **Device Success:** ability to position, deploy and retrieve the intact MO.MA device during the index procedure
2. **Technical Success:** Device Success + ability to successfully implant a carotid stent and obtain a residual stenosis < 30% during the index procedure (evaluated by the Angio Corelab)
3. **Procedural success:** Technical success without the occurrence of any MACCE or unresolved antegrade flow blockage intolerance during the index hospitalization

Serious Adverse Events



- **Site reported SAE = 16.4% of subjects (ITT)**
- **No (0%) Unanticipated Adverse Device Effects (UADE)**

Results 1° Endpoint

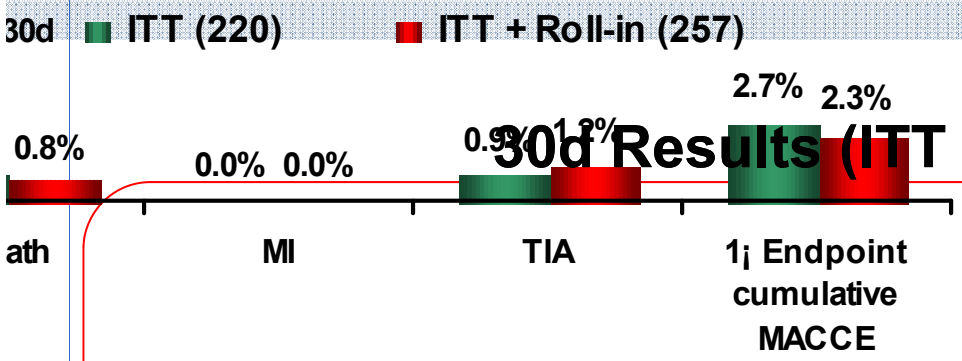
ARMOUR

	ITT (N=220)	Roll-In (N=37)	Full Analysis (N=257)
30d MACCE rate	**2.7% (6/220)**	**0.0% (0/37)**	**2.3% (6/257)**
Any myocardial infarction	**0.0% (0/220)**	0.0% (0/37)	**0.0% (0/257)**
Stroke	**2.3% (5/220)**	0.0% (0/37)	**1.9% (5/257)**
- **Minor Stroke**	**1.4% (3/220)**	0.0% (0/37)	**1.2% (3/257)**
- **Major Stroke**	**0.9% (2/220)**	0.0% (0/37)	**0.8% (2/257)**
Death	**0.9% (2/220)**	0.0% (0/37)	**0.8% (2/257)**
MACCE rate (procedural)	**1.8% (4/225)**	0.0% (0/37)	**1.5% (4/262)**
MACCE rate (at discharge)	**1.8% (4/225)**	0.0% (0/37)	**1.5% (4/262)**

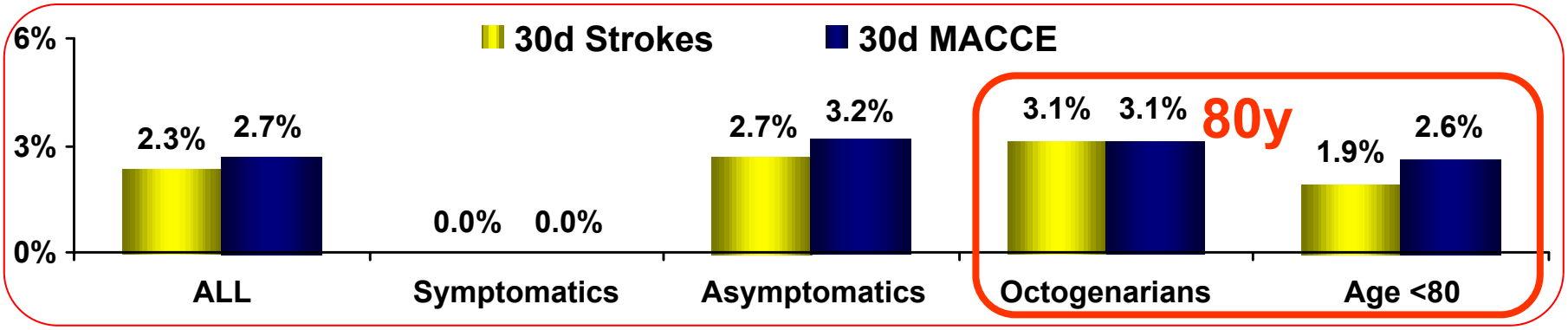
Results 1° Endpoint

ARMOUR

30d Results (ITT & Full Population)



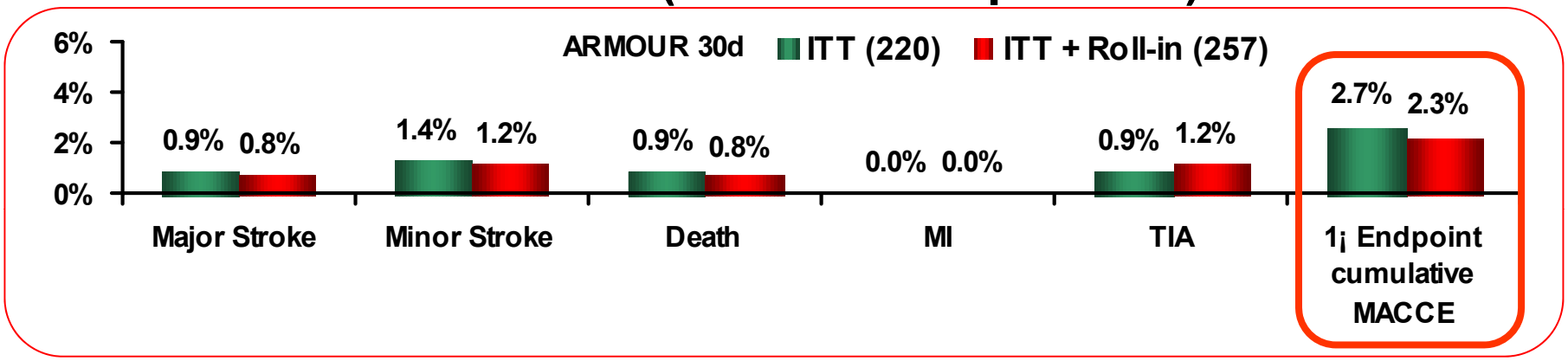
30d Results by Symptoms and Age (ITT)



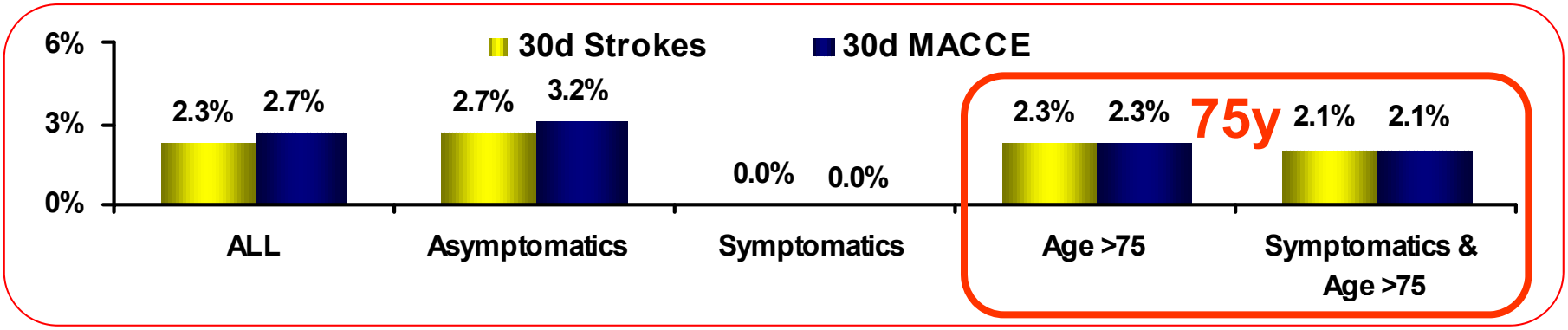
Results 1° Endpoint

ARMOUR

30d Results (ITT & Full Population)



30d Results by Symptoms and Age (ITT)



Results 2° Endpoints (ITT)

MO.MA Device Success	98.2%
Technical Success	94.6%
Procedural Success	93.2%
Restenosis at 30 days	1.6%
TLR at 30 days	0.0%
Access Site Complications	3.1%

Conclusions

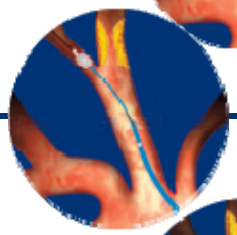
- **ARMOUR demonstrated ease of use with the MO.MA device with a limited learning curve (zero MAACE events in the lead-in phase)**
- **ARMOUR confirmed the safety and effectiveness of MO.MA proximal protection for CAS in high surgical risk patients with different FDA approved carotid stents**
- **Cumulative 30 day event rate of 2.7% in ARMOUR compares very favourably with historical and recent CAS study results**
- **There is no apparent increase risk of MACCE events in symptomatic patients or the elderly with the MO.MA device**

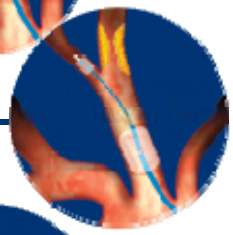
Additional Slides and Images

Simple Steps to Full-Time Proximal Cerebral Protection

1. **Placement of Mo.Ma Ultra device**

2. **Balloon Inflation**

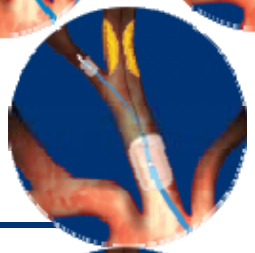




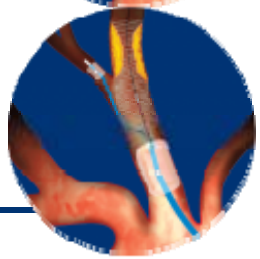
External Carotid Artery (ECA)

Common Carotid Artery (CCA)

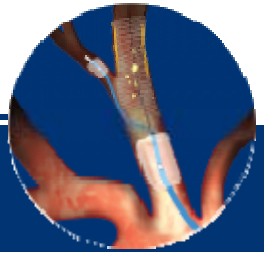
3. **Introduction of guidewire into the Internal Carotid Artery (ICA)**



4. **Placement of stent**

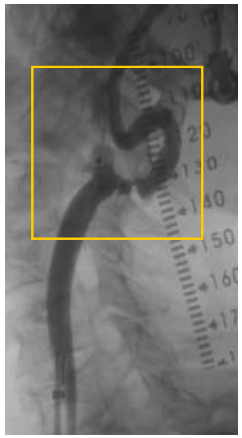


5. **Aspiration of blood and debris**

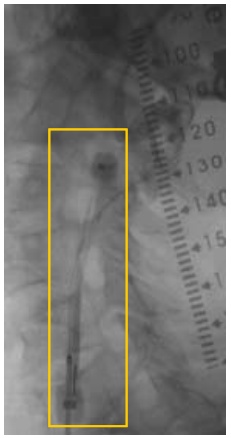


Mo.Ma Ultra- *for all your carotid needs*

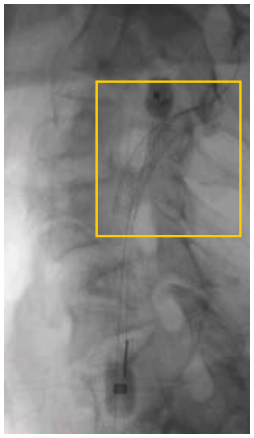
Soft ulcerated plaque…



Distal balloon inflation

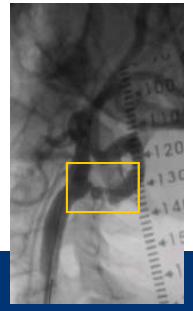


Proximal Flow Suspension



Stent deployment

…and Anatomical complexity



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MO.MA Ultra

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Final Result