EMPiRE: A Multicenter Registry Evaluating Neuroprotection During Carotid Stenting with a Novel Flow Reversal System

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GORE Flow Reversal System
Procedure Outcomes

(N=245)	Mean	(Min, Max)
Procedure Time (minutes)	80	(25, 345)
Flow Reversal Time (minutes)	15	(2, 56)
Fluoroscopy Time (minutes)	20	(6, 164)
Hospital Days	1	(0, 24)

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GORE Flow Reversal System
Procedure Technical Results

96.3% GORE Flow Reversal System Success (n=236)

3.7% GORE Flow Reversal System Technical Failure (n=9)

- **Unable to tolerate flow reversal (n=3)**
- **Balloon sheath rupture (n=2)**
- **Tortuous anatomy (n=2)**
- **Unable to position device (n=2)**

99.2% Carotid Stent Success (n=243)

i.e. tech failure does not preclude success

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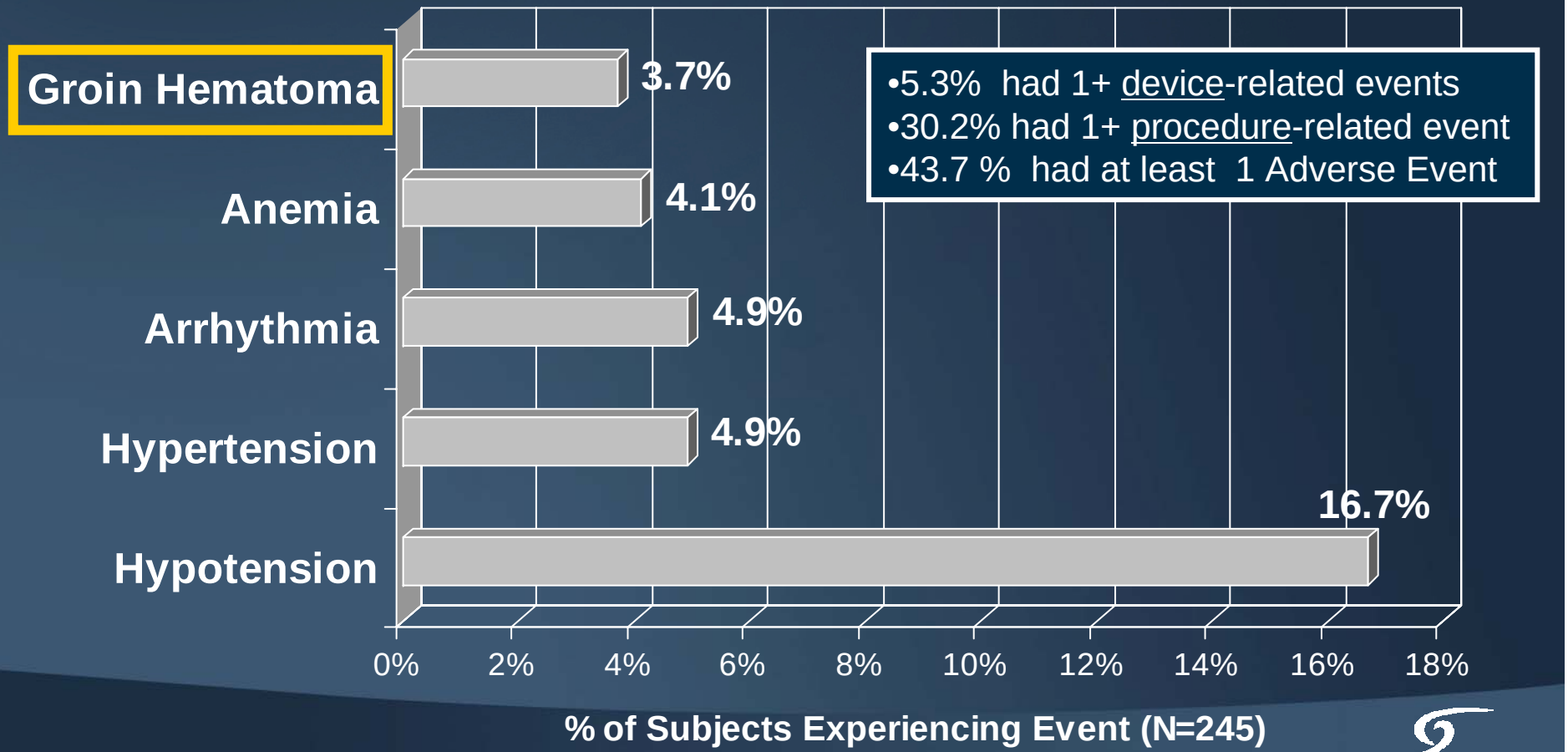
EMPiRE—Flow Reversal Intolerance

- Intolerance reported in 6 (2.4%) subjects
  - Flow Reversal successfully used in 3/6
  - Flow Reversal discontinued in 3/6
- No permanent neurological deficits—intolerance resolved when balloons deflated

EMPiRE Adverse Events



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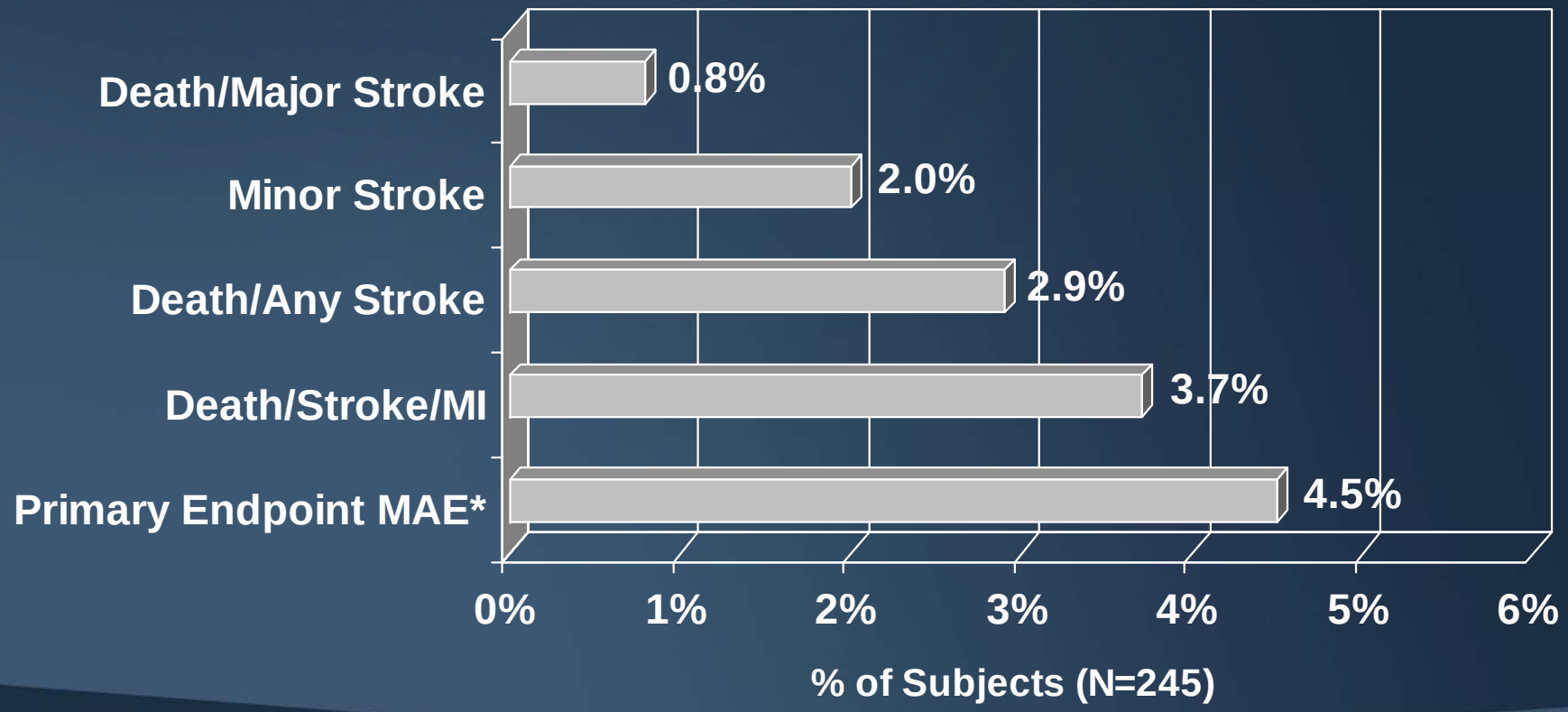
EMPiRE Major Adverse Event Rates



* Includes TIA – not typically included in CAS MAE rate

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EMPiRE Primary Endpoint: Major Adverse Events

Number of Subjects by Type of Event (Non-Hierarchical)	
All Enrolled Subjects (N=245)	N (%)
Death	2 (0.8%)
Neurological	**2 (0.8%)**
Major Stroke	2 (0.8%)
Hemorrhagic, Major Ispilateral	**1 (0.4%)**
Hemorrhagic, Major Non-Ipsilateral	**1 (0.4%)**
Minor Stroke	5 (2.0%)
Ischemic, Minor Ipsilateral	**5 (2.0%)**
Myocardial Infarction	2 (0.8%)
Non Q-Wave MI	**2 (0.8%)**
TIA	2 (0.8%)
TIA – Ipsilateral	**1 (0.4%)**
TIA – Non-Ipsilateral	**1 (0.4%)**
Subjects with One or More MAE	11 (4.5%)

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EMPiRE Major Adverse Events by Timing and Type

Onset	Description of Major Adverse Event
Day 0	Stroke - hemorrhagic, major ipsilateral (Death on Day 1)
	Stroke - ischemic, minor ipsilateral
	Stroke - ischemic, minor ipsilateral
	Stroke - ischemic, minor ipsilateral
	TIA - ipsilateral
Day 1	Non-QMI
Day 2	Stroke - ischemic, minor ipsilateral
Day 4	TIA - non-ipsilateral (ipsilateral TIA Day 12 and 13)
Day 7	Non-QMI
Day 11	Stroke - ischemic, minor ipsilateral
Day 16	Stroke - hemorrhagic, major non-ipsilateral (Death on Day 21)

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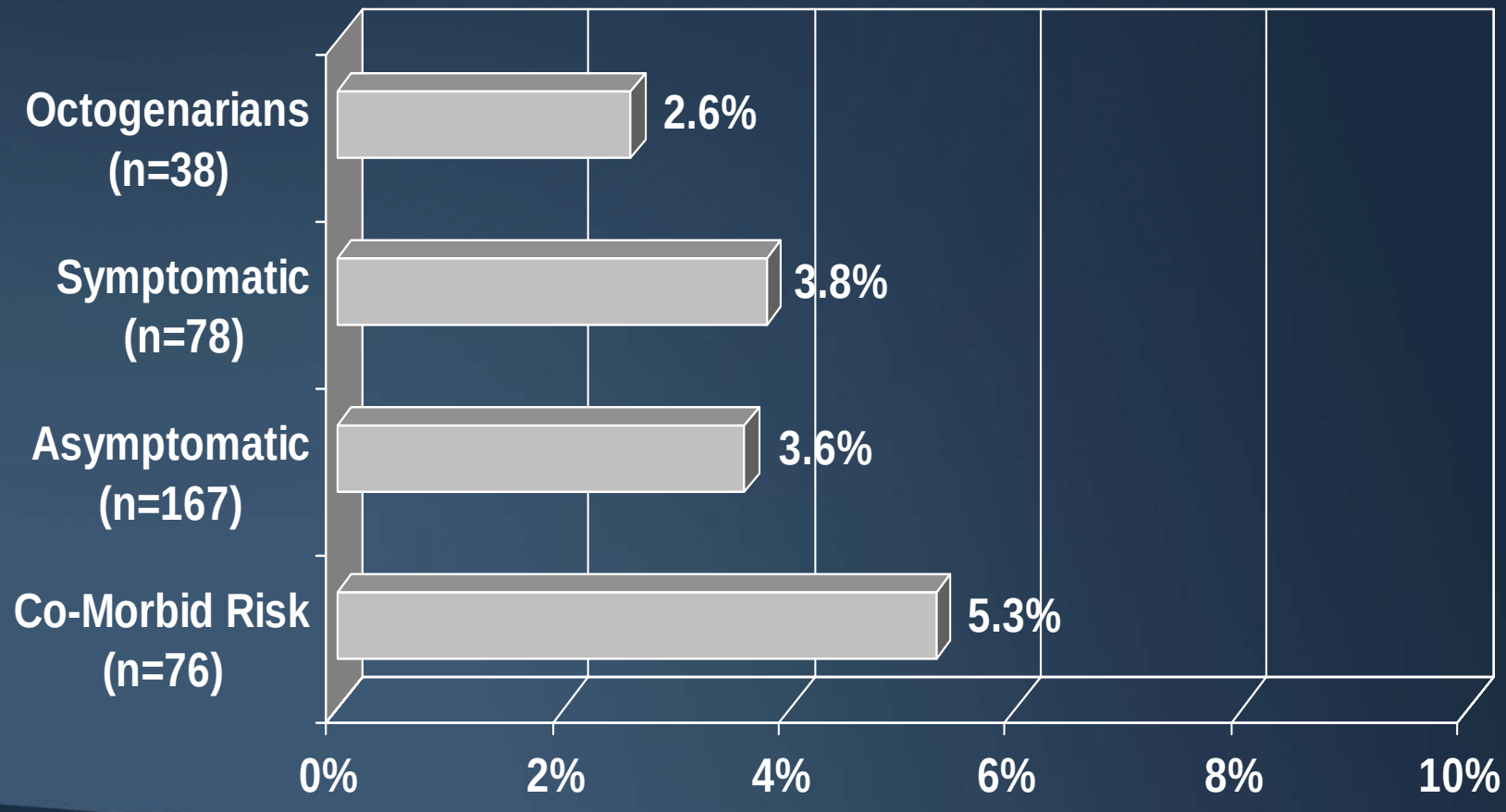
EMPiRE Major Adverse Event Rates by Subgroup (Stroke, Death, MI)



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Comparison to AHA Guidelines

- AHA Guidelines for the treatment of symptomatic and asymptomatic patients (death/stroke rates):
  - Symptomatics: 6%
  - Asymptomatics: 3%
- EMPiRE death/stroke:
  - Symptomatics: 2.6%
  - Asymptomatics: 3.0%

Summary of EMPiRE Results

- Met Study Primary Endpoint
  - Low death rate of 0.8%
  - Low death/stroke rate of 2.9%
  - Low MAE rate of 3.7% (4.5% w/ TIA)
- Low MAE rate of 2.6% for octogenarians
- Low MAE rate of 3.8% for symptomatic subjects
- Technical Success Rate of 96.3 %
- Low Intolerance Rate of 2.4%
- Acceptable access site complication rate of 3.7%

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Conclusions from EMPiRE

- GORE Flow Reversal System appears safe and efficacious for embolic protection during carotid angioplasty and stenting
- GORE Flow Reversal System offers potential advantages over other embolic protection devices:
  - Embolic debris is directed away from the brain
  - Not necessary to cross target lesions unprotected
  - Provides option for patients with unsuitable anatomy for distal embolic protection (e.g., tortuous ICA, limited landing zone)