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Proximal Flow Control System (Mo.Ma) for CAS:
Stop Flow and Block Stroke

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Protection methods

- Distal anti-embolic measures
  - Distal balloon occlusion
    - PercuSurge GuardWire (Abbott)
  - Distal filtering devices
    - FilterWire, Spider FX, NeuroShield, AccuNet

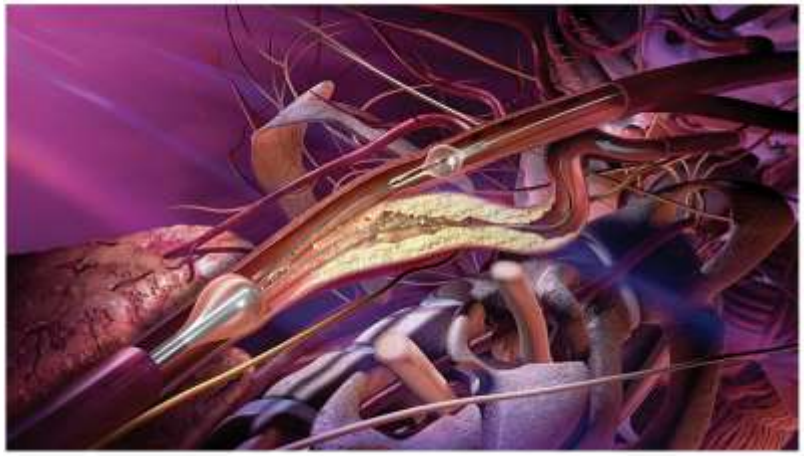
- Proximal anti-embolic measures
  - Flow arrest by occluding the ECA and CCA simultaneously
    - Mo.MA Ultra
  - Flow reversal with use of balloon occlusion catheters
    - PAES (Parodi AntiEmbolic System)
    - Gore Flow reversal system
    - Transcervical technique

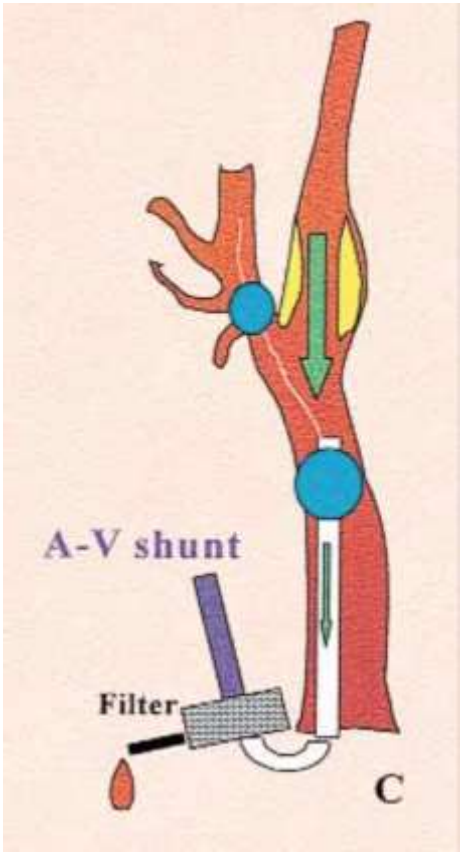
Personal experience with distal protection devices

- PercuSurge
  - To cumbersome to handle
- FilterWire
  - Not infrequent difficulty in lesion cross
  - Flow arrest with profuse debris
  - Device-related vasospasm
- Spider FX
  - Not infrequent tangling with open-cell stent mesh hampering capture catheter insertion
  - Insecurity in protection!

Proximal carotid protection with
Proximal Flow Control System

- Flow reversal
  - Parodi Anti-Embolic System (PAES, ArteriA)
  - Gore Flow reversal system (GORE)
- Flow arrest (Endovascular clamping)
  - Mo.Ma Ultra

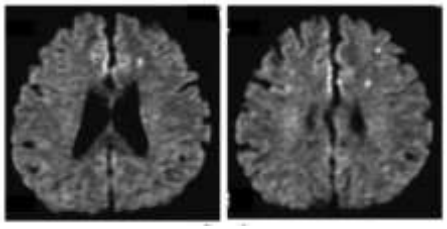




Flow Reversal with PAES

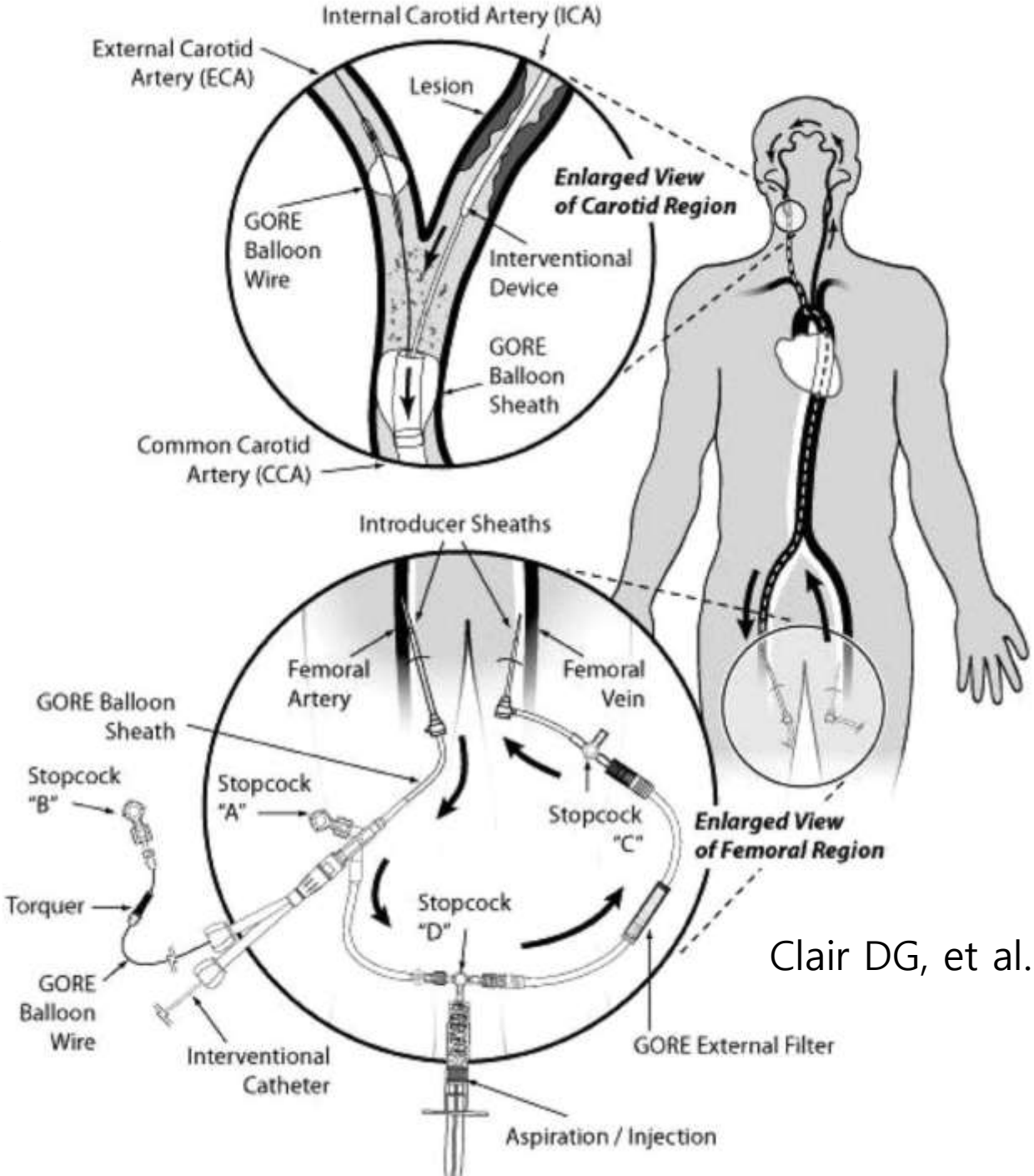
- Use of the Parodi anti-embolism system: Italian trial results.
  - Successful flow reversal in 28 of 30 patients
  - A complete absence of MES

- DWI after CAS done under reversed carotid flow
  - CAS with PAES in 70 pts, diagnostic coronary angiography as control
  - DWI HSI comparison: 18.2% vs 11.5% (p=.62 Fisher exact test)



Adami C, et al. JET 2002
Asakura F, et al. AJNR 2006

GORE Flow Reversal System



Clair DG, et al. CCVI 2011

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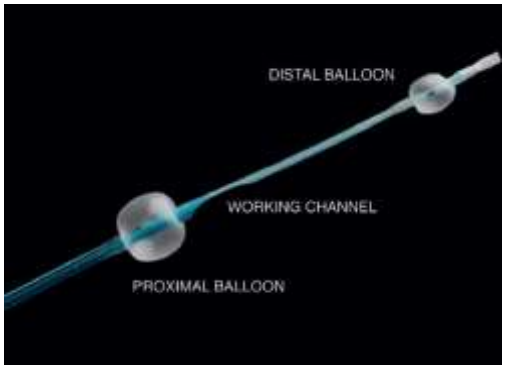
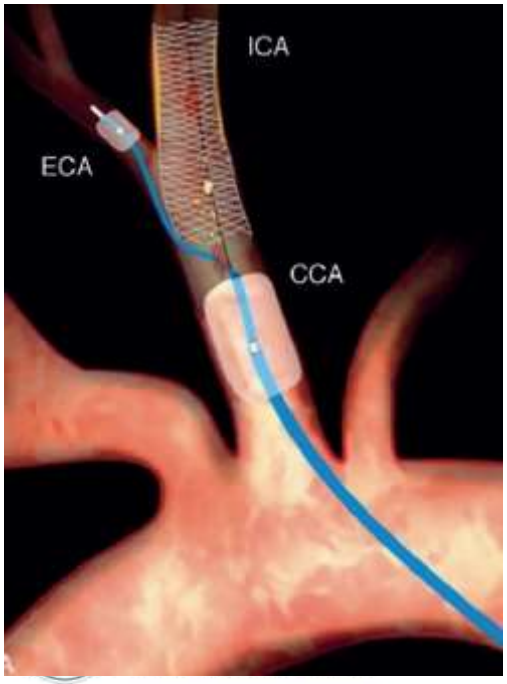
EMPiRE Study

- Embolic Protection with Reverse Flow clinical study
  - 30-day outcome with GORE system
- 245 subjects
  - MAE (including TIA) within 30 days
  - Intolerance to flow reversal 2.4%
- Results
  - 4.5% all MAE
  - Stroke and death 2.9%
  - Major stroke 0%
- The stroke and death rate in this study was among the lowest in CAS trials.

Clair DG, et al. CCVI 2011

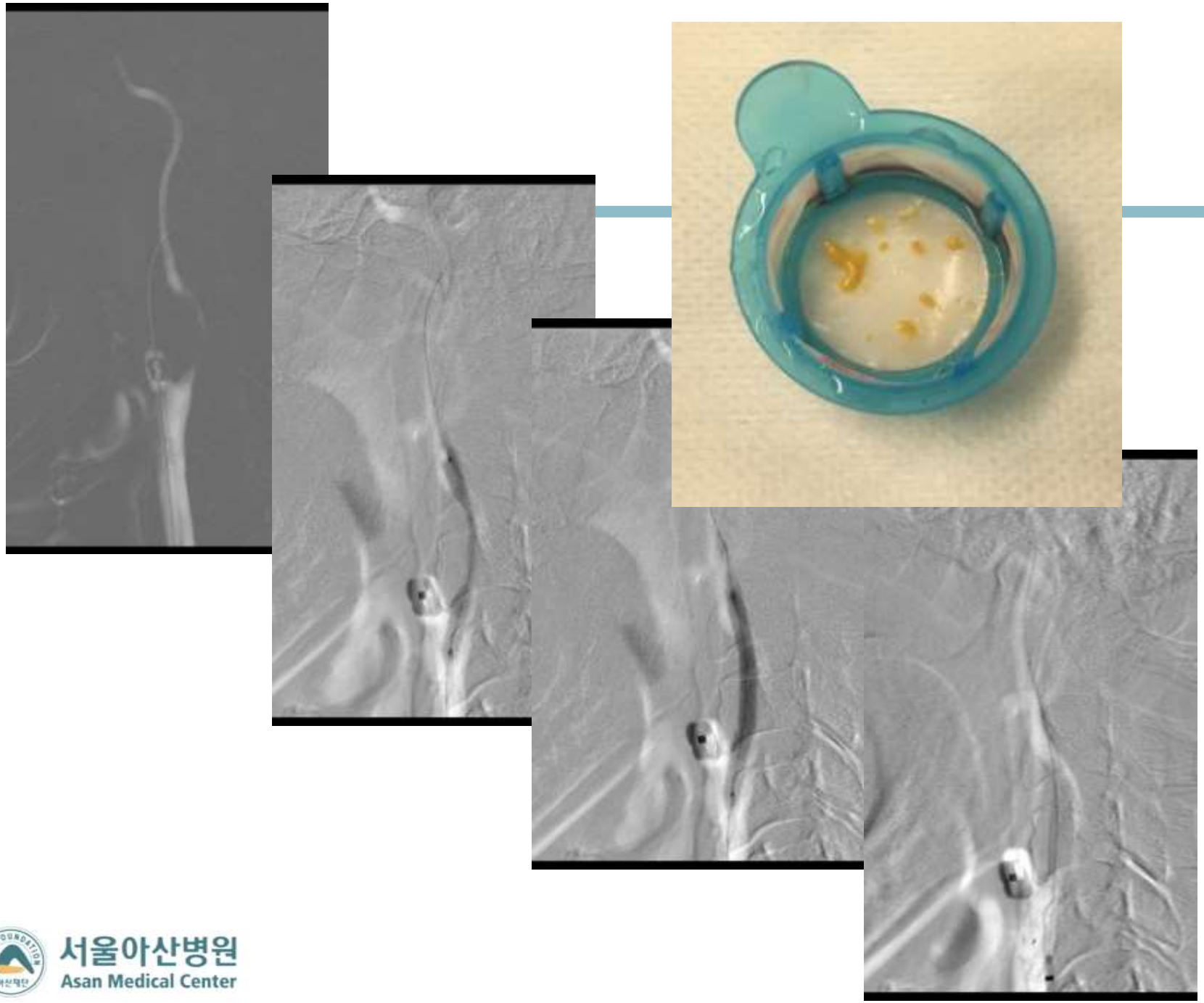
Flow Arrest with Mo.Ma Ultra





- Device
  - Single catheter system with both antegrade and retrograde flow cessation
  - Semi-compliant balloons
    - 3 to 6 mm for ECA
    - 5 to 13 mm for CCA
  - Working channel ID 0.083 in (2.12 mm)

A 74-year-old man presented with recent right side weakness without DWI abnormality.



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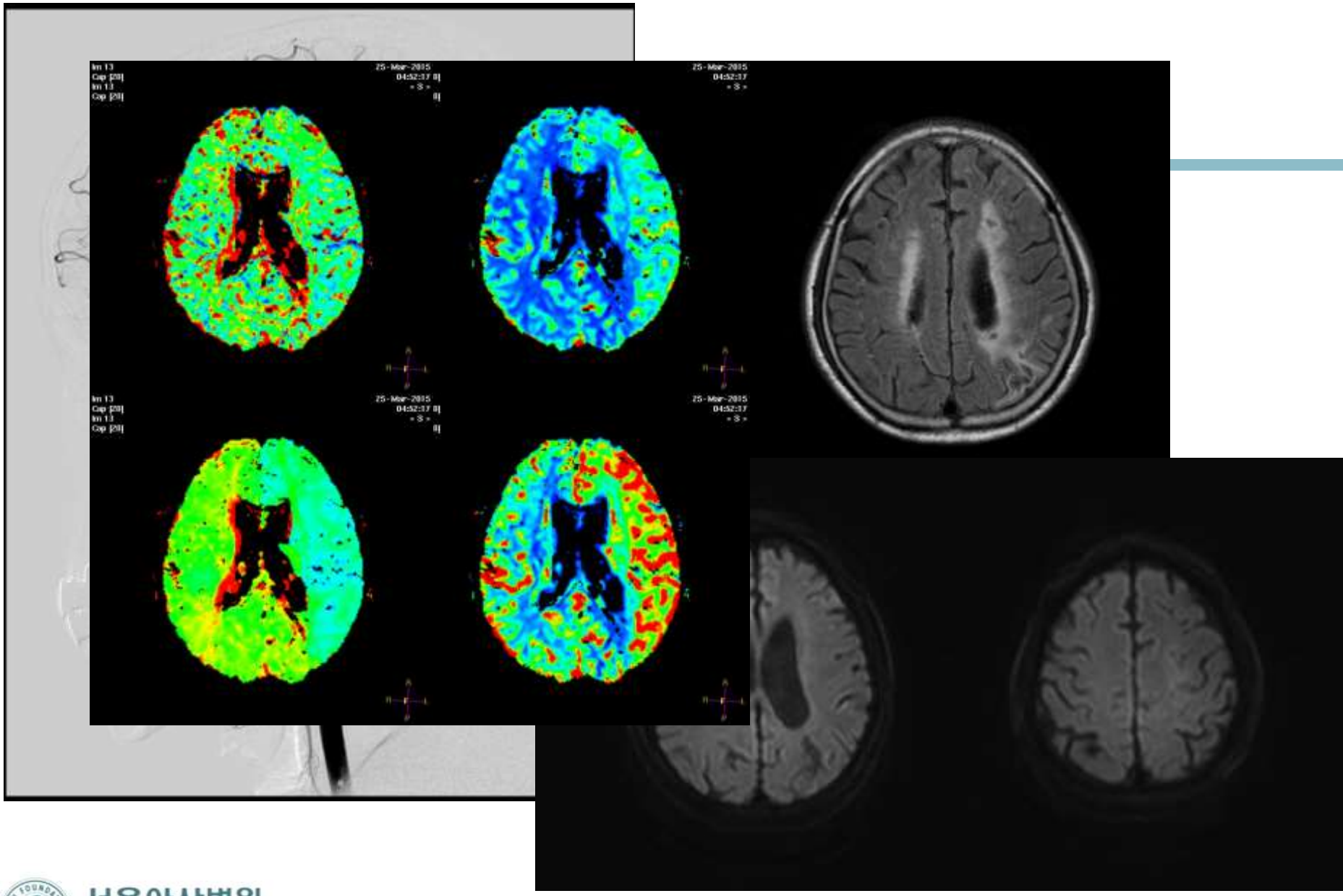

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Protection performance of Mo.MA compared with FilterWire

- Using Carotid Wallstents, small size RCT (21 vs 21 patients)
- During 3 phases of CAS, significant reduction of MES with Mo.Ma
  - 196 vs 57 MES
    - During wire passage: 25 vs 1.8
    - During stent deployment: 73 vs 11
    - During ballooning: 70 vs 12
- Post-DWI high signal lesions
  - No significant statistical difference
  - 9/21 (43%) with FilterWire and 2/14 (14%) with Mo.Ma

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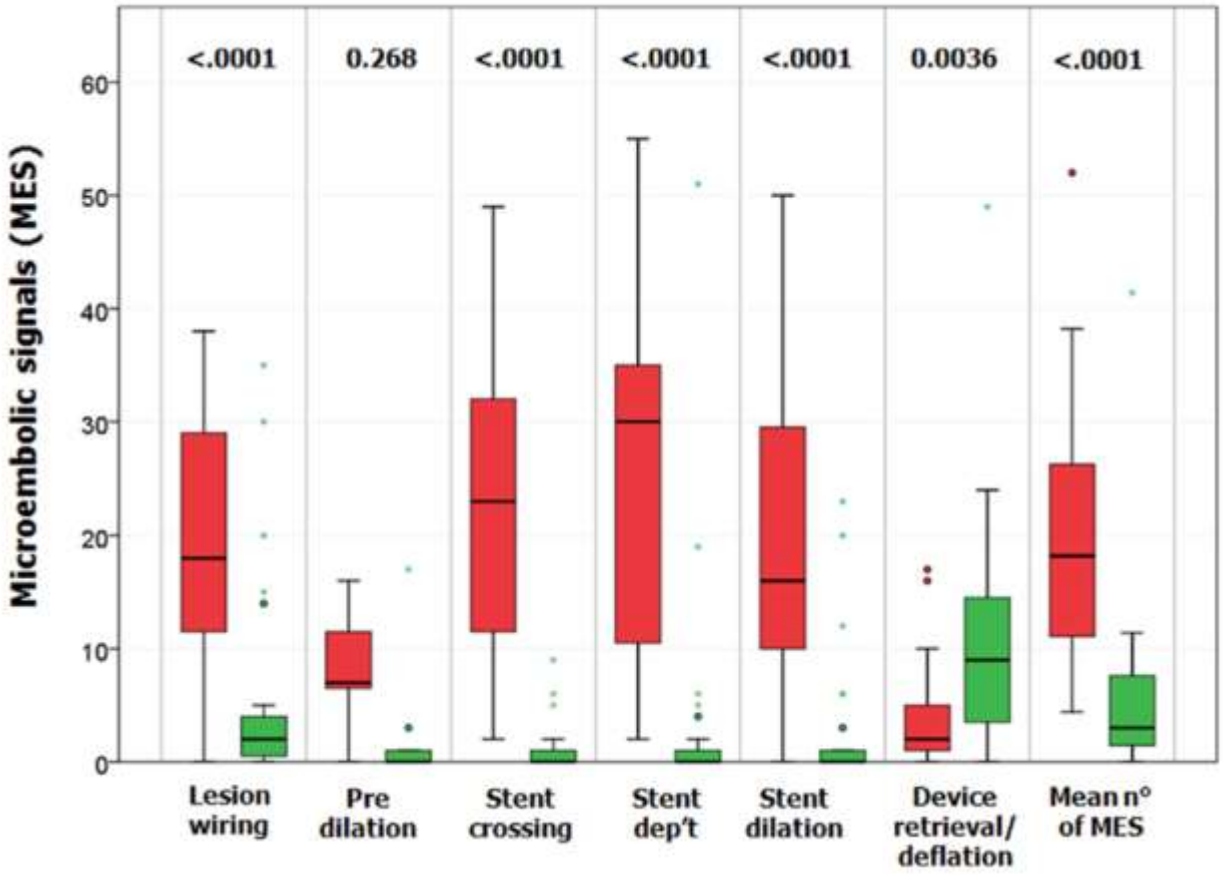
Schmidt A, et al. JACC 2004

MESs seen each procedural step



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MO.MA Proximal Cerebral Protection Device: ARMOUR Trial

- Enrolled 262 subject from 25 sites
  - 37 for roll in and 225 pivotal subjects from 2007 to 2009
  - 30-day safety (MACCE) and effectiveness of Mo.Ma

- Results
  - Total procedure time 38 min with a flow cessation time of 6.7 min
  - Intolerance to flow cessation 13.8%
    - 12.9% resolved within 20 min after deflation
  - Device success 98.2%
  - Technical success with less than 30% of residual stenosis 94.6%
  - Procedure success (without 30-day MACCE) 93.2%
  - 30-day MACCE rate 2.7%

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Ansel GM, et al. CCVI 2010

ARMOUR Trial: Subgroups

TABLE VI. 30 Day Results by Symptoms and Age—Intention to Treat Population

Group	30 Day stroke rate	30 Day MACCE rate
All subjects (N = 225)	2.3% (5/220)	2.7% (6/220)
Symptomatic (N = 34)	0.0% (0/32)	0.0% (0/32)
Asymptomatic (N = 191)	2.7% (5/188)	3.2% (6/188)
Age ≥80 octogenarians (N = 65)	3.1% (2/65)	3.1% (2/65)
Age <80 (N = 155)	1.9% (3/155)	2.6% (4/155)

- Conclusion
  - The absence of stroke in symptomatic patients is the lowest rate reported in any independently adjudicated prospective multicenter registry trial to date.

Ansel GM, et al. CCVI 2010

From April 2012 when the Mo.Ma Ultra became available in Korea

to March 2015 (For 3 years)

AMC RADIOLOGY EXPERIENCE WITH MO.MA

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Choice of protection devices

- Principle
  - Since Mo.Ma has been available, we preferred the device as the device of choice for elective CAS.
  - Acute stroke presented with ICA occlusion or combined ICA stenosis and thrombosis
    - Balloon-tipped guiding catheter (Optimo, Cello) was the device of choice
- Other variation of protection method
  - Unprotected
  - Distal filter devices

Number of cases in quarterly base

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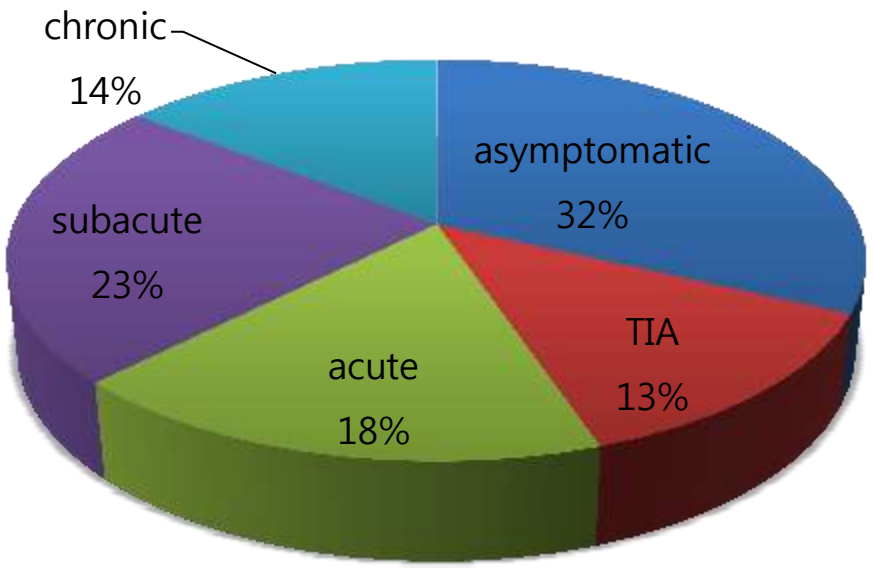
Elective CAS Patients

- Patients: 125
  - 107 men
  - Median age: 90 (33-85)
- Symptoms



- Protection

– Unprotected	14	11.2%
– Distal protectors	9	7.2%
– Balloon-tipped guiding catheter	12	9.6%
– Mo.Ma	90	72%

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Procedural Results with Mo.Ma

- 90 patients, 101 carotid arteries (both in 11 patients)
- Technical failure regarding application of Mo.Ma in 7 (7.8%)

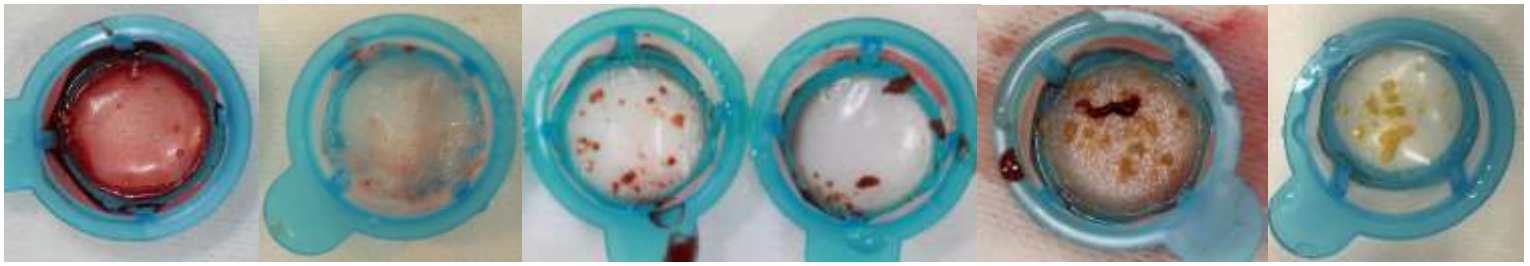
Cause of failure	Case	Solution	Complication
Pt's incooperation	1	CEA	
Long and tortuous arch	1	CEA	
Marked brachiocephalic tortuosity	1	Distal filter	Microembolism
Acute angulation btw arch and CCA	1	Distal filter	
Intolerance to occlusion	1	Distal filter	
Lesion cross failure	1	Abortion	
Aspiration failure after stenting	1	Distal filter	

Procedural Results

- Patient become symptomatic during balloon occlusion in 7/86 (8.1%)
  - Need procedural switch only in 1 (a distal filter was used after balloon deflation)

- Placement of stent without control angiography
  - Various stents (2 Carotid Wallstent, 6 Acculink, 53 Protégé, 26 Cristallo)
  - Misplacement of the stent requiring another stent in 1

- Sig



Clinical outcome results

Event	Case	Outcome	Residual
TIA with irritability	4	Resolved	No
New cortical infarct	1	Minor stroke	Yes
Other territorial infarct	1	Major stroke (hemianopsia)	Yes
Massive infarct (HARM)	1	Major stroke	Yes

- Mortality: none
- Any events in 7 (7.8%)
- Symptomatic within 30 days in 3 (3.8%)
- Obviously this is a retrospective review.

How to cope with an intolerant situation

- No need to rush
  - The patient is just symptomatic, not injured yet.

- 4 options
  - Proceed the procedure
    - You can proceed the procedure if the symptom is not severe or occurred at later steps of the procedure.
  - Stop the procedure and get ready to reinitiate the flow and then decide whether you can retry flow arrest or not.
    - Retry occlusion
    - Use of additional distal protection device
  - Abort the procedure if switching to distal protection is not possible.

Usefulness of pre-occlusion test

- Most of the intolerant patients showed the symptom within 30 sec.
  - Test occlusion for 30 seconds and then the patient's condition is OK you can proceed the procedure.
  - Test occlusion for more than 30 seconds and release the CCA balloon
    - Proceed the procedure only when the patient is OK
- Limited value
  - Increases the risk of additional procedural step.
  - Very rare procedural diversion cases.
  - The symptom does not necessarily mean a complication. It is a transient symptom only.

Technical Issues

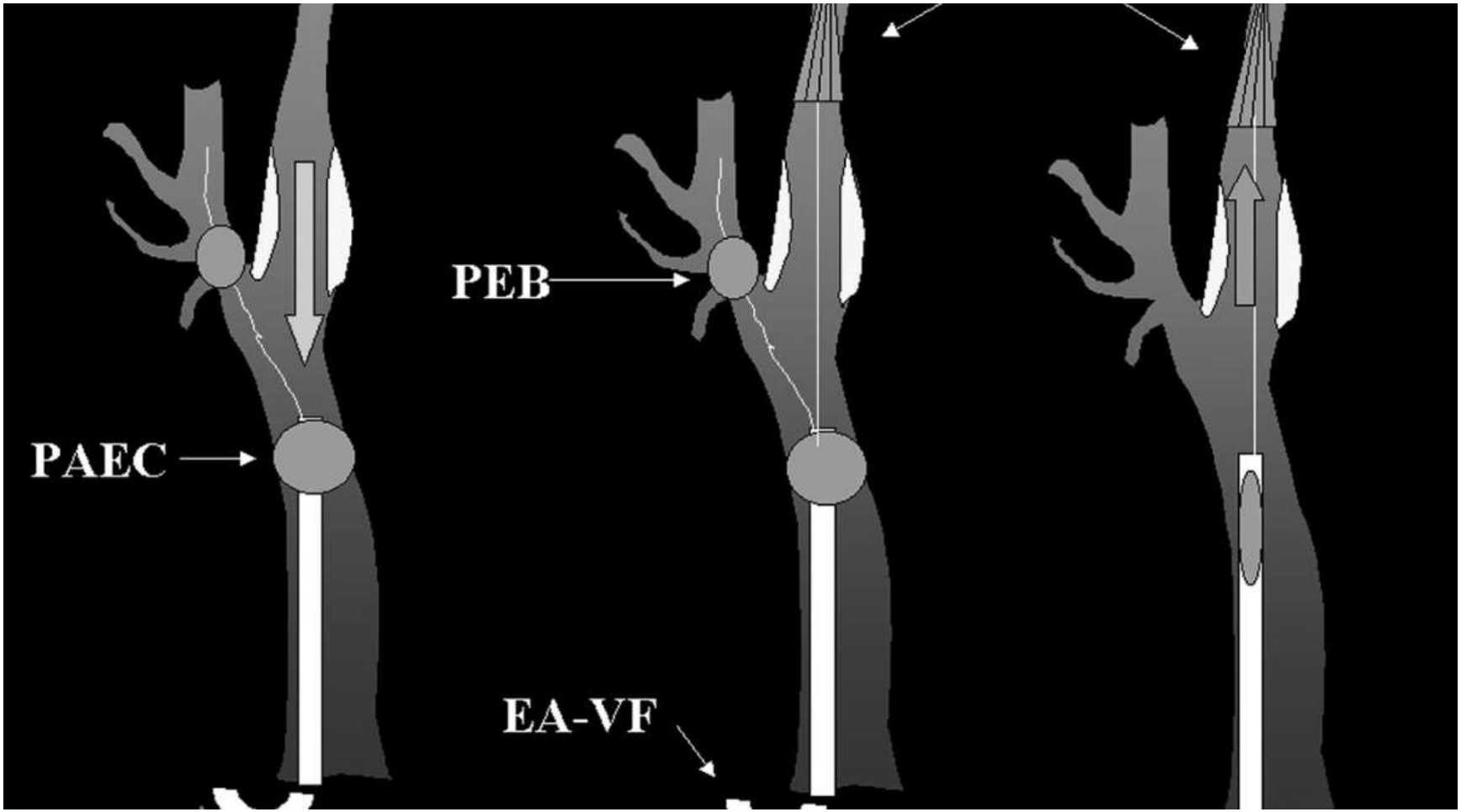
- Preparation and delivery of the device into the target
- How to protect the carotid with secure occlusion of the CCA and ECA
  - Especially isolation of the ECA branches
- Lesion crossing
  - Guidwire passage before or after flow arrest
- Balloon and stenting, stenting and ballooning, and balloon-stent-balloon
- Aspiration technique
  - Allowing spontaneous reflux of the blood during device delivery

Limitations of the device

- Use of a protection device does not always provide a secure anti-embolic effect
  - Adverse effects of using a complicated device should be considered.

- Mo.Ma
  - A little bulky
  - Difficulty in delivery
  - Not hundred percent secure flow arrest
  - Possible flow change due to additional device delivery through the stagnant segment
  - Intolerance to occlusion

Seat belt and Air bag Technique



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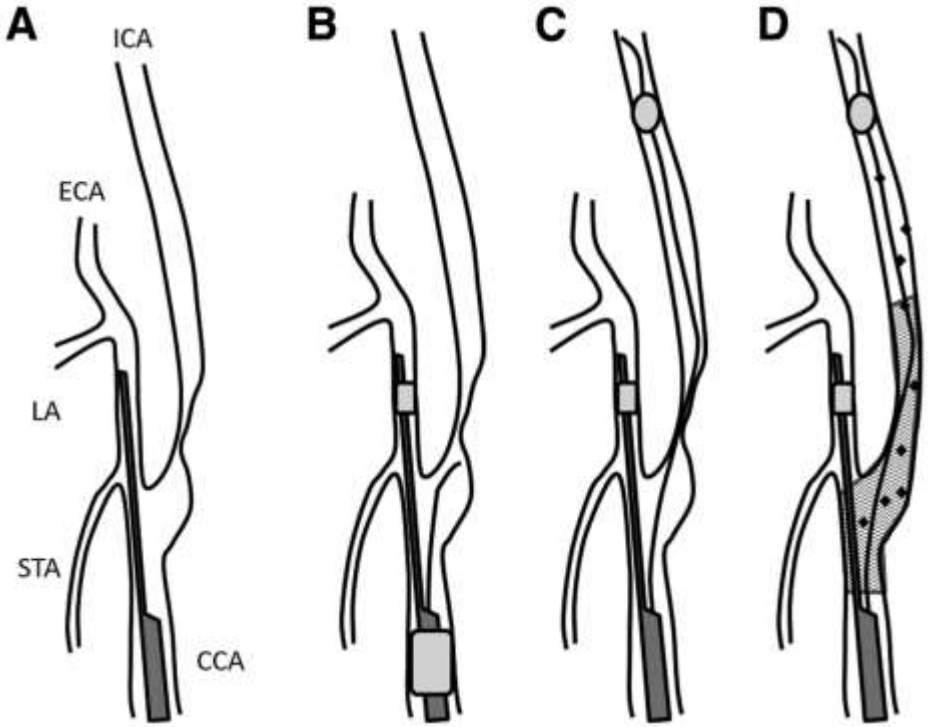
Parodi JC, et al. JET 2002

Tighter Approach: Combined use of protection devices

- Triple balloon protection technique
  - MoMa Ultra + GuardWire



Asai K, et al. JSCVD 2014

Summary

- For protected CAS, proximal flow control is a good option for successful procedure.
- Decrease in microembolic hits on TCD is obvious.
- Clinical benefit of the reduced number of hits remains to be proven.
- Understanding the device and technical limitation of current system is important.
- Both proximal and distal protection devices can be complimentary.