

## Distal vs. Proximal Protection with Carotid Stenting



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## Revascularization of Extra-cranial Carotid Disease

### **Guiding Principles For Patient Selection and Mode of Revascularization (Who? How?)**

- Symptomatic vs. Asymptomatic
- Severity of Carotid Stenosis
- High vs. Average surgical Risk
- Age, Gender and Co-morbidities

## Guideline Recommendations for Carotid Stenting

### Asymptomatic Patients

Prophylactic CAS might be considered in selected patients (stenosis  $\geq 70\%$  on Doppler US,  $\geq 60\%$  angiographically, or  $\geq 80\%$  on CTA or MRA). The advantage of revascularization over current medical therapy alone is not established.



### Symptomatic Patients

Symptomatic patients at average or low surgical risk with ipsilateral carotid stenosis  $>70\%$  (or  $>50\%$  angiographically) can undergo CAS as an alternative to CEA if the anticipated rate of peri-procedural stroke or mortality is  $<6\%$



### Additional Recommendations

It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery



AHA/ASA Guidelines for 1ry Prevention of Stroke. Goldstein LB et al. Stroke 2011;42:517-584  
2011 Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease. Circulation 2011;124:489-532



## Need for Embolism Protection Devices (EPDs)

- No contemporary head-to-head randomized trials comparing use of EPDs to unprotected carotid stenting
- Older evidence in favor of EPD use from the global registry

Global Registry	No EPD (n=6753)	EPD Protection (n=4221)	P value
Death & Stroke	5.29%	2.23%	p<0.05

- Contemporary evidence from the EVA-3S experience

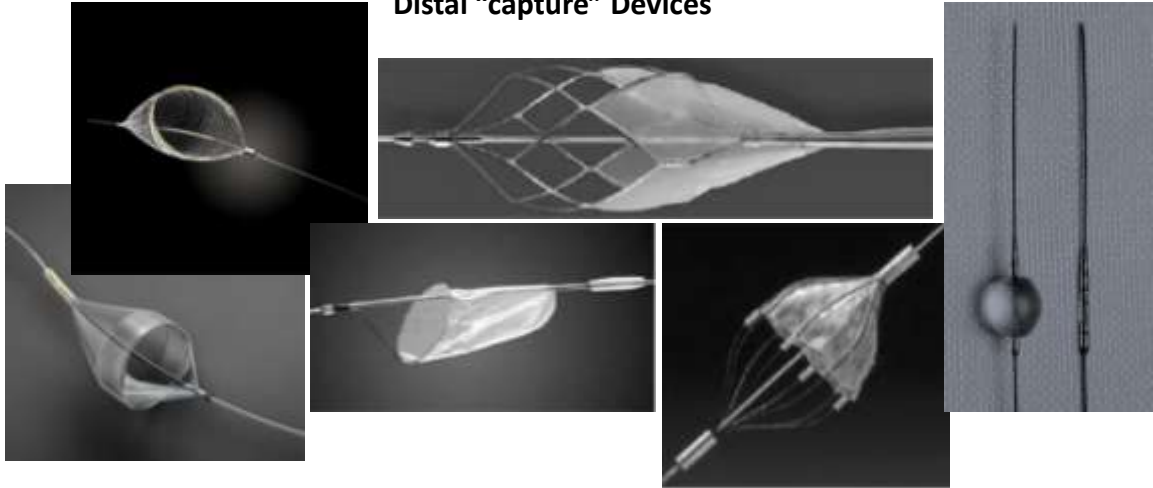
EVA-3S	No EPD (n=20)	EPD Protection (n=227)	P value
Death & Stroke	25%	7.9%	p=0.03

Wholey M et al. Catheter Cardiovasc Interv 2003;60:259-266  
Mas JL et al. N Engl J Med 2006;355:1660-1671



## Embololic Protection Devices

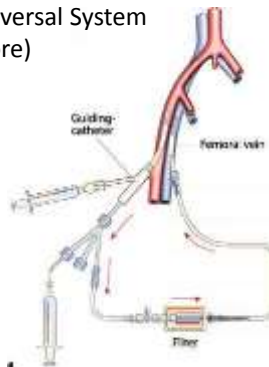
### Distal "capture" Devices



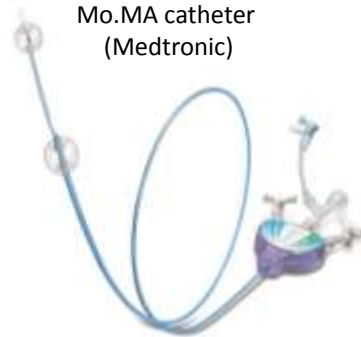
## Embololic Protection Devices

### Proximal "occlusion" Devices

Parodi Flow Reversal System  
(Gore)



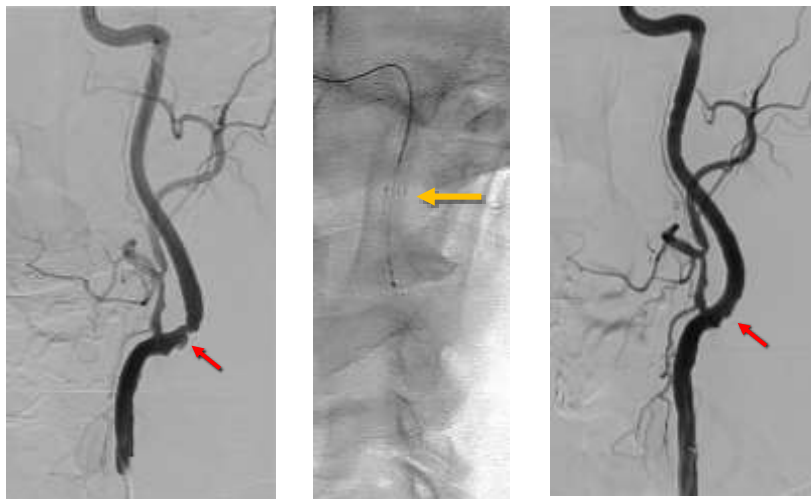
Mo.MA catheter  
(Medtronic)



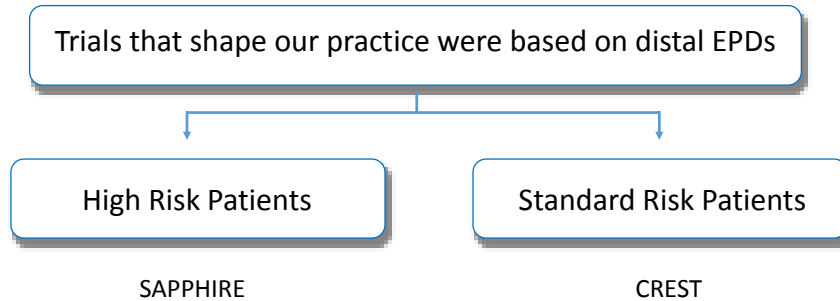
## Pros and Cons of Distal vs. Proximal EPDs

	Distal EPDs	Proximal EPDs
Access profile	Typically 6F	Larger 9-10 F
Presence of PAD	Easier to use	More risk of complications
Difficult Arch	Easier to deliver	Bulkier device
Lesion Crossing	No protection	Protection already in place
Lesion Crossing	Device on wire	Simple 0.014" wire
Flow during procedure	Continuous	interrupted
Time allowed for procedure	Unlimited	Should be <10 minutes
Use with contralateral occluded carotid	More acceptable	Can be problematic
Efficacy of cerebral protection	Depends on pore size	Depends on effective occlusion
Supportive literature	+++	+

## Distal Embolic Protection

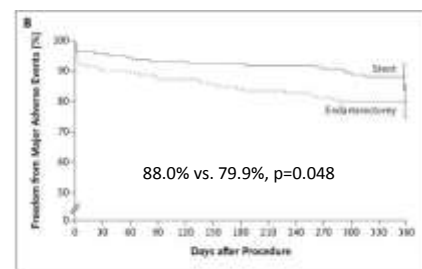


## What do We Know about Distal EPDs?



## The SAPPHERE Trial

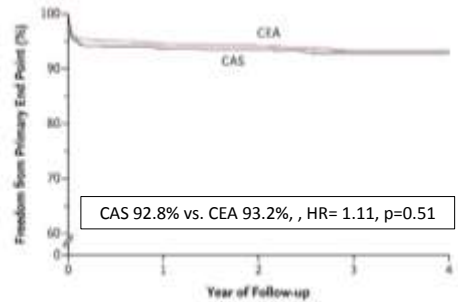
- CEA vs. CS with distal EPD in high risk patients
- Experienced operators
- EPD mandatory per protocol
- 334 randomized patients
- Symptomatic and asymptomatic
- Primary Endpoints:  
Death/stroke/ MI within 30 days +  
Death/ipsilateral stroke between 31 days and 1 year
- Any early procedure-related ipsilateral stroke: 4.3%



Actual Treatment Analysis

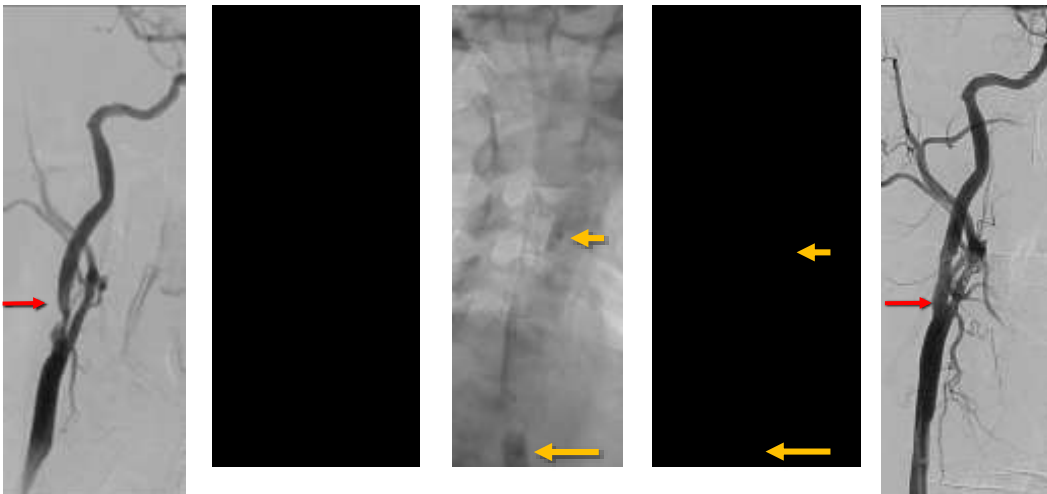
## The CREST Trial

- CEA vs. CS with distal EPD in average surgical risk patients
- Experienced operators
- EPD mandatory per protocol
- 2500 patients over 8 years
- Symptomatic and asymptomatic
- Primary Endpoints:  
Death/stroke/ MI within 30 days +  
Death/ipsilateral stroke between after 4 years
- Any early procedure-related ipsilateral stroke: 4.1%

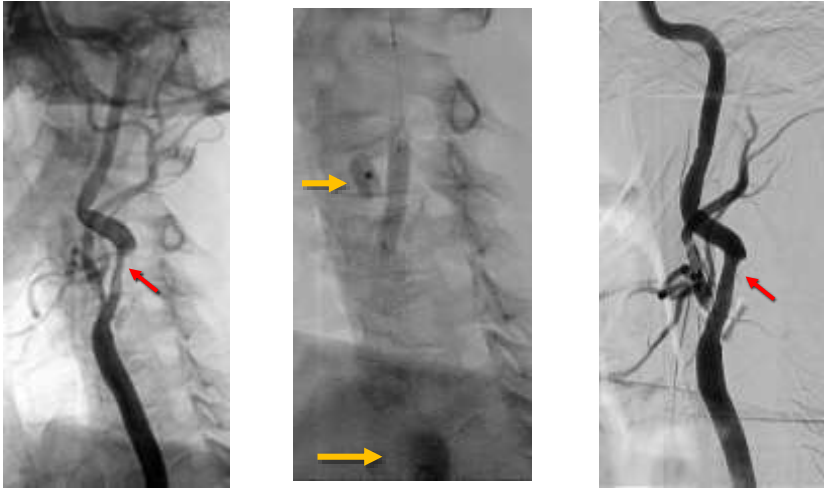


Brott TG et al. N Engl J Med 2010;363:11-23

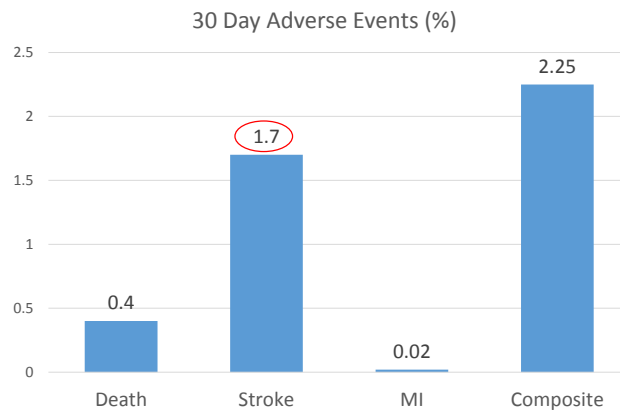
## Proximal Embolic Protection



## Proximal Embolic Protection

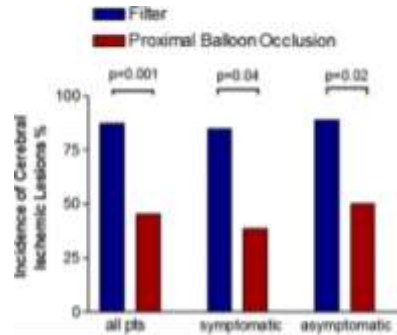
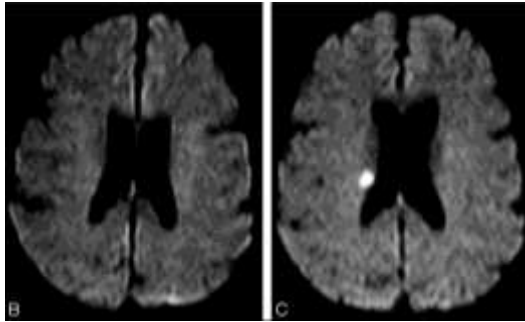


## Early Experience with Proximal EPD (Mo.Ma)



Bersin RM et al. Catheter Cardiovasc Interv 2012;80:1072-1078

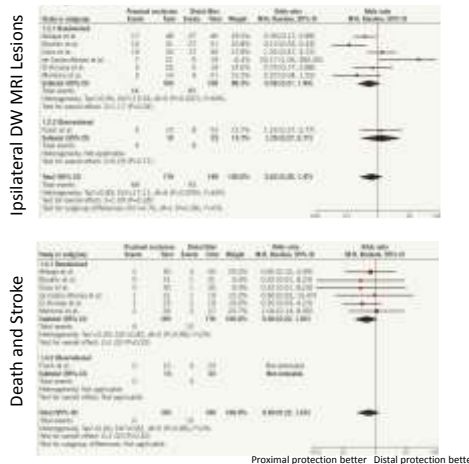
# The PROFI Study: Proximal vs. Distal Protection



Bijklic K et al. J Am Coll Cardiol. 2012;59(15):1383-1389

# Proximal vs. Distal Protection Comparative Trials

- Meta-analysis of 7 small comparative studies, 6 randomized and 1 observational, n=392 patients
- Post-procedure DW/MRI lesions – >60% of all CAS with protection (risk factors: DM and symptoms)
- MACCE tracked
- Trend towards improved outcome with proximal protection, but no statistically significant difference



Cassese S et al. EuroIntervention 2015; 11(2):238-46



## Clinical Outcomes with Proximal vs. Distal Protection

- Retrospective analysis of clinical outcomes of >10,000 consecutive elective CS procedures in NCDR
- Only 5.8% received CS with P-EPD
- Baseline characteristics – more symptomatic patients and Afib/flutter in P-PED
- Trend towards improved outcome with proximal protection, but no statistically significant difference before and after propensity matching

	In-Hospital Outcomes					
	Before Propensity Matching			After Propensity Matching		
	F-EPD (n = 9,656)	P-EPD (n = 590)	p Value	F-EPD (n = 2,032)	P-EPD (n = 508)	p Value
Death or stroke	234 (2.4)	9 (1.5)	0.164	40 (2.0)	8 (1.6)	0.560
Mortality	40 (0.4)	1 (0.2)	0.730	9 (0.4)	1 (0.2)	0.697
Stroke	209 (2.2)	9 (1.5)	0.296	33 (1.6)	8 (1.6)	0.937

	30-Day Outcomes					
	Before Propensity Matching			After Propensity Matching		
	F-EPD (n = 7,211)	P-EPD (n = 482)	p Value	F-EPD (n = 1,469)	P-EPD (n = 406)	p Value
Death or stroke	300 (4.2)	12 (2.5)	0.072	59 (4.0)	11 (2.7)	0.219
Mortality	53 (0.7)	2 (0.4)	0.582	12 (0.8)	2 (0.5)	0.747
Stroke	264 (3.7)	11 (2.3)	0.114	49 (3.3)	10 (2.5)	0.373

Giri Jet al. J Am Coll Cardiol Intv 2015; 8: 609-15

## Proximal vs. Distal EPDs - Conclusions

- It is reasonable to assume that embolism protection enhances the safety of carotid stenting, although no evidence from a direct head-to-head randomized trial
- Options of EPDs have expanded, but can be broadly classified into proximal “occlusion” and distal “capture” or “filter” devices
- Most of the literature that shapes our practice today is based on use of distal filter devices
- Proximal protection devices seem to reduce objective evidence of cerebral embolism, but the evidence of improvement in clinical outcomes remains marginal
- An adequately powered prospective randomized trial is needed to reach definitive conclusions