Extracranial Carotid Artery Stenting With or Without Distal Protection Device

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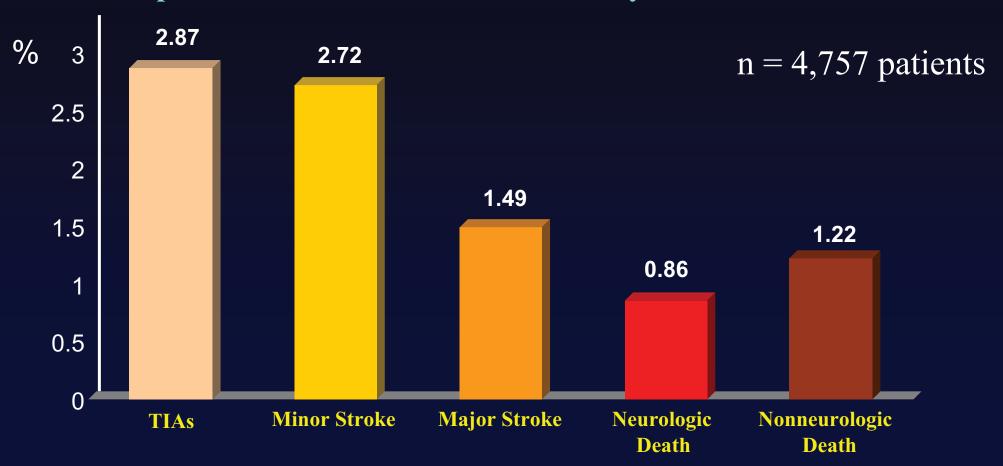


Backgrounds

- Although surgical endarterectomy has been known to be the standard treatment modality of carotid artery stenosis, it had several limitations in high-risk patients, particularly with coronary artery disease.
- Carotid angioplasty and stenting has been suggested to be a safer and more cost-effective alternative to carotid endarterectomy in the management of symptomatic carotid artery disease.

30-Day Procedure Complications

- Global Experience in Cervical Carotid Artery Stent Placement

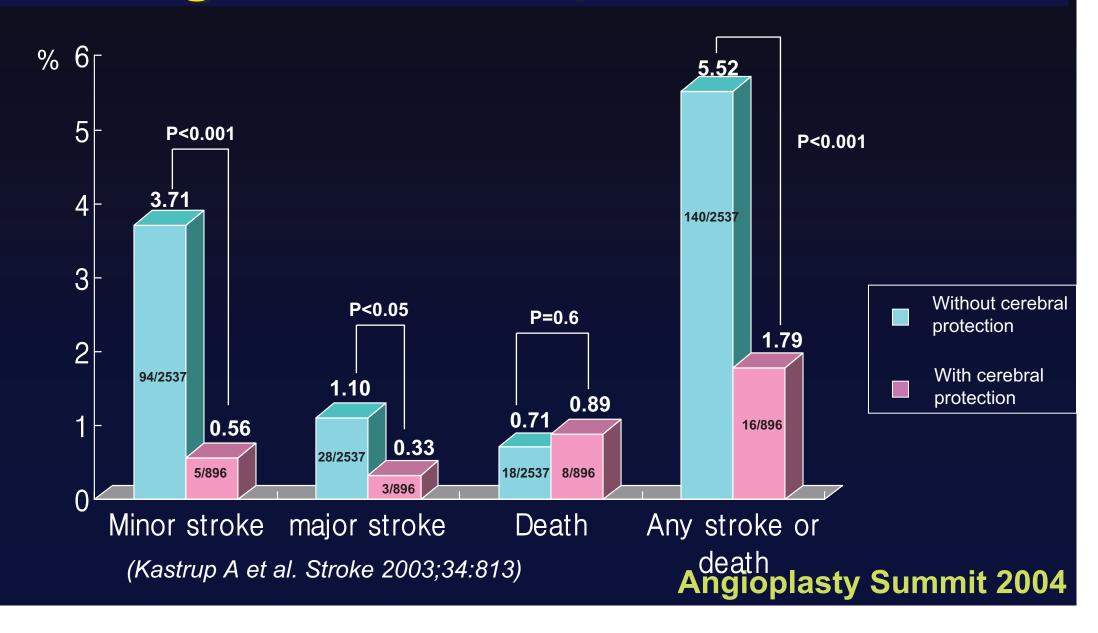


Cathet. Cardiovasc. Intervent. 50: 160-167, 2000.

Backgrounds

- Obstructive carotid artery lesions are known to contain friable thrombotic and atherosclerotic components that have the potential to embolize during intervention and may be responsible for the majority of the neurologic events during carotid artery stenting.
- A number of "distal protection" strategies, designed to capture embolic debris released during carotid intervention , are currently being evaluated for their efficacy in minimizing the risk of embolic neurologic events.

Backgrounds- 30 day clinical event rates



Objective

 The purpose of this study is to evaluate the feasibility, safety and short(30-day), mid-term(6-month) clinical follow up results of elective carotid artery stenting with or without distal protection device in patients with carotid artery stenosis

Method

Jun 1997 ~ Sep 2003, 58 pts (62 lesions)were included

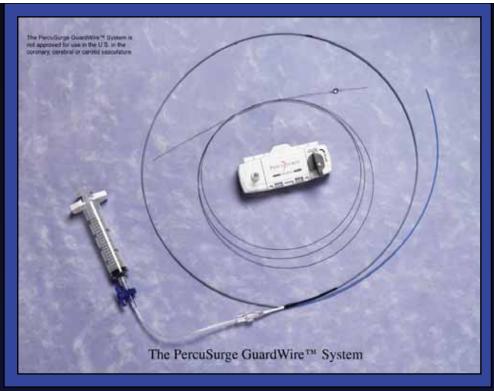
- Inclusion criteria
- Symptomatic and asymptomatic pts with carotid artery stenosis(>60%)
- Informed consent
- Exclusion criteria
 - Intracranial tumor or arteriovenous malformations
 - Severely disabled as a results of stroke or dementia
 - Intracranial stenosis that exceeded the severity of the extracranial stenosis
 - Peripheral vascular disease to prevent vascular access
 - Acute ischemic neurologic stroke or past 48hrs
 - Total occlusion of the target carotid artery

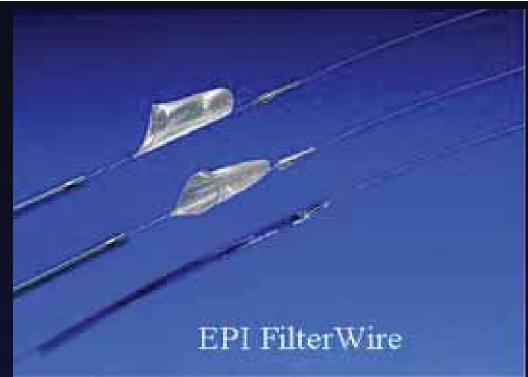
Method

Stenting Protocol

- Transvenous pacemaker(till 1999)
- Heparin 5,000U bolus IV after arterial sheath
- 9 Fr guiding catheter or 7Fr Tuohy Borst Introducer
- Cross the stenosis with extra-support wire
- Drug regimen: aspirin 300mg indefintely,
 ticlopidine 250mg or clopidogrel 75mgfor 4wks
- Protection device(from Sep 2001): 19 case(30.7%)

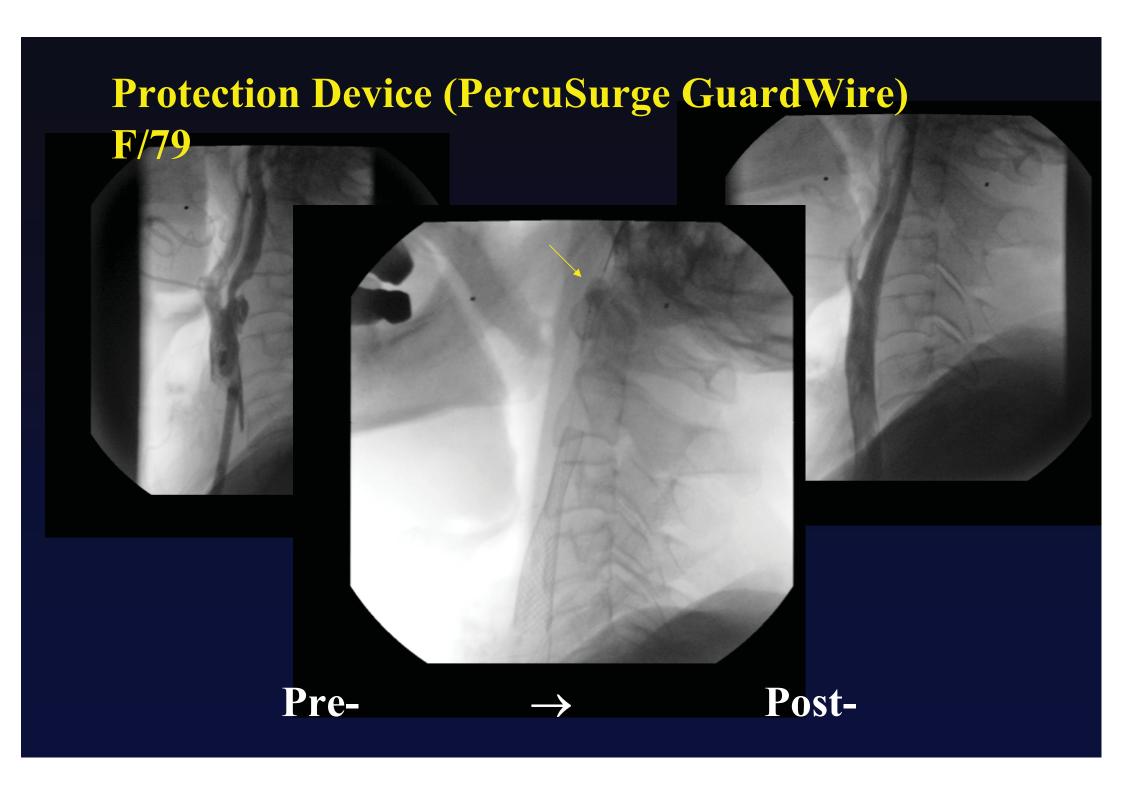
PercuSurge –13 case EPI filter-6 case

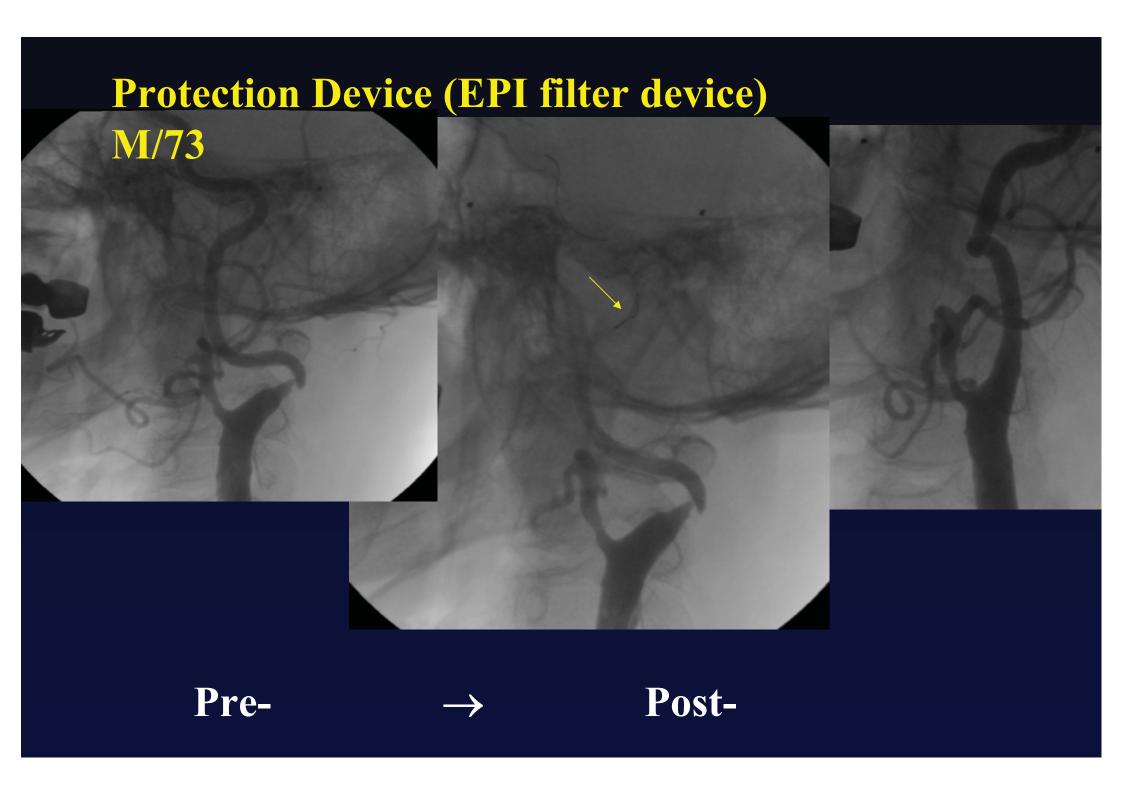




PercuSurge GuardWire system

EPI FilterWire





Results - Clinical Characteristics

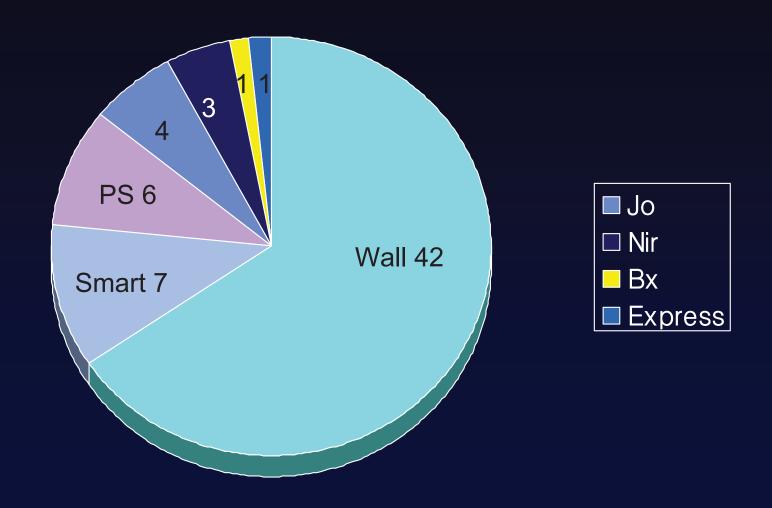
Men	45(77.6%)
Age(yr)	67.4±7.5
Cardiovascular risk factor	
Hypertension	44(75.9%)
Smoking	36(62.1%)
Diabetes	18(31%)
Hypercholesterolemia	14(24.1%)
Past History	
MI	10(17.2%)
CVA	13(22.4%)
PTCA	28(48.3%)
High Risk Patients	31(53.4%)
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Results - Lesion Characteristics

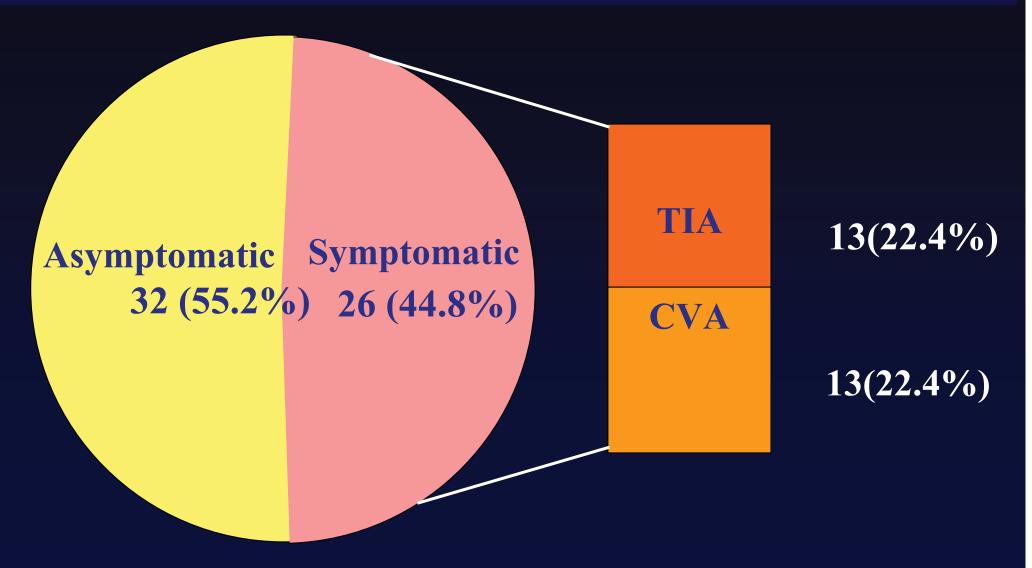
Right / Left	32(51.6%) / 30(48.4%)
Common CA	4 (6.4%)
Internal CA	58(93.6%)
Combined coronary stenosis	41(70.7%)
Bilateral CA	4 (6.9%)

CA; carotid artery

Results - Types of Stents



Results - Presenting Symptoms

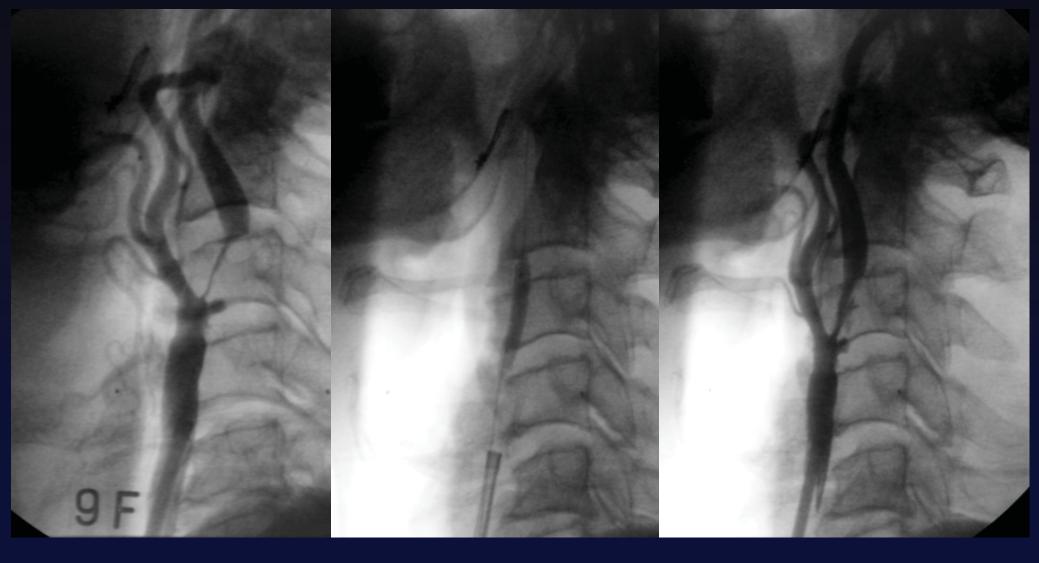






Total occlusion of LICA

Critical stenosis of RICA



Pre-

Balloon Inflation

Post-balloon





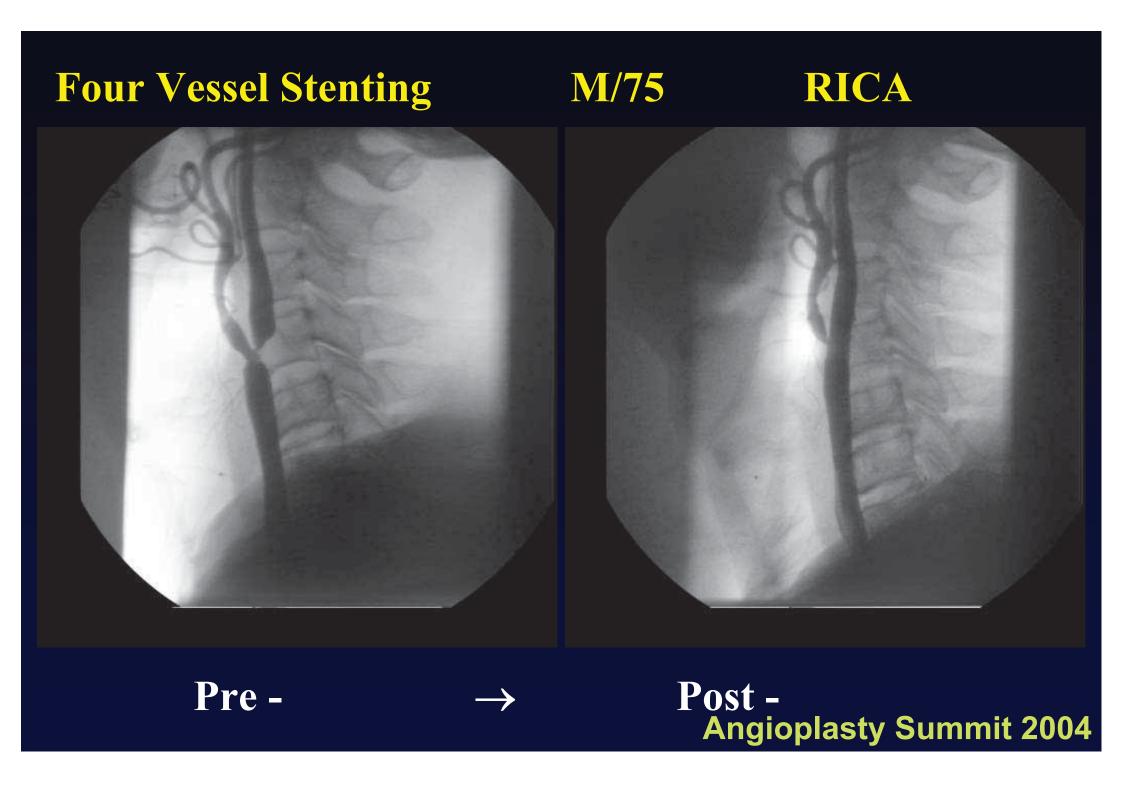
Stent placement (Self expendable nitional stent)

Post-Inflation



Pre-

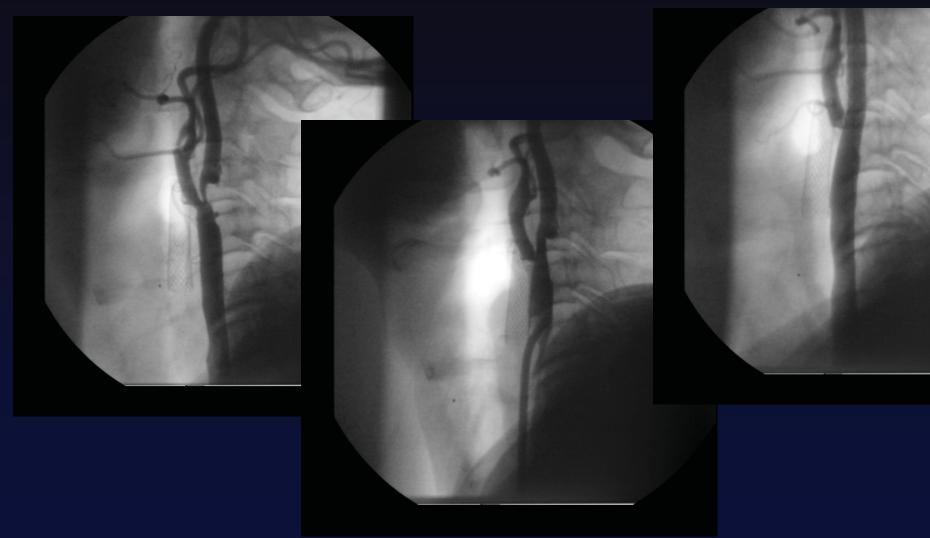
Post-stenting cerebral angiography



RVA Four Vessel Stenting CB Post -Angioplasty Summit 2004 Pre-

Four Vessel Stenting

LICA



Pre-

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Post -Angioplasty Summit 2004



Four Vessel Stenting

LVA



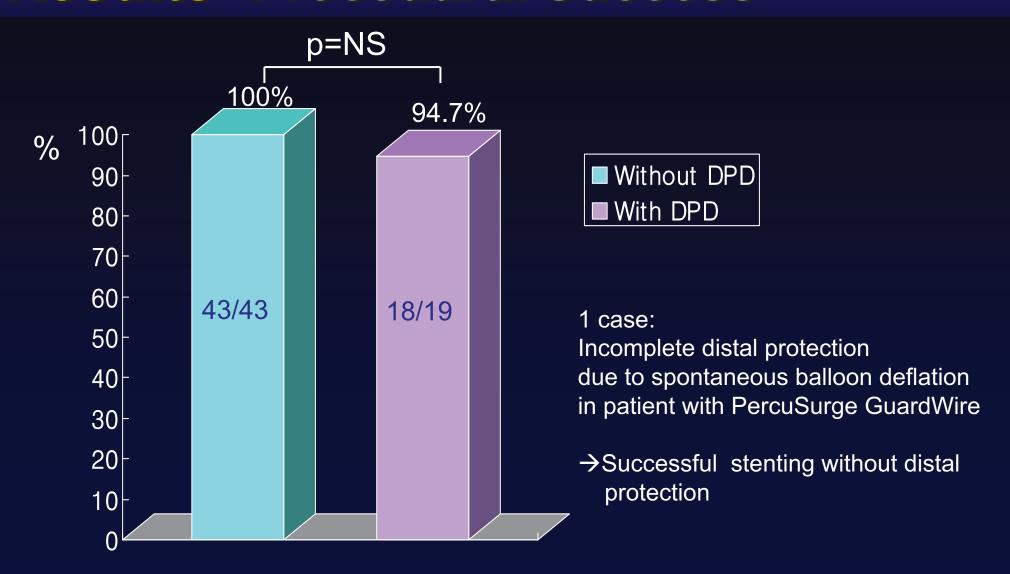


Pre-

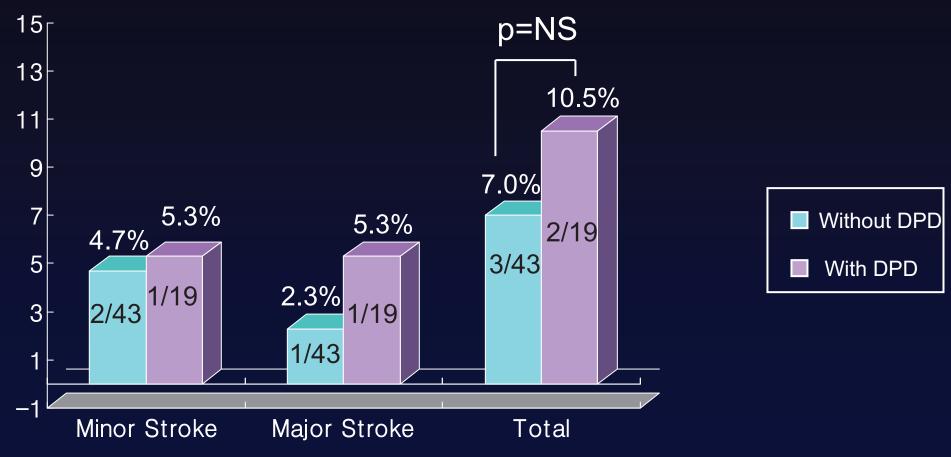
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Post -Angioplasty Summit 2004

Results Procedural Success

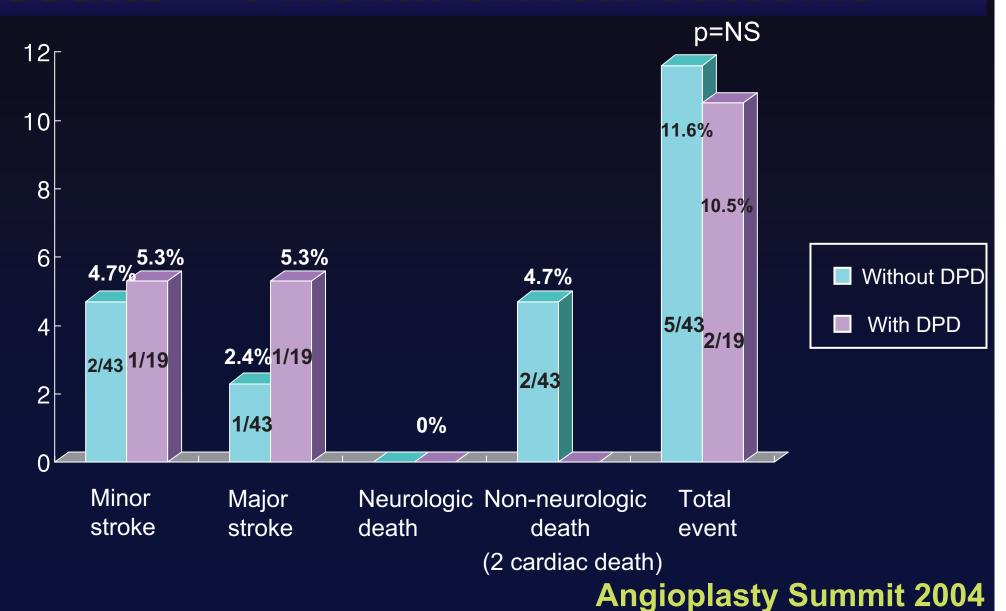


Results 30-day clinical outcome



Major stroke: 2 hemorrhagic stroke due to hyperperfusion, No major embolic stroke

Results – 6 month clinical outcome



Results - Baseline QCA data

	Pre	Post	
RVD(mm)	5.93 ± 1.45		
MLD(mm)	1.46 ± 0.78	5.01 ± 1.28	
%DS	77.4 ± 8.4	13.7 ± 12.9	
Length(mm)	18.8 ± 10.1		

Results

PercuSurge GuardWire Experience and Result

- Technical success rate: 12/13 (92.3%)
- Balloon inflation time: 6 min 27sec ± 1min 42sec
- Aspirated material: 12/12(100%)
- Direct stenting: 6/12(50%)
- Clinical Results: 1 hemorrhagic stroke developed within 24 hrs after stenting due to hyperperfusion

Results

EPI Filter Wire Experience and Result

- Technical success rate: 6/6 (100%)
- Visible filtered material: 2/6(33.3%)
- Clinical Results: 1 minor embolic stroke developed within 30 days after stenting

Hyperperfusion Syndrome

Sundt et al. first described in 1981 Recognized complication of CEA

- Triad: Unilateral headache, Focal seizure, ICH
- Symptoms: Usually developed 5 to 7 days after CEA
- Speculations: Elevated ipsilateral cerebral blood flow
- Incidence of ICH after CEA: From a recent review of the literature
 0.3 to 1.2%

Associated with elevated BP at the time of presentation

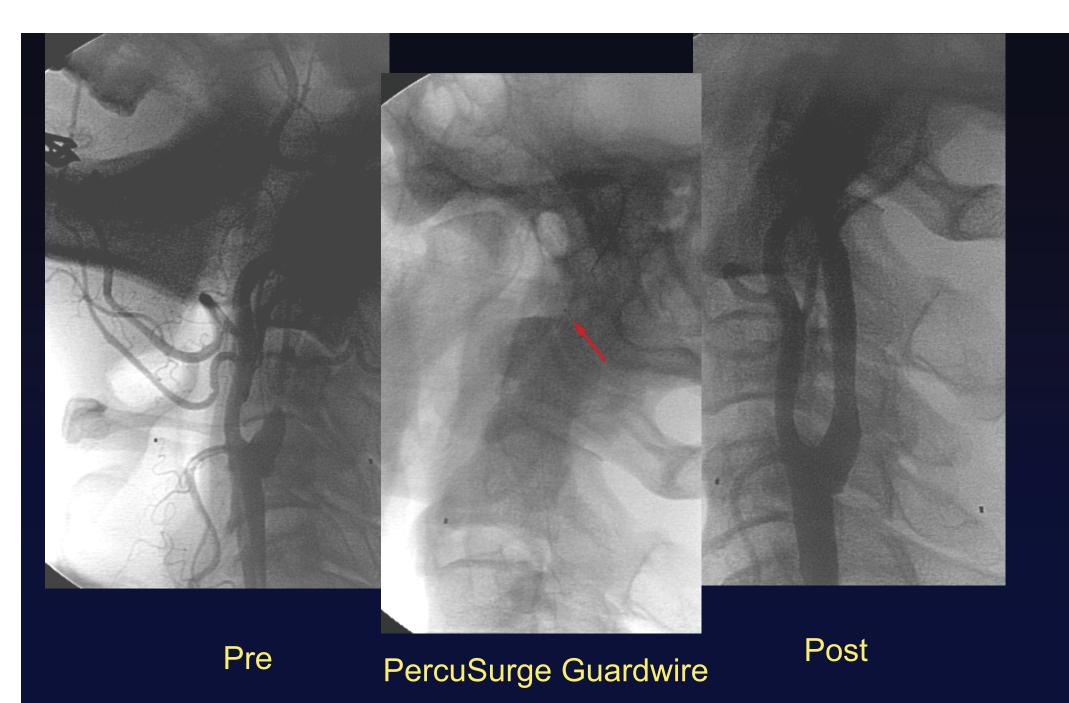
ICH after carotid stenting

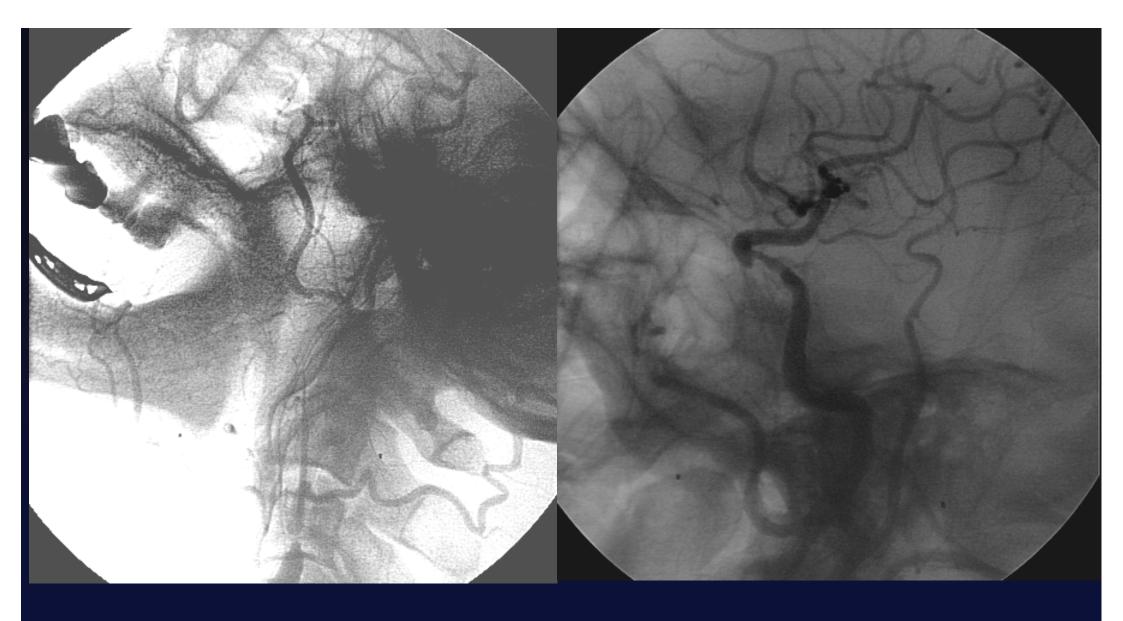
Gachon data (N=58): 2/58 (3.5%)

Morrish et al (N=90): 4/90 (4.4%)

Patient Profile of ICH post-stenting

	Patient 1	Patient 2
Age/Sex	74/M	76/M
Target lesion	RICA	LICA
% stenosis (%)	95	99
Presenting Sx	yes	yes
Contralateral carotid artery stenosis	occluded	No significant stenosis
Residual stenosis after CAS (%)	10	20
Time to onset of neurologic Sxs	7 days	1 hour
Clinical Outcome	fatal	fatal
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Pre-

Post-stenting cerebral angiography



Left basal ganglia hemorrhage after stenting

Summary

- Clinical event rate during the 30 days(short term) and 6
 month(mid-term) of follow-up was not significantly different
 in carotid artery stenting between protected and nonprotected group.
- 2 hemorrhagic strokes developed in patients with subtotal carotid artery occlusion, and severe carotid stenosis combined with contralateral occusion

Conclusions

- Carotid stenting is a safe and feasible procedure with high immediate success rate and relatively low major clinical events during the follow up periods.
- However, intracerebral hemorrhge can occur after carotid stenting possibly due to cerebral hyperperfusion injury.
- Furthermore, the use of neuroprotection devices will contribute to the decline in embolic event rates.