Comparison of Three Filter Devices' Performance In Carotid Stenting: A Randomized, Single Center Study

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Presenter Disclosure Information

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Within the past 12 months, the presenter or their spouse/partner have had the financial interest/arrangement or affiliation with the organization listed below.

Nothing to disclose

Background

Carotid artery stenting (CAS) with systematic use of distal protection is an expanding alternative option to surgery treatment for carotid artery stenosis.

Among protection devices, filters are used in more than 90% of procedures.

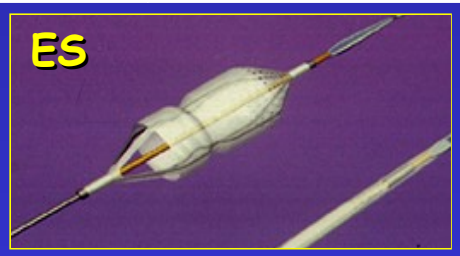
However, studies comparing peformance of different types of filters in CAS are lacking.

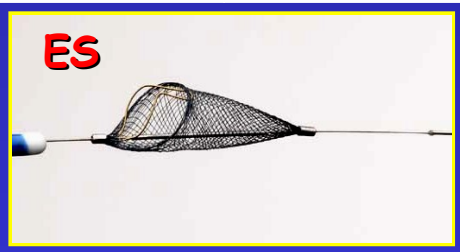
Aim of the study

To compare three different filter devices in consecutive "real-world" patients treated with CAS for carotid artery stenosis.

Filter types

	Crossing profile (Fr)	Filter size (mm)	Pores size (μμ)	Filter Length (cm)
Filterwire EZ *(BSCI)*	3.2	3.5-5.5	110	1.5
EmboShield *(Abbott Vasc.)*	3.7	3-6	140	2.6-3.3
Spider *(eV3)*	3.2	3-7	110	1.5-2.6





Study end-points

Primary end-point: *Filter success*

- ✓ Lesion crossing by filter + filter positioning/ deployment & retrival
- ✓ No cross-over to other filters ("buddy-wire" technique allowed)
- ✓ No angiographic complications (dissection, thrombosis) or side-effects (spasm) due to the filter

Study end-points

Secondary end-points

- ✓ Procedural Success
- ✓ Procedural time*

- ✓ Death
- ✓ Major/minor stroke
- ✓ Q/non-Q MI
- ✓ Composite end-point

} within 30 days from the procedure

* *From guide catheter positioning to its removal*

Methods-1

167 consecutive patients with carotid artery stenosis (≥ 50% if symptomatic and ≥ 75% if asymptomatic) were randomized to three different filters before CAS:

EmboShield (ES), Abbott Vascular n=51

FilterWire EZ (FW), BSC n=57

Spider (SP), eV3 n=59

Methods-2: *Study protocol*

Guide-to-guide time

Baseline angiogram

↓

Predilation/direct technique and stent type
(operator's discretion)

↓

Randomization

ES | FW | SP

↓

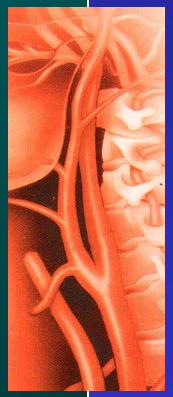
Predilation/Direct stenting

↓

Post-dilation

↓

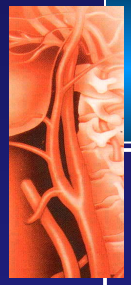
Final angiogram



Patient characteristics-1

	ES (%)	FW (%)	SP (%)	P (*)
Age (years)	69±8	69±8	70±8	0.89
Male gender	67	61	67	0.73
CAD	73	75	67	0.51
PVD	36	28	35	0.57
Smoking	52	49	52	0.83
Hypertension	89	84	78	0.26
Hypercholesterolemia	84	94	86	0.09
Diabetes (type 1+2)	11	24	25	0.15
High-risk pts	28	26	15	0.21

(*) *Statistical analysis by ANOVA*

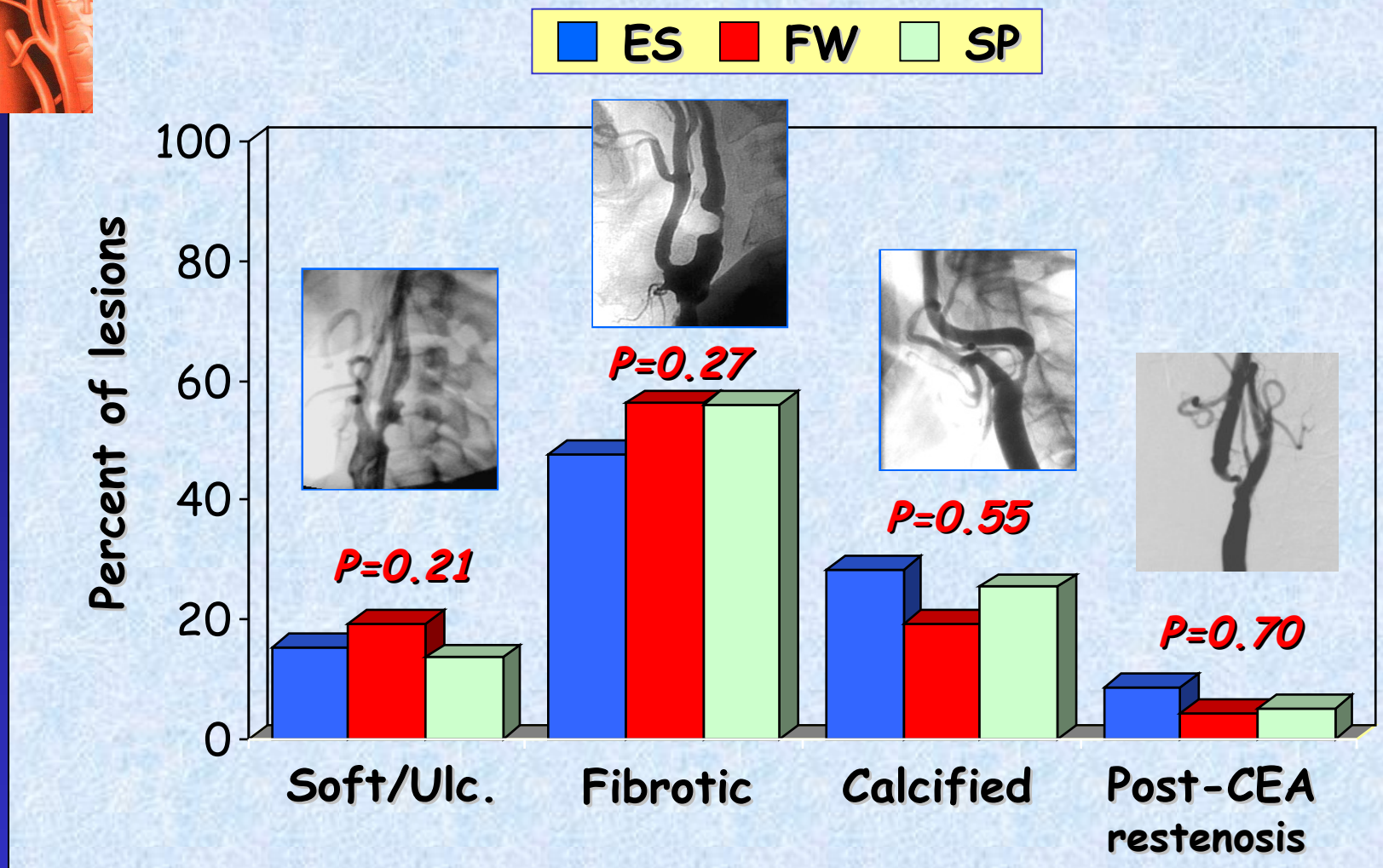


Patient characteristics-2

	ES (%)	FW (%)	SP (%)	P (*)
Symptomatic	31	23	40	0.11
Asymptomatic	69	77	60	0.11
Right ICA	60	49	49	0.85
Left ICA	40	51	51	0.67
Contralat.occlusion	6.5	10.5	5	0.51
Contralateral CAS/CEA	17	22	7	0.12
US stenosis	86±7	83.5±7	86±7	0.55
NASCET stenosis	65±10	66±11	68±10	0.52

(*) *Statistical analysis by ANOVA*

US Plaque Morphology



(*) *Statistical analysis by ANOVA*

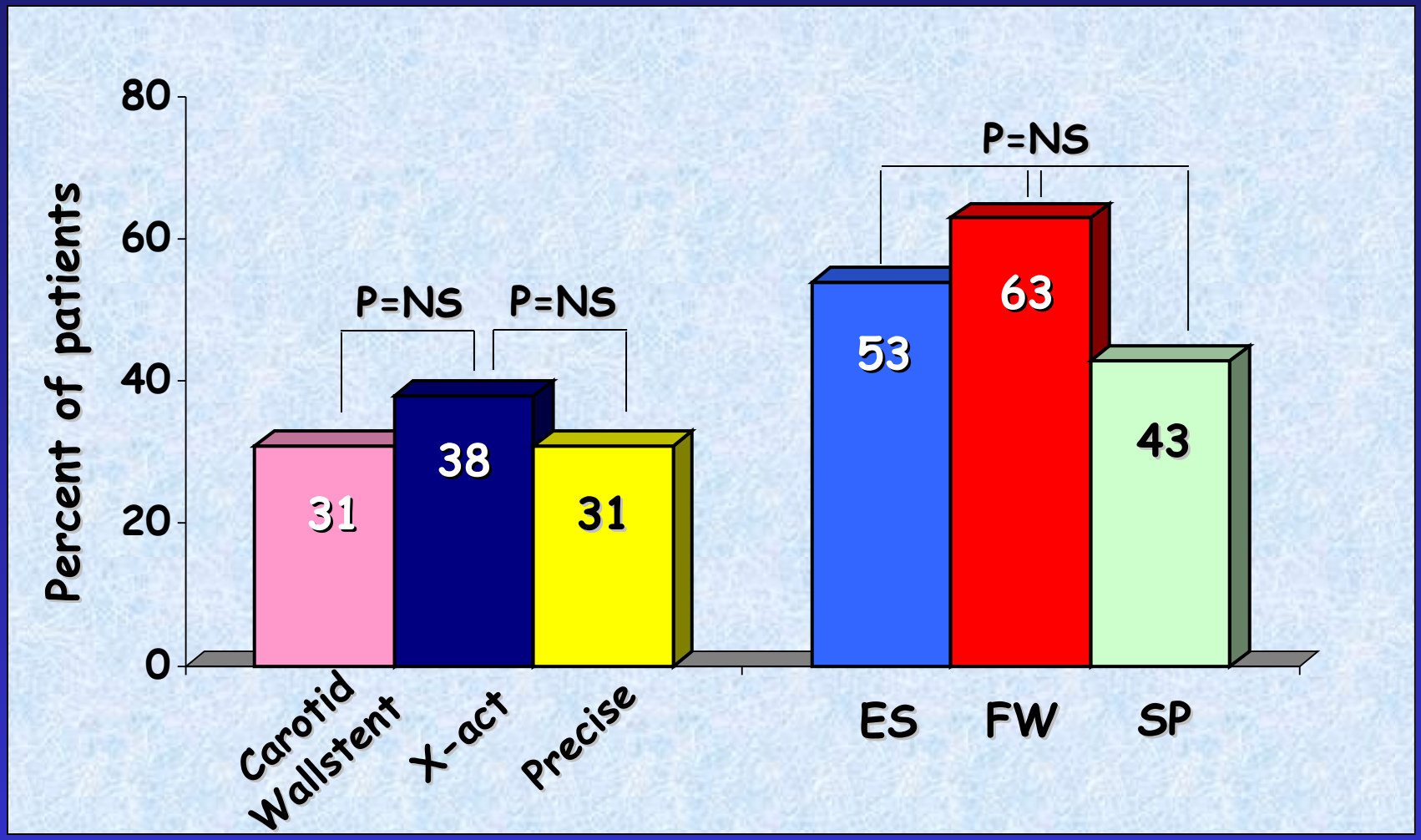
Medical Treatment

- **Pre-procedure**
  ASA 100 mg/die + Ticlopidine 500 mg/die or
  Clopidogrel 300 mg loading dose, then 75 mg/die at least 1 wk before admission.

- **Intra-procedure**
  Heparin 100 mg/Kg i.v.(ACT >250").
  Atropine 0.5-1 mg i.v. before stent postdilation

- **Post-procedure**
  Ticlopidine 500 mg/die or Clopidogrel 75 mg/die for 30 days.
  ASA indefinitely.

Procedural Characteristics

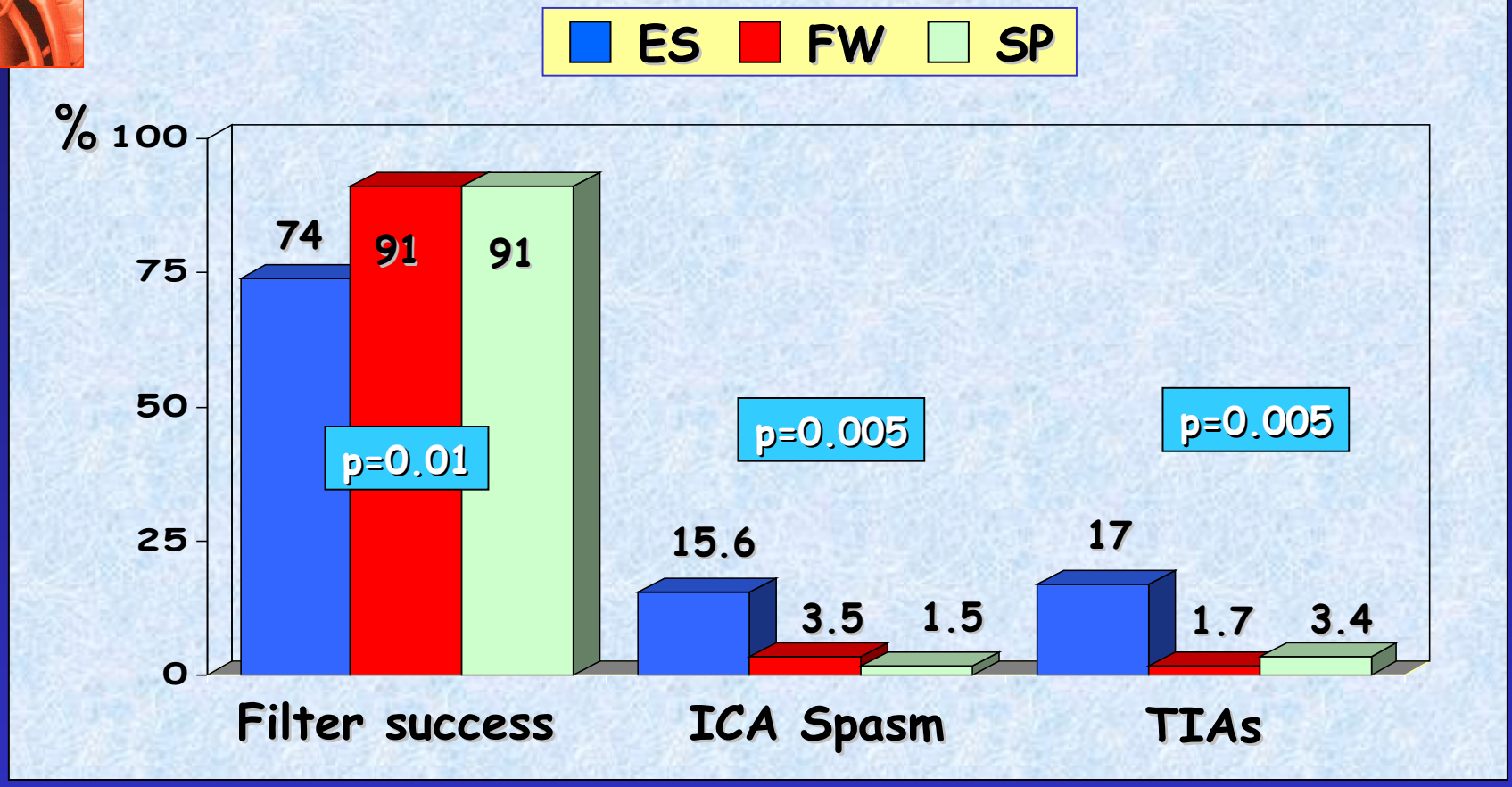


Filters Results

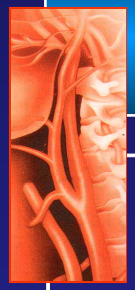
	ES (n=51)	FW (n=57)	SP (n=59)	P (*)
Crossing lesion (%)	47/51 (92)	54/57 (95)	56/59 (95)	0.70
Filter positioning (%)	50/51 (98)	56/57 (98)	57/59 (97)	0.84
Filter retrival (%)	50/51 (98)	57/57 (100)	59/59 (100)	0.98
Cross over (%)	2/51 (3.9)	1/57 (1.75)	1/59 (1.7)	0.28
Filter spasm (%)	8/51 (15.6)	2/57 (3.5)	1/59 (1.7)	0.003
Filter success (%)	38/51 (74)	52/57 (91)	54/59 (91)	0.005

(*) *Statistical analysis by ANOVA*

Filters Results



ANOVA with post-hoc analysis by Bonferroni

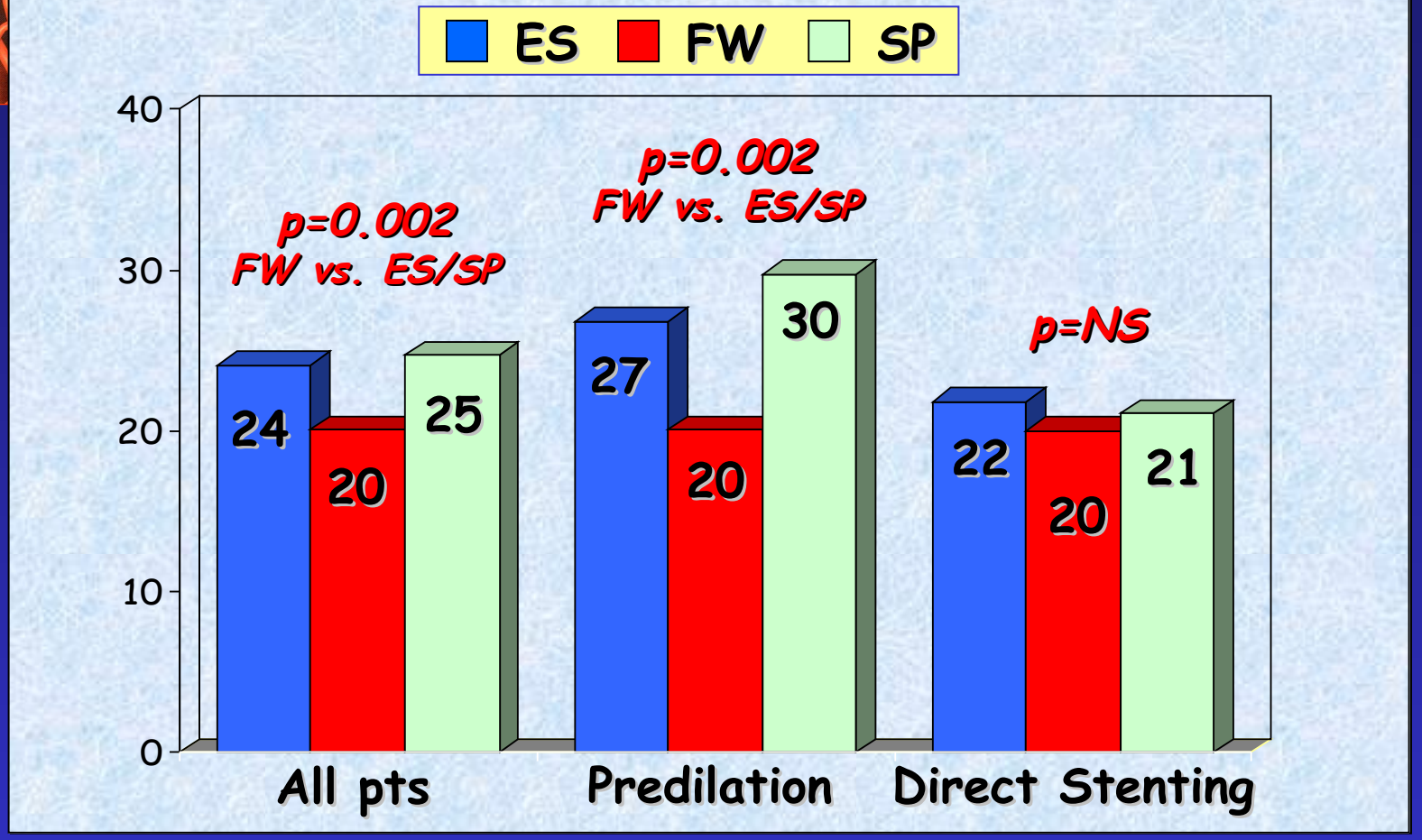


Procedural Success

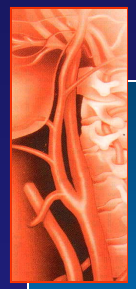
	ES (n)	ES (%)	FW (n)	FW (%)	SP (n)	SP (%)	P
Proc. Succ.	51/51	100	57/57	100	57/59	97	-
Death	0/51	0	0/57	0	0/59	0	-
Q/non-Q MI	0/51	0	0/57	0	0/59	0	-
Major Stroke	0/51	0	0/57	0	0/59	0	-
Minor Stroke	0/51	0	0/56	0	2/59*	3,4	-
Cum. MACCE	0/51	0	0/57	0	2/59	3,4	-

** 1 pt contrast encephalopathy. Full recovery in 1 wk.*
1 pt PRIND; full recovery in 3 days.

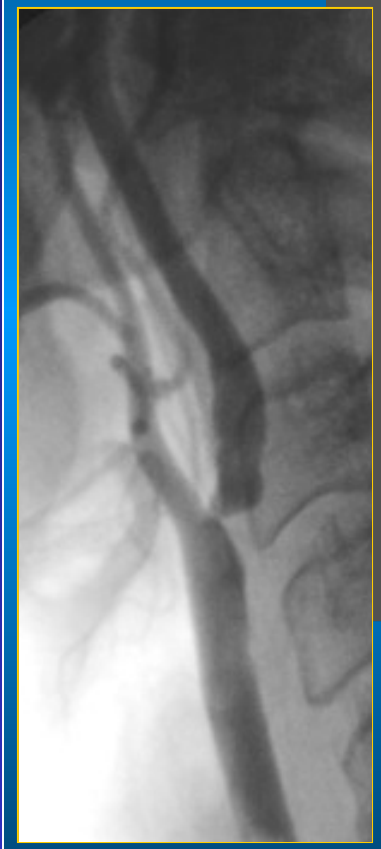
Guide-to-Guide Time



PS: In 45% ES/SP pts the filter was OTW



Case # 28



ICA spasm+TIA after ES filter positioning

After X-act stent deployment+NTG: spasm & TIA reversal

Conclusions

- ✓ CAS was accomplished with high procedural success and low rate of complications with each of the 3 filters.
- ✓ The lower filter success rate observed with the EmboShield was mainly due to spasm occurrence.
- ✓ Larger CRT are needed to assess whether any association exists between filter-induced spasm and neurological complications.