



**Innovations
in Cardiovascular
Interventions**



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Endovascular management of Intracranial Atherosclerotic disease

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- Atherosclerotic disease of the intracranial vessels accounts for about 8- 10% of ischemic strokes.



Northern Manhattan Stroke Study, Stroke, 1995

- 438 patients with acute cerebral infarction
- Atherosclerotic strokes: 17%
- Extracranial: 9%
- Intracranial: 8%
- Lacunar infarction: 30%
- Cardiac embolism: 21%
- Cryptogenic infarcts: 31%
- Other causes: 1%



- Intracranial atherosclerotic stroke
 - 1% of whites
 - 6% of blacks
 - 11% of hispanics
- Race-ethnicity is a determinant of IA Stroke increased by differences in stroke risk factors
- African americans and Asians appear more likely to have ICS



- IAD most common cause of stroke world-wide !?



- **WHAT IS THE ANNUAL RATE OF STROKE in ICS AFTER THE 1st EVENT?**



WASID (2005)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Comparison of Warfarin and Aspirin for Symptomatic Intracranial Arterial Stenosis

Marc I. Chimowitz, M.B., Ch.B., Michael J. Lynn, M.S.,
Harriet Howlett-Smith, R.N., Barney J. Stern, M.D., Vicki S. Hertzberg, Ph.D.,
Michael R. Frankel, M.D., Steven R. Levine, M.D., Seemant Chaturvedi, M.D.,
Scott E. Kasner, M.D., Curtis G. Benesch, M.D., Cathy A. Sila, M.D.,
Tudor G. Jovin, M.D., and Jose G. Romano, M.D.,
for the Warfarin–Aspirin Symptomatic Intracranial Disease Trial Investigators*

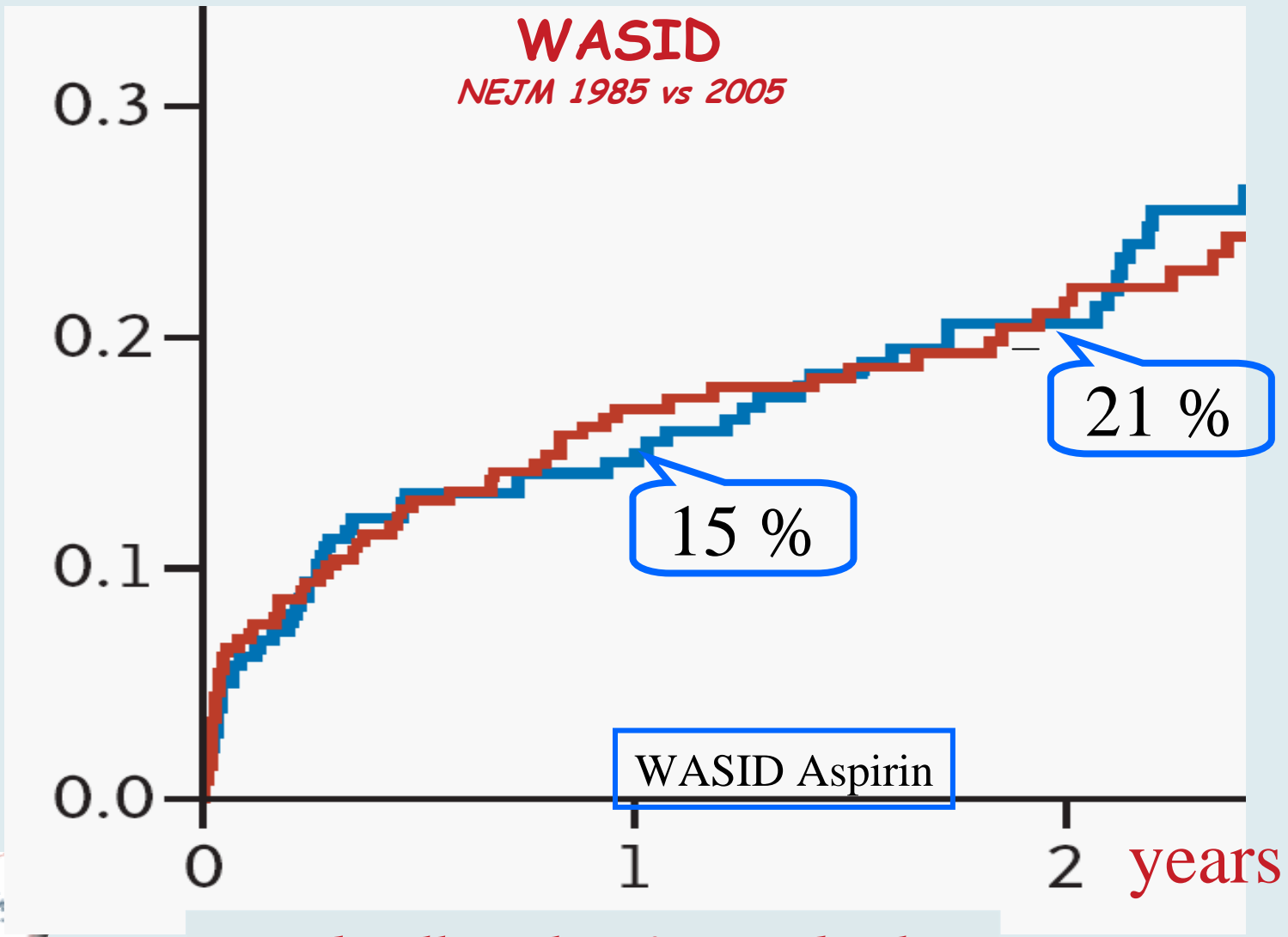


569 patients, ICA : 21 %, MCA : 32 %, Vertebral : 20 %, Basilar : 20 %
(50-99 % stenosis achieved in 87 % of the patients)

	Aspirin	Warfarin
One-year stroke rate:	12%	11%
Death	4.3	9.7
Major bleeding	3.2	8.3
MI and sudden death	2.9	7.3

"Warfarin is NOT recommended", Aspirin is as effective and safer





Wasid : all strokes & vasc deaths ;

Subgroup of high
risk
intracranial
stenoses ?



Severity of stenosis

- Rate of stroke:
 - $\geq 70\%$ stenosis = 18% @1 year
 - $< 70\%$ stenosis = 7% @ 1 year



Time from qualifying event to enrollment

ICS \geq 70% :yearly rate of ipsilateral stroke

Event less than 30 days before enrollment: 23%

Event more than 30 days before enrollment: 10%



High-risk at inclusion (*Wasid data*) (*Stroke in the territory of the stenotic vessel*)

N=569	YES	NO	p
NIHSS > 1 (n : 204)	20	10	0.001
Stenosis ≥ 70 % (n : 355)	19	10	0.001
≤ 17 days (n : 288)	17	10	0.03
Female (n : 219)	17	11	0.06



High risk subgroup

- Patients with:
 - Severe stenosis (70-99%)
 - Stroke within 30 days prior to enrollment

Have the highest rate of ipsilateral stroke:
22.9% at one year, 25% at 2 years



Strategies for Endovascular revascularization



- Difficult access especially in the anterior circulation
- Case-series, no demonstration of safety and efficiency
- Current indication of endovascular management: recurrence of stroke under optimal medical treatment



Percutaneous Transluminal Balloon angioplasty

- 120 patients, multiple centers
- 5.8 % periprocedural stroke and deaths
- Yearly event rate of 3.2% (ipsilateral stroke and neurological deaths)
- 40-months follow-up



Marks, Stroke, 2006; 37, 1016- 1020

Percutaneous Transluminal Balloon angioplasty

- Acute vessel recoil in 40.3%
- Acute occlusion
- Post residual stenosis # 40%
- Dissection (intimal flap) > 20%



Marks, Stroke, 2006; 37, 1016- 1020

Coronary stents

- Rigidity limits the access
- Periprocedural complication rates between 0 and 36%
- Residual stenosis < 10%



THE WINGSPAN devices, Boston scientific

- Self-expanding Intracranial Stent
- Low radial force



THE WINGSPAN « PROCEDURE »

- PTA balloon sized 80% of the normal diameter first, followed by stent placement
- Hybrid between the PTA and stenting strategies



Technical improvements

- JNS, 2002: Staged stent-assisted angioplasty for...
- JNS, 2003 : Comparison of periprocedure complications resulting from direct stent placement...and staged placement in the basilar artery
- Radiology, 2004 : Recurrent symptomatic high-grade intracranial stenosis: safety and efficacy of undersized stents.....



WINGSPAN: Initial results

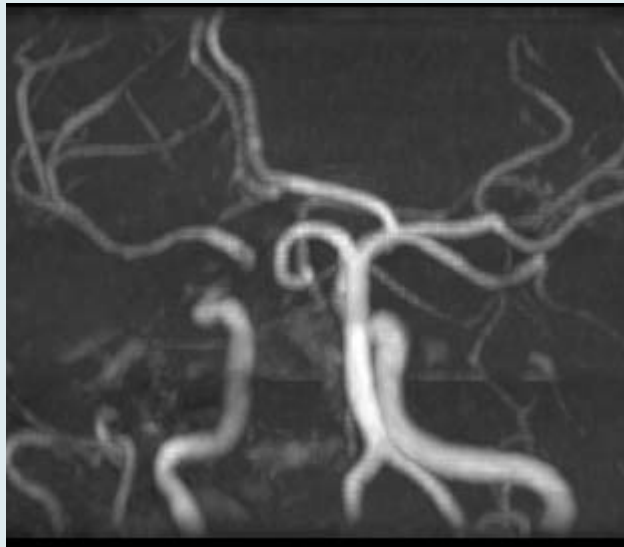
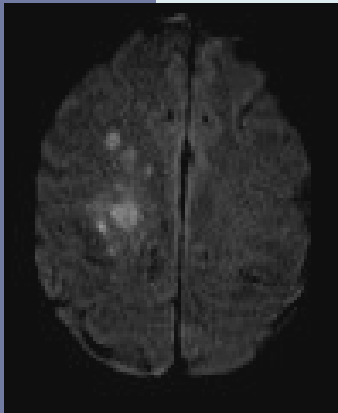
- Low rates of periprocedural morbidity and mortality (4.4%) in a series of 45 patients



Bose, The winspan study presented at ASNR Toronto 2005

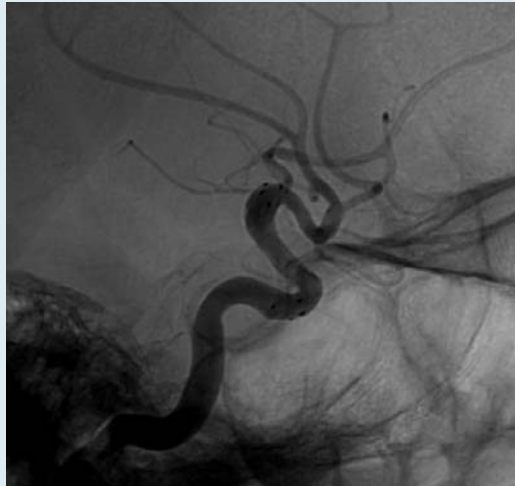
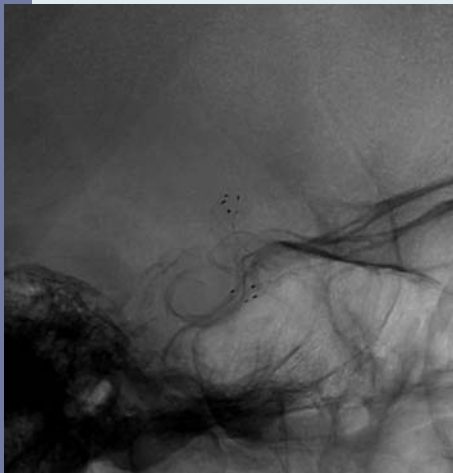
- 63 year-old woman
- Recurrent left hemiparesis and aphasia refractory to medical treatment
- MR:
 - Right intracranial carotid stenosis
 - Watershed infarction
- Acute worsening, emergency procedure





WINGSPAN Procedure





Complete recovery at 3 months under aspirin and plavix



Multicentric study: Lyon, Montpellier, Nice, Toulon

Endovascular treatment with intracranial stent
(WINGSPAN).

50 patients included

- Any stroke, IC hemorrhage or death:
 - 12% within 30 days
 - 16% within 6 months
 - Imaging follow-up to be completed



WINGSPAN :Current results

- 129 patients
- Success rate: 96.7%
- Mean pre-stent stenoses: 82%
- Mean post-stent stenoses: 20%
- 54 to 38% stenosis / 44 to 27% before and after wingspan deployment.



NIH registry for 70-99% symptomatic ICS Zaidat, Neurology, 2008; 70:1518-1524

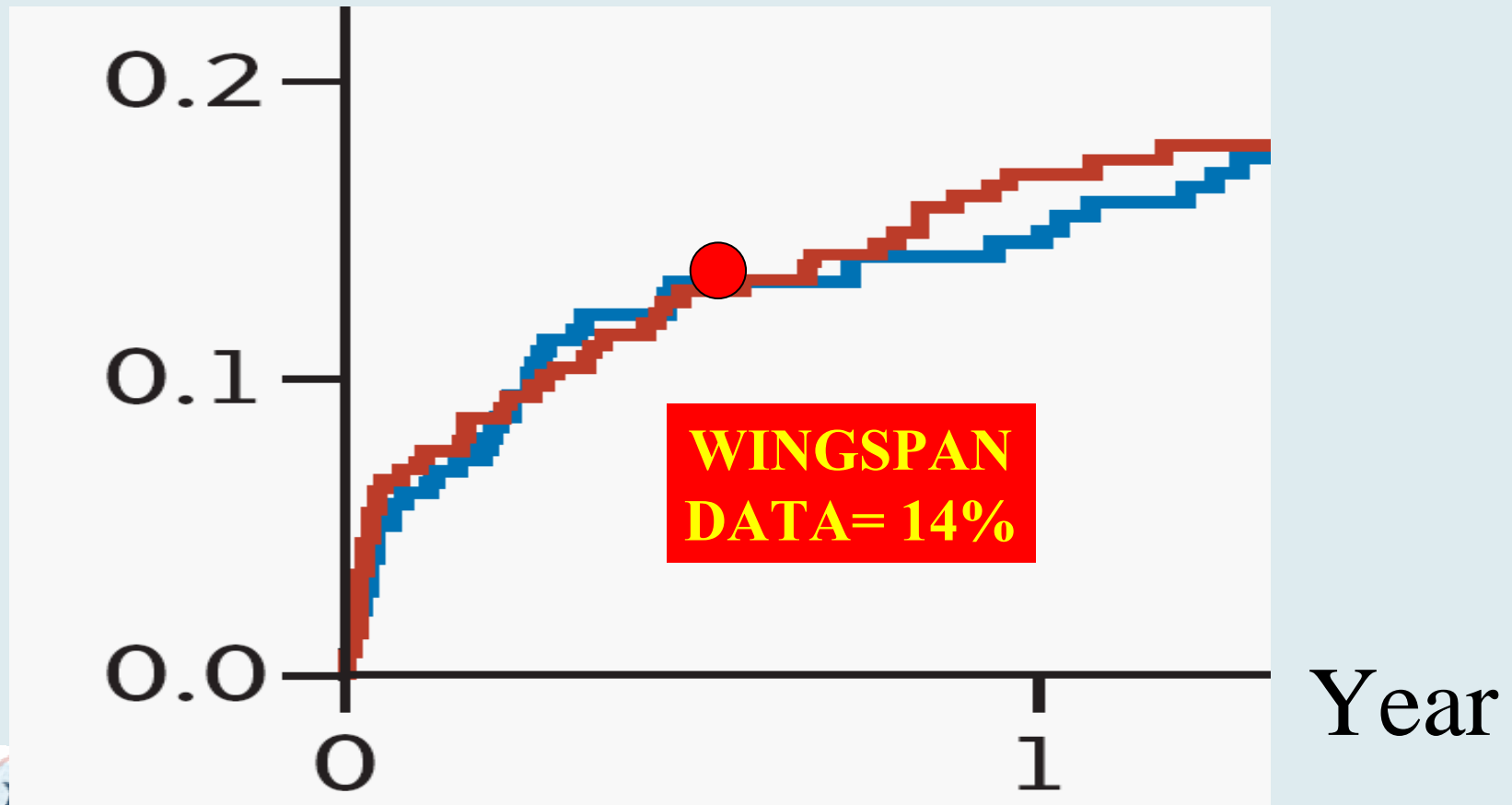
WINGSPAN :Current results

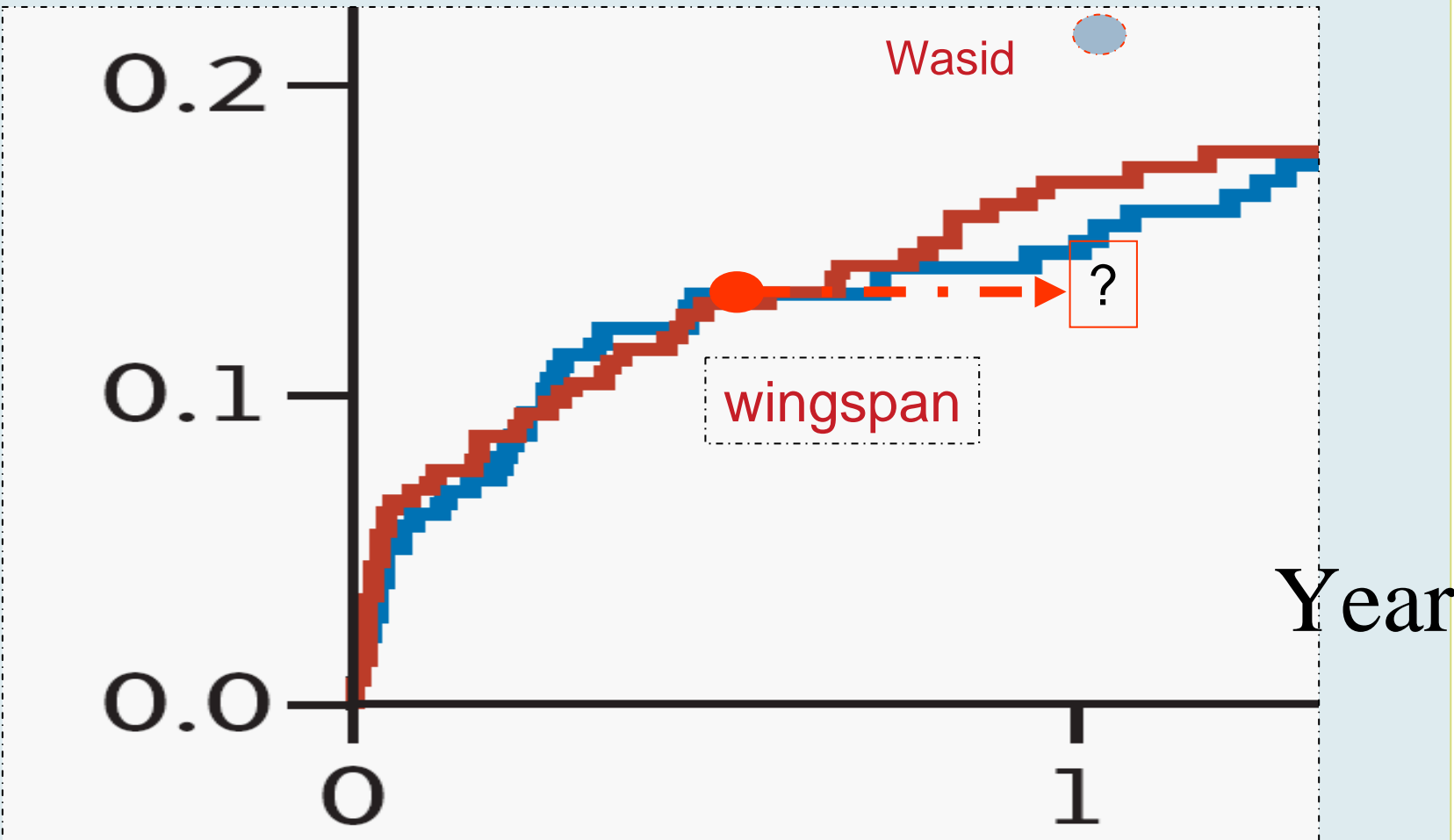
- Any stroke, IC hemorrhage or death within 30 days or ipsilateral stroke beyond 30 days =14% at 6 months:
 - 6.2% within 24 hours
 - 9.6% within 30 days (3.4% during days 2 to 30)
 - 14% at 6 months



NIH registry for 70-99% symptomatic ICS Zaidat,
Neurology, 2008; 70:1518-1524

WASID vs NIH registry





**WASID >70% + 30 days vs
NIH registry**



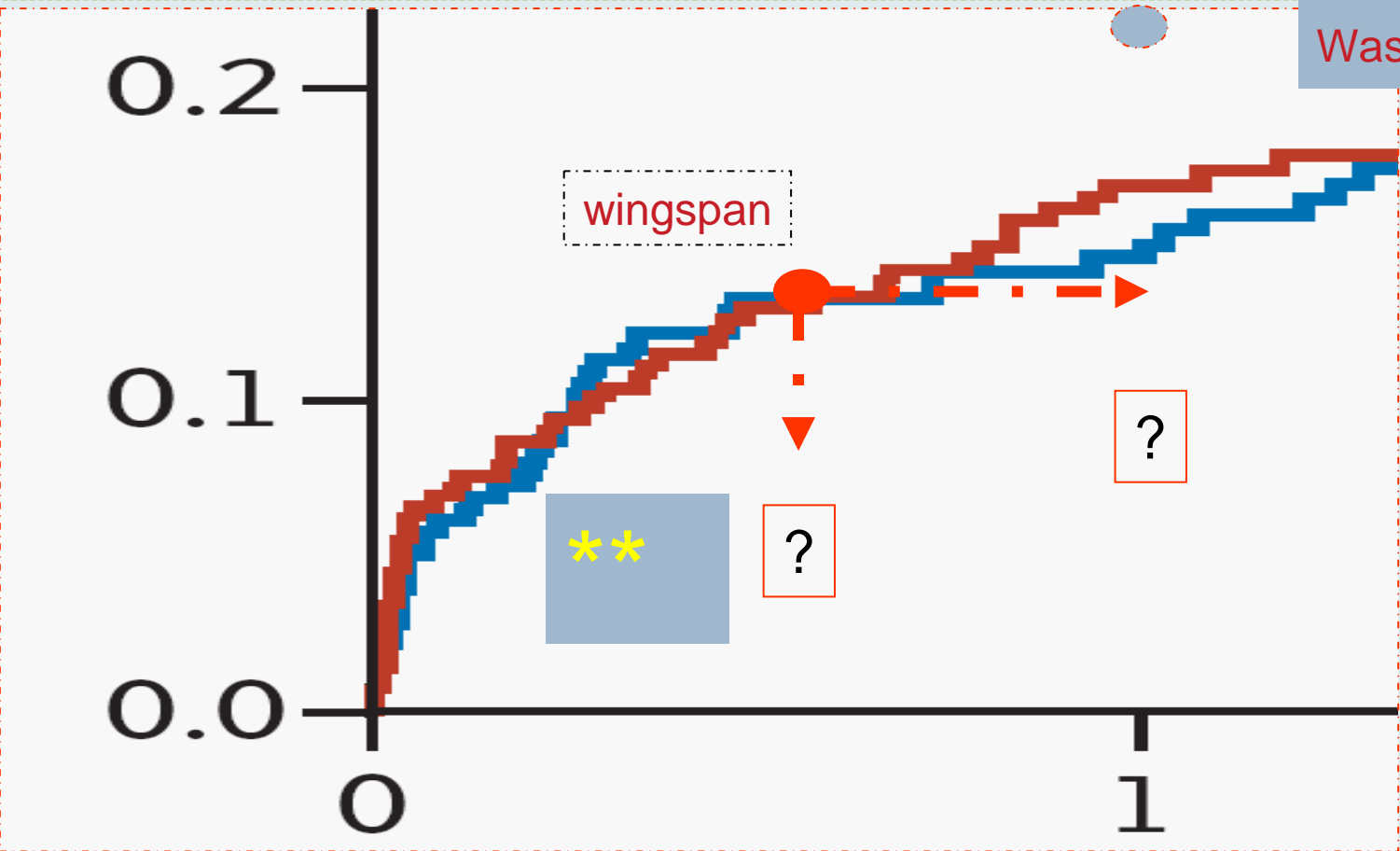
Rate of stroke and death within 30 days or stroke in the territory after 30 days :

- Low enrolling centers < 8 patients: 23%
- High enrolling centers > 14 patients: 9%

Mean percent of stenosis was the only factor significantly different between patients at high vs low recruiting centers: High = 80% Low = 86%



NIH registry for 70-99% symptomatic ICS Zaidat, Neurology, 2008; 70:1518-1524



WASID >70% + 30 days *vs NIH registry High recruiting centers **



WINGSPAN: Intrastent restenosis

- Definition: >50% residual stenosis
- Overall restenosis rate= 31% (+ 4 cases of complete occlusion), 9% symptomatic
- ≤ 55 yo vs > 55 yo: 50 vs 33%
- ≤ 55 yo and supraclinoid S: #90% ISR 40% symptomatic! Specific entity?
- Overall except this later group: 24% ISR, 4% symptomatic



Turk et al, AJNR, 2008; 29: 23-27

Conclusion 1: randomized trial

- **SAMMPRIS: Stenting and Aggressive Medical Management for preventing Recurrent stroke in Intracranial Stenosis:**
 - Phase III multicenter trial
 - TIA or non disabling stroke within 30 days prior to enrollment: *first event*
 - caused by 70-99% stenosis of a major ICS
 - randomized to intensive medical therapy alone or intracranial angioplasty and stenting with the wingspan stent.



CONCLUSION

- **Drug-eluting stents**
 - off-label
 - Coronary, less flexible stents
 - Antiplatelet therapy for life?
- **Other self-expandable IC stents:**
 - Off-label
 - Self-expandable

