

Minor Stroke, Major Consequences

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Presenter Disclosure Information

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Unlabeled uses disclosure: tPA in 3-4.5 hour window is not FDA approved

Grants Support:

- Florida Regional Coordinating Center for StrokeNet, PI (NIH/NINDS)
- Mechanisms of Early Recurrence in Intracranial Atherosclerotic Disease-MyRIAD, PI (NIH/NINDS)
- Transitions of Care Stroke Disparity Study-TCSD-S, PI (NIH/NIMH)
- Florida Stroke Registry, co-I (State of Florida)
- Mild and Rapidly Improving Stroke Study-MaRISS, PI (Genentech)

Other activities:

- Steering Committee, PRISMS Trial (Genentech)

Mild Stroke: Outline

- Epidemiology
- Short and long term outcomes
- Causes of poor outcomes
- Safety of thrombolytics
- Growing use of IV lytics
- Thrombolysis in non disabling stroke: PRISMS Trial
- Defining disabling stroke
- The MaRISS study
- Experience with endovascular approaches
- Conclusions

Mild & Rapidly Improving Stroke common

MS & RIS in population based studies

Population	Median NIHSS	NIHSS 0-5
GCNK (Reeves 2013)	3	
Corpus Christi (Brown 2004)	3	
NOMAS (Dhamoon 2009)		54.6%

MS & RIS presenting to ED

Author	Definition MS/RIS	Time	N	MS/RIS %
Smith 2011	MD judgment	≤2h	93,517	31%
George 2009	MD judgment	≤3h	2,670	34%
Barber 2001	MD judgment	≤3h	1,168	31%
Kleindorfer 2004	NIHSS 0-4	≤3h	406	43%

Exclusion Criteria for Mild Deficits in Prior Randomized Thrombolysis Trials

Trial	Exclusion Criterion
NINDS Parts 1 & 2	“Rapidly improving or minor symptoms”
ECASS I and II	Scandinavian Stroke Scale score <50
ATLANTIS A and B	“NIHSS <4 and normal speech & visual fields”
ECASS III	“Symptoms rapidly improving or only minor”
EPITHET	NIHSS <5
IST 3	Symptoms considered likely to resolve completely within the next few hours (ie TIA)

Mild stroke not studied in randomized thrombolysis trials

Trial	NIHSS 0-4
NINDS A	16 (5%)
NINDS B	13 (4%)
ECASS I	34 (5%)
ECASS II	47 (6%)
ATLANTIS A	10 (7%)
ATLANTIS B	47 (8%)
EPITHET	98 (12%)
IST 3	400 (13%)

Outcome of Mild & RIS not treated with IV lytics

Author	Definition MS/RIS	N	Poor Outcome definition	Outcome
Smith 2005	MD judgment	128	Not d/c home	27%
Willey 2012	MD judgment	48	Not d/c home	23%
Hills 2006	MD judgment	32	Not d/c home	34.4%
Smith 2011	MD judgment	29,200	Not d/c home	28.3%
Kenmuir 2015	NIHSS 0-4	869	Not d/c home	35.2%
Barber 2001	MD judgment	98	mRS 3-6 at d/c	32%
Sun 2011	NIHSS 0-3	49	mRS 3-6 at d/c	34.7%
Rajajee 2006	NIHSS ≤ 4	39	mRS 3-6 at d/c	20.5%
Barber 2001	MD judgment	98	mRS 3-6 at d/c	33.7%
Nedeltchev 2007	NIHSS ≤ 5 or $\downarrow \geq 4$	162	mRS 2-6 at 90 d	23.5%
Fischer 2010	NIHSS ≤ 5	249	mRS 2-6 at 90 d	32%
Huisa 2012	NIHSS ≤ 5	74	mRS 2-6 at 90 d	31.1%
Urria 2013	NIHSS ≤ 5	84	mRS 2-6 at 90 d	19%
Khatry 2012	NIHSS ≤ 5	136	mRS 2-6 at 90 d	29%
Coutts 2012	NIHSS 0-3	499	mRS 2-6 at 90 d	15%
Van der Berg 2009	MD judgment	27	mRS 2-6 at 90 d	11.5%
Leira 2012	NIHSS 0-6	194	GOS >1 & BI <95 at 90 d	32%

Short term outcomes in mild and rapidly improving stroke not treated with thrombolytics

Outcomes	NIHSS 0-5 N=27751	NIHSS >5 N=4832	P value
Discharge home	76.1	49.0	<.0001
Independent ambulation*	76.4	50.0	<.0001

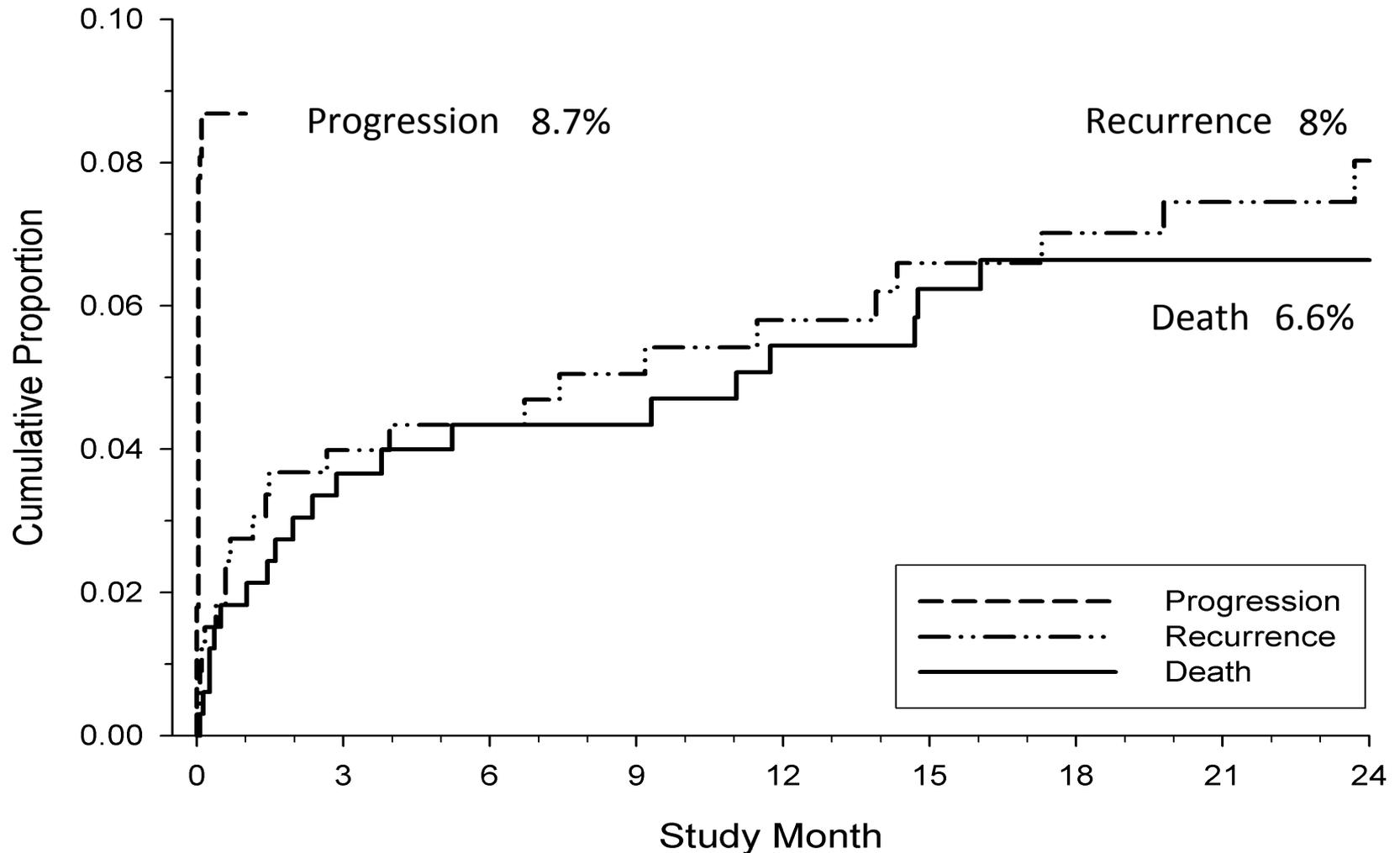
Amongst patients arriving within 4.5 hours and no other exclusions for treatment

* Restricted to those with documented ability to ambulate independently at baseline.

Causes for Poor Outcome after Mild and/or Rapidly Improving Stroke

- Low score in NIHSS does not exclude disabling symptoms¹
- Worsening after initial event in 8-10%^{2,3}
 - Collateral flow failure⁴
- Rapid improvement associated with symptom re-occurrence⁵
 - Large vessel re-occlusion after tPA in 12%⁶
- Other causes: systemic/metabolic events, hemorrhagic transformation, etc.

Clinical Progression in Minor Stroke



Infarct growth associated with poor outcomes

ASAP Study: N=169, DWI <24 h and at 5 d, 90 d follow up

- Median baseline NIHSS 6 (IQR 3-13), DWI 4.6 cc (IQR 1.6-39.5)
- 5 day DWI growth: none 15%, **>0-10 cc 56%**, **>10 cc 29%**
- For each 10 cc DWI growth: mRS 0-1 OR=0.57 (p=0.01)
- For each 10 cc DWI growth: BI \geq 95 OR=0.75 (p=0.056)

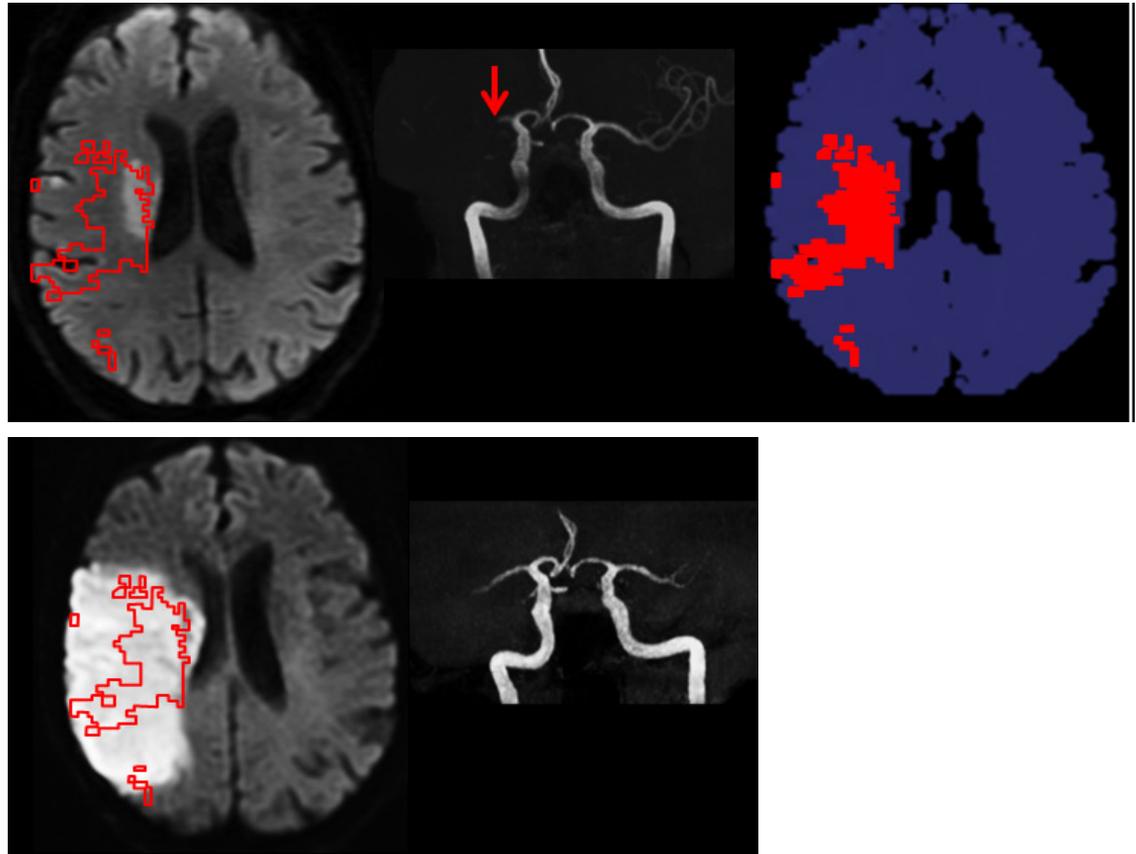
ASAP NIHSS 0-5 subgroup (n=96)

- Poor outcome (mRS 2-6) in **79% with >10% infarct growth**

Deterioration due to extrapenumbral extension

40 cases with early neurological deterioration (Δ NIHSS ≥ 4 at 24h) post tPA, 10 unexplained (no ICH, edema, new embolic stroke, seizure)

DWI growth beyond mismatch in 9/10 suggesting hemodynamic factors

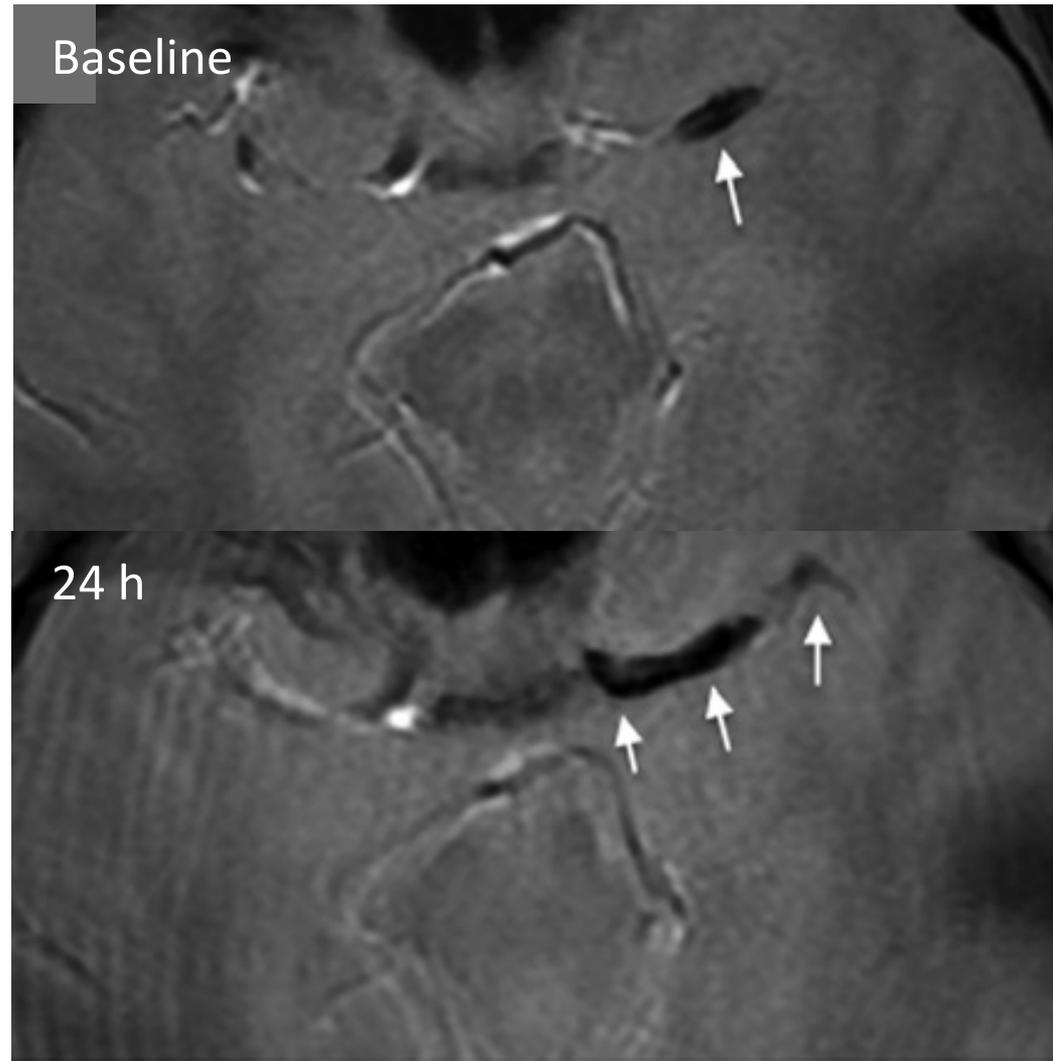


Deterioration due to clot extension

120 with LVO and IV rtPA,
no recanalization of f/u
MRA

22 with unexplained early
neurological deterioration

Susceptibility vessel signal
extension in 34%, more
common in END: 59% vs.
29% without, $p=0.02$



Outcome in Mild Stroke treated with IV lytics

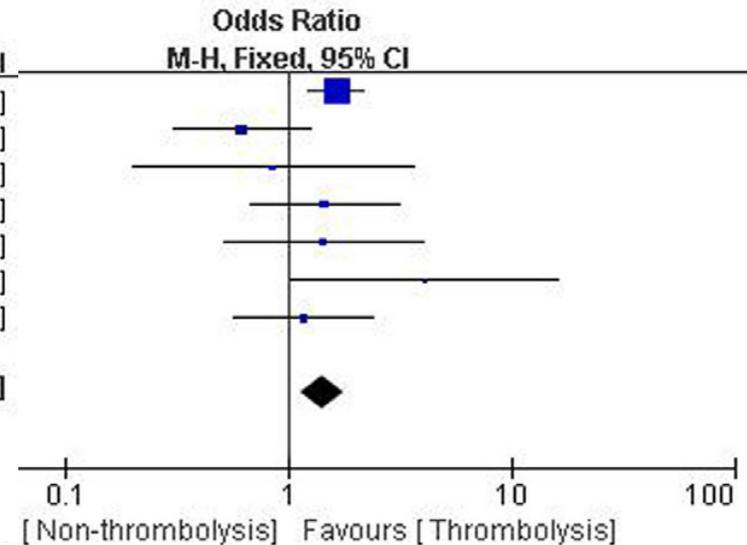
Author	Definition MS	N	Poor outcome definition	Outcome
Willey 2013	NIHSS ≤ 5	516	Not d/c home	36%
Urta 2013	NIHSS ≤ 5	119	mRS 2-6 at 90 d	17%
Huisa 2012	NIHSS ≤ 5	59	mRS 2-6 at 90 d	42.4%
Steffenhagen 2009	NIHSS ≤ 5	77	mRS 2-6 at 90 d	25.3%
Wendt 2012	NIHSS ≤ 4	107	mRS 2-6 at 90 d	26%
Khatri 2010 (NINDS)	NIHSS ≤ 5	42	mRS 2-6 at 90 d	21.4%
Strbian 2013	NIHSS ≤ 6	488	mRS 2-6 at 90 d	19.7%

Meta-analysis of alteplase in mild stroke

Non-randomized studies

Study or Subgroup	Thrombolysis		Non-thrombolysis		Weight	Odds Ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total		
Greisenegger et al 2014	328	445	281	445	56.9%	1.64 [1.23, 2.18]
Huisa et al 2012	34	59	51	74	14.8%	0.61 [0.30, 1.25]
Khatri et al 2010	33	42	13	16	3.1%	0.85 [0.20, 3.63]
Khatri et al 2015	33	55	26	51	8.3%	1.44 [0.67, 3.11]
Nesi et al 2014	41	47	67	81	4.8%	1.43 [0.51, 4.01]
Ng et al 2016	31	34	28	39	1.8%	4.06 [1.03, 16.06]
Urta et al 2013	99	119	68	84	10.3%	1.16 [0.56, 2.41]
Total (95% CI)		801		790	100.0%	1.43 [1.14, 1.79]

Total events 599 534
 Heterogeneity: $\text{Chi}^2 = 9.28$, $\text{df} = 6$ ($P = 0.16$); $I^2 = 35\%$
 Test for overall effect: $Z = 3.14$ ($P = 0.002$)



OR for mRS 0-1: 1.43 (1.14,1.7)

Publication	Origin	Cases	Definition	Time to needle (hours)
Khatri et al ²¹	USA	58	≤5	<3
Huisa et al ¹⁸	USA	133	≤5	<3
Urta et al ¹²	Spain	203	≤5	<4.5
Greisenegger et al ¹¹	Austria	890	≤5	<3
Nesi et al ¹³	Italy	128	≤6	<3
Khatri et al ¹⁴	USA	106	≤5	<3
Ng et al ¹⁶	Australia	73	≤3	<4.5

Stroke severity and outcomes in mild stroke (NIHSS 0-5) treated with IV rtPA within 4.5 hours

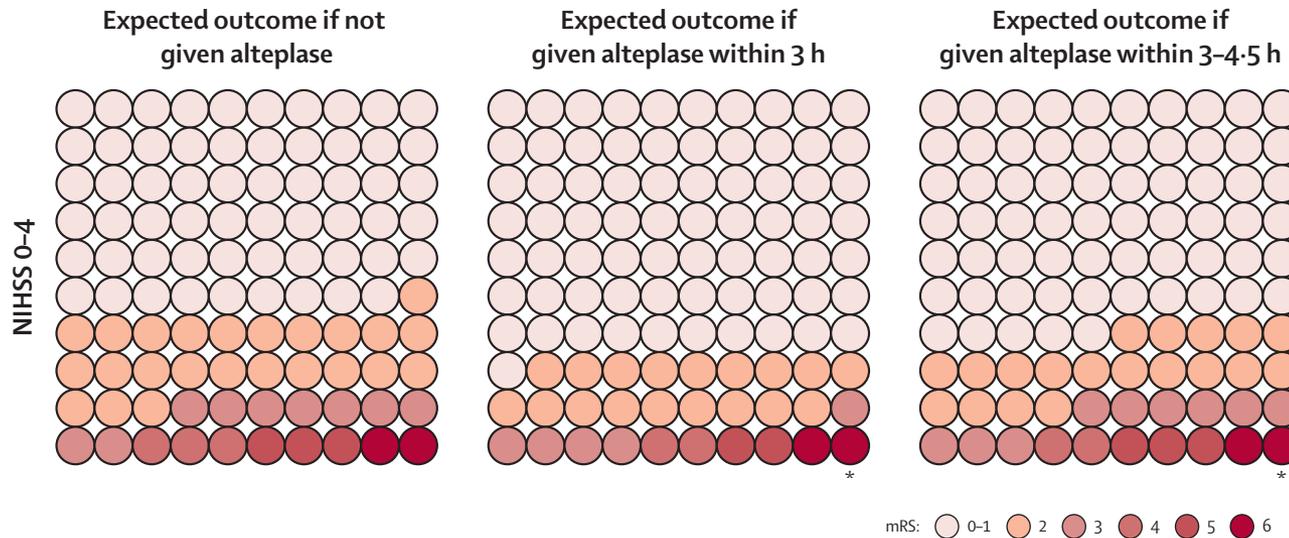
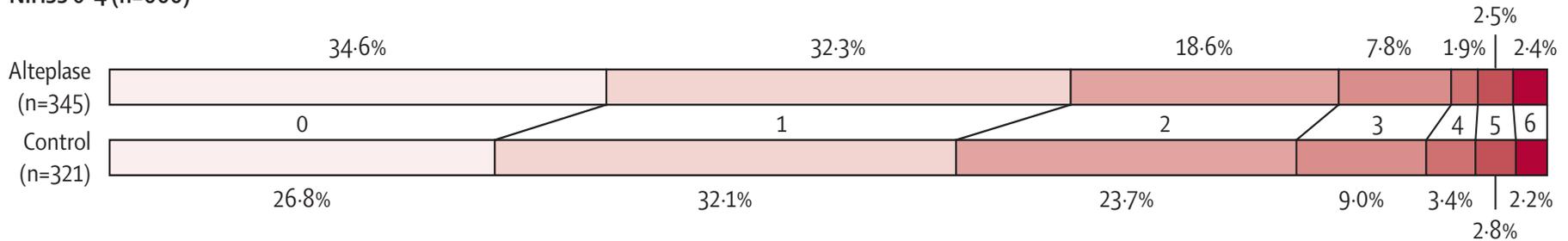
Outcome	NIHSS 0 <i>N=192</i>	NIHSS 1 <i>N=409</i>	NIHSS 2 <i>N=771</i>	NIHSS 3 <i>N=1155</i>	NIHSS 4 <i>N=1583</i>	NIHSS 5 <i>N=1800</i>	Univ p-value
LOS \geq 3 days	67.7	62.4	67.2	70.7	75.1	78.2	<0.0001
Discharge home	83.3	81.7	78.0	73.6	68.3	63.7	<0.0001
Independent ambulation*	82.1	78.3	78.8	70.6	68.1	63.8	<0.0001

* Restricted to those with documented ability to ambulate independently at baseline (N=4,221)

Outcomes in Mild Stroke: data from RCT

Total enrolled in prior RCTs: 666 (IST-3 n=400)

NIHSS 0-4 (n=666)



Subcohort analysis of IST 3 trial: mild stroke

Subgroup in IST3: 106 patients with NIHSS ≤ 5 within 3 h of onset

- Alive & Independent (OHS 0-2): 84% vs. 65%, aOR 3.3, 95% CI 1.2, 8.8
- Favorable outcome (OHS 0-1): 60 vs. 51%, aOR 1.9, 95% CI 0.8, 4.4

Oxfordshire Handicap Score (OHS) at 6 Months

■ OHS 0 ■ OHS 1 ■ OHS 2 ■ OHS 3 ■ OHS 4 ■ OHS 5 ■ OHS 6

Control Arm (n=51)



IV rt-PA Arm (n=55)



Symptomatic ICH after IV lytics in Mild Stroke

Author	Definition MS	Time	N	sICH
Khatri 2010 (NINDS)	NIHSS ≤ 5	≤ 3 h	42	2%
Steffenhagen 2009	NIHSS ≤ 5	≤ 3 h	77	2.6%
Tanne 2002	NIHSS ≤ 5	≤ 3 h	115	4.5%
Huisa 2012	NIHSS ≤ 5	≤ 3 h	59	5%
Wendt 2012	NIHSS ≤ 4	≤ 4.5 h	107	1%
Urra 2013	NIHSS ≤ 5	≤ 4.5 h	119	0
Strbian 2013	NIHSS ≤ 6	≤ 3 h	488	2%
Hassan 2010	NIHSS ≤ 6	≤ 3 h	27	3.7%
Greisenegger 2014	NIHSS ≤ 5	≤ 3 h	445	2.5%

Treatment complications in Mild Stroke (NIHSS 0-5) treated with IV rtPA within 4.5 hours

Outcome	Total Population (N=5,910)	Treated 0-3 hours (N=4,643)	Treated 3-4.5 hours (N=1,267)	Univariate p-value
Symptomatic ICH*	1.84	1.96	1.42	0.20
Life threatening/serious systemic hemorrhage	0.20	0.24	0.08	0.27

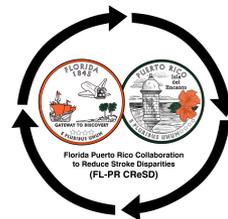
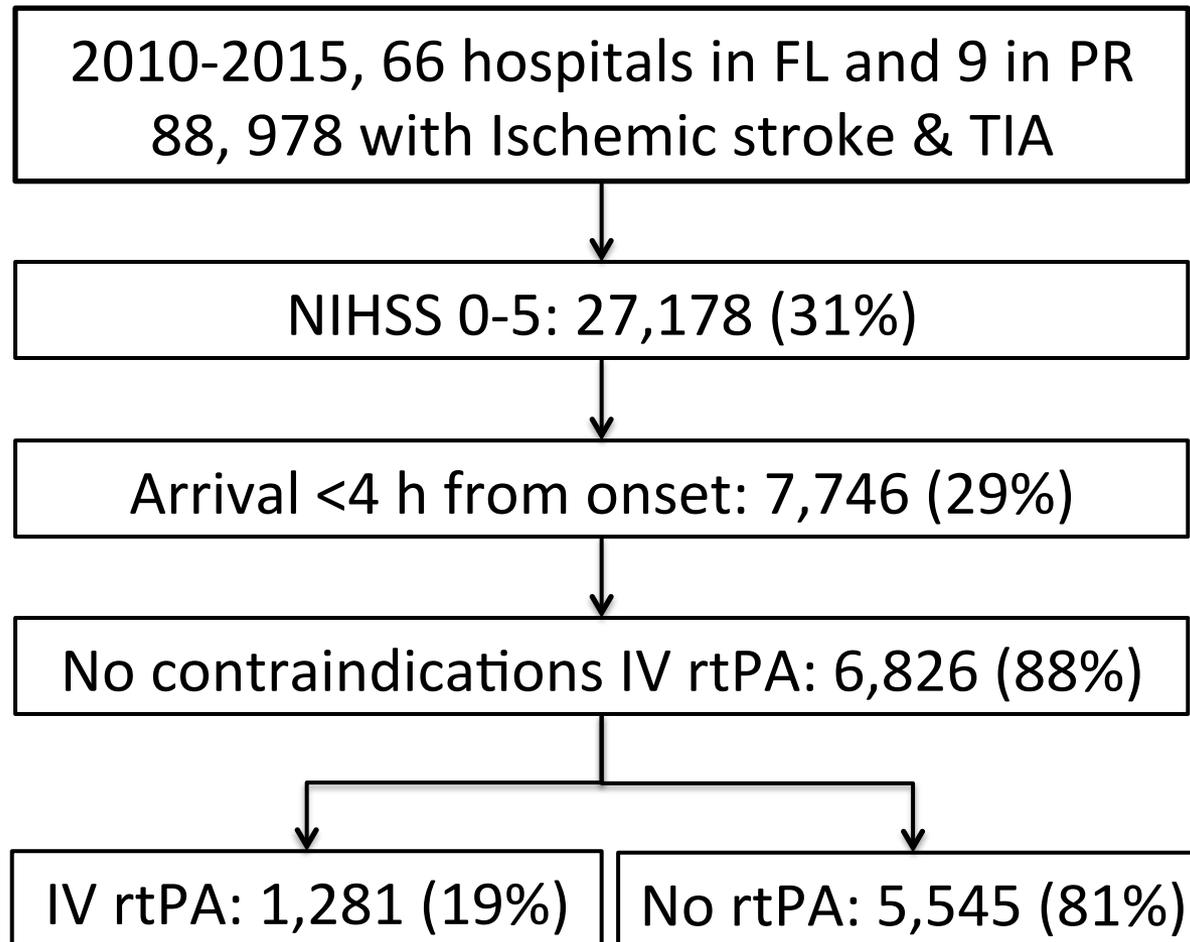
* No difference across 6 NIHSS scores

Proportion of Mild Stroke treated with IV lytics

Author	Source	Definition Mild Stroke	N	Mild Stroke %
Ahmed 2010	SITS 2002-2010	NIHSS 0-5	20,101	13.2%
Stecksen 2012	Riks-Stroke 2007-2010	NIHSS 0-5	28,462	26.4%
Willey 2013	SPOTRIAS 2005-2009	NIHSS 0-5	2,626	21.3%
Schwamm 2013	GWTG-S 2003-2011	NIHSS 0-4	50,798	11.9%
Romano 2015	GWTG-S 2010-2012	NIHSS 0-5	31,119	13.5%

IV thrombolytics in patients with NIHSS ≤ 5

Florida Stroke Registry



IV thrombolytics in patients with NIHSS ≤ 5

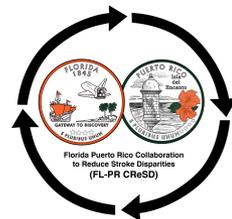
Florida Stroke Registry

Thrombolysis (OR, 95% CI)

- Academic hospital: 2.02 (1.39-2.95)
- Arrival 0-2 v. ≥ 3.5 h: 8.16 (4.76-13.98)
- Higher NIHSS: 1.87 (1.77-1.98)
- Aphasia: 1.35 (1.12-1.62)
- Faster DTCT: 1.81 (1.53-2.15)

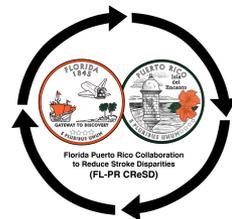
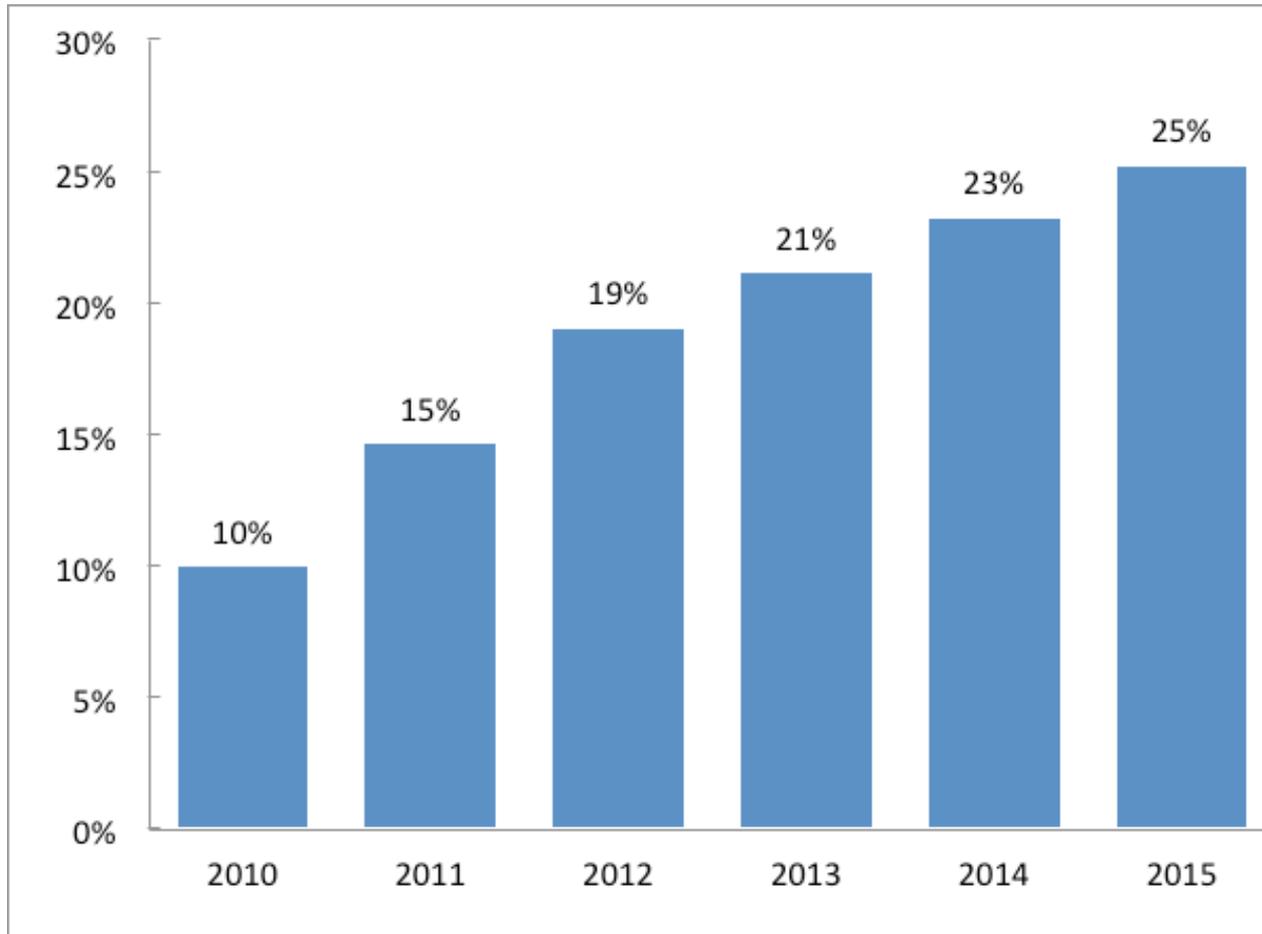
No Thrombolysis (OR, 95% CI)

- Older age: 0.98 (0.97-0.98)
- NHB v. NHW: 0.80 (0.69-0.93)
- Prior stroke/TIA: 0.61 (0.52-0.72)
- HTN: 0.74 (0.64-0.87)
- PVD: 0.67 (0.46-0.97)
- Off hour arrival: 0.87 (0.77-0.99)

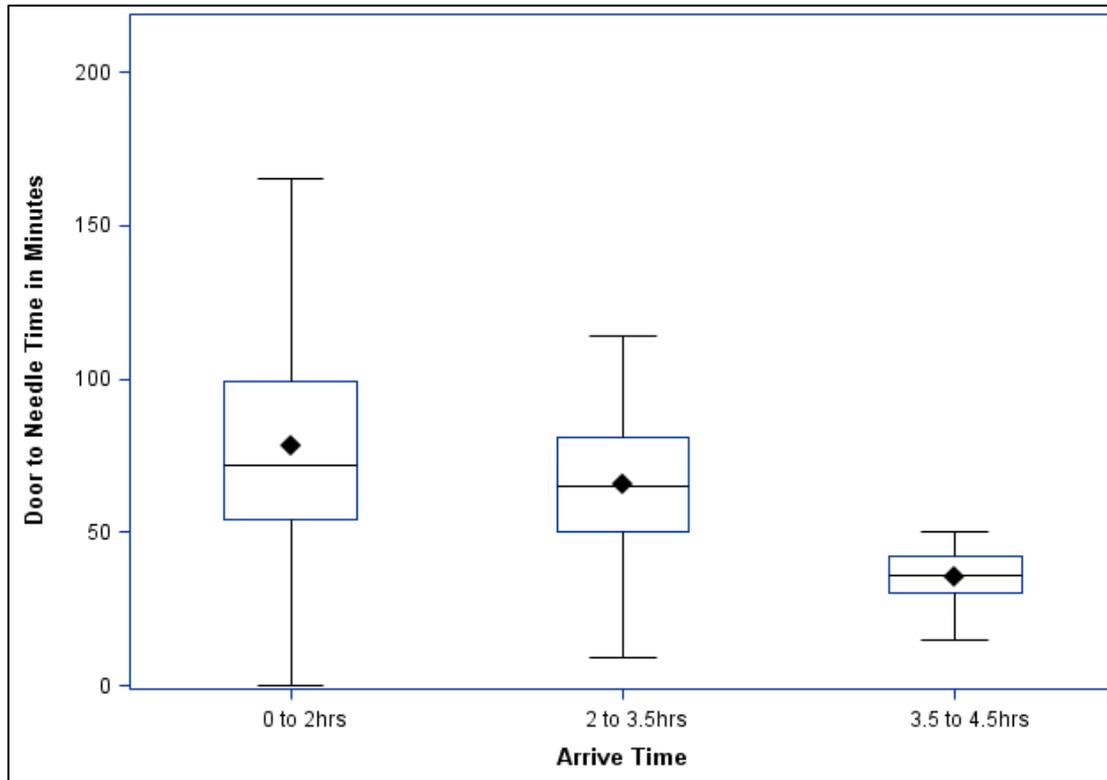


*MV analysis

IV thrombolytics in patients with NIHSS ≤ 5 Florida Stroke Registry



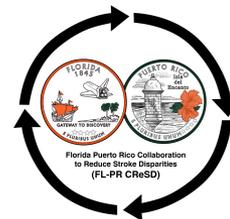
Time to Thrombolysis in Mild Stroke



Fast thrombolysis- DTN<60 min

- Aphasia: OR 1.36
- EMS arrival: OR 1.89
- Academic: OR 1.93
- Prior IS: OR 0.64

10 min delay in onset to arrival: faster lysis
OR 1.08 (95%CI 1.05,1.11)



Gaps in knowledge

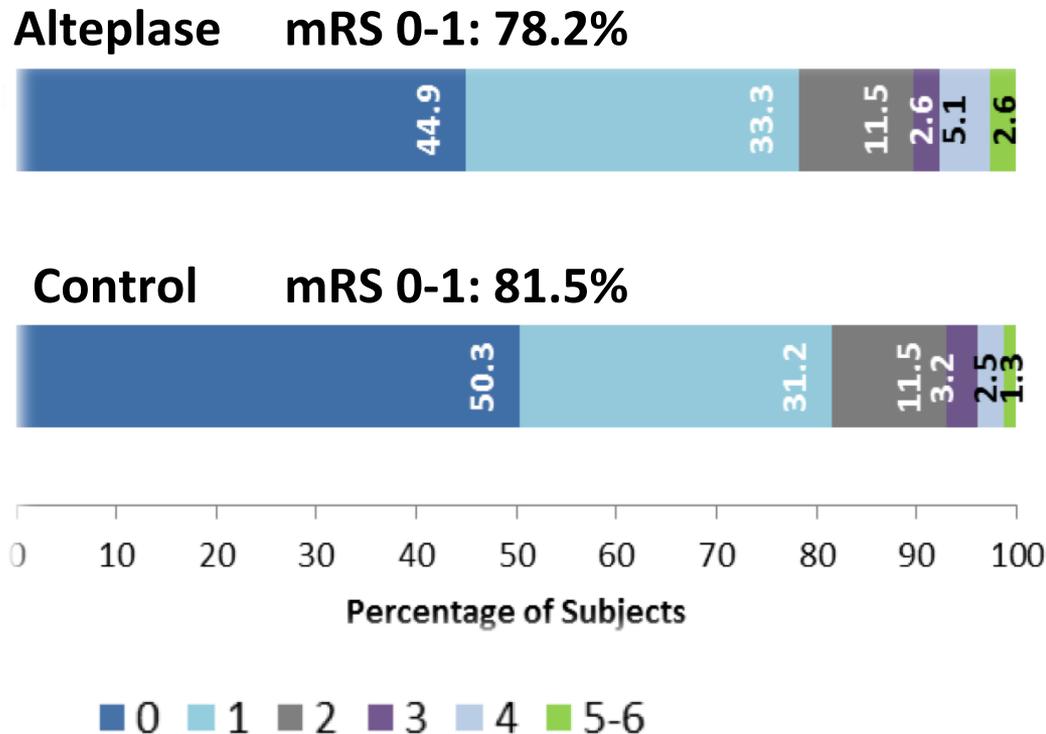
- Detailed outcome analysis in mild/rapidly improving stroke lacking.
 - Discharge outcomes may not represent final outcome.
 - Modified Rankin Scale unidimensional with ceiling effect.
 - Predictors of outcomes not evaluated.
- Retrospective comparisons between treated and untreated mild/rapidly improving stroke patients at high risk for bias.

PRISMS Trial

- Evaluate efficacy and safety of alteplase in minor not clearly disabling stroke.
- Eligibility: NIHSS 0-5, able to do all ADL, study drug <3 hours.
- IV alteplase + aspirin placebo vs. IV alteplase placebo + aspirin.
- Stopped by sponsor for enrollment below target: 313/948 enrolled.



Thrombolysis in mild *non disabling* stroke: PRISMS 90 day outcomes



**mRS 0-1 at 90 d:
ARD -1.1 (-9.4, 7.3)***

*Adjusted for Rx, age, time onset, NIHSS

Excluding mimics (n=40):
mRS 0-1 at 90 d: 77.5% v. 80.7%
ARD -1.4 (-10.5, 7.7)

Post-hoc analysis (Bayesian):
Prob. Benefit: 23%
Prob. benefit >6%: 1.9%

PRISMS Exploratory Outcomes

	IV Alteplase	Placebo	Risk Difference or OR (95% CI)
Modified Rankin Scale ^e 0	70 (44.9%)	79 (50.3%)	-3.6% (-14.2%, 7.1%)
NIHSS 0-1	108 (85.7%)	98 (81.7%)	1.3 (0.65, 2.6)
Barthel Index ^f 95-100	107 (79.3%)	118 (88.7%)	0.5 (0.3, 1.1)
Glasgow Outcome Scale ^g 1	110 (81.5%)	113 (85.6%)	0.8 (0.4, 1.6)
Total NIHSS Score, mean (SD)	1.2 (3.75)	0.8 (2.01)	0.4 (-0.4, 1.1)
Ambulatory performance ^h (meters per second)	0.95 (0.34)	0.98 (0.44)	-0.03 (-0.13, 0.08)
European Quality of Life [EQ-5D-3L], ⁱ mean (SD)	0.81 (0.21)	0.83 (0.20)	-0.02 (-0.07, 0.03)
Stroke Index Scale-16 (SIS-16), ^j mean (SD)	85.1 (21.0)	86.3 (21.4)	-1.1 (-6.2, 4.0)

- **Modified Rankin Scale: 0 (symptom free) to 6 (dead)**
- **Barthel Index: 0 (totally dependent) to 100 (self-care and mobility without assistance)**
- **Glasgow outcome: 1 (good recovery) to 5 (death)**
- **Ambulatory performance: comfortable walking speed over 6 meters**
- **European Quality of Life: 0 (death) to 1 (perfect health)**
- **Stroke Index Scale-16: 0 to 100, higher scores=better physical performance**

Thrombolysis in mild *non disabling* stroke: PRISMS complications

Secondary outcomes	Alteplase (n=154)	Aspirin (n=153)	Absolute risk diff (95% CI)
sICH 36 h (mod NINDS)	3.2%	0	3.3% (0.8%, 7.4%)
sICH 36 h (SITS MOST)	1.3%	0	1.3% (-1.2%, 4.6%)
90 d mortality	0.6%	0	

sICH SITS-MOST: PH2 + NIHSS₄

sICH NINDS: any worsening and blood on CT

Defining Disabling Symptoms

PRISMS Definition of Mild Stroke

NIHSS ≤ 5 and “Not Clearly Disabling”

- Consider the following...

- Can patient still do basic ADLs and/or return to work?

- >Basic ADLs: Dressing/bathing, Eating, Ambulating (walking),

- Toileting, Hygiene (“DEATH”)

- Use TREAT Task Force definition of disabling as guideline

Defining Disabling Symptoms

Complete hemianopsia (≥ 2 on the NIHSS question 3), or

Severe aphasia (≥ 2 on NIHSS question 9), or

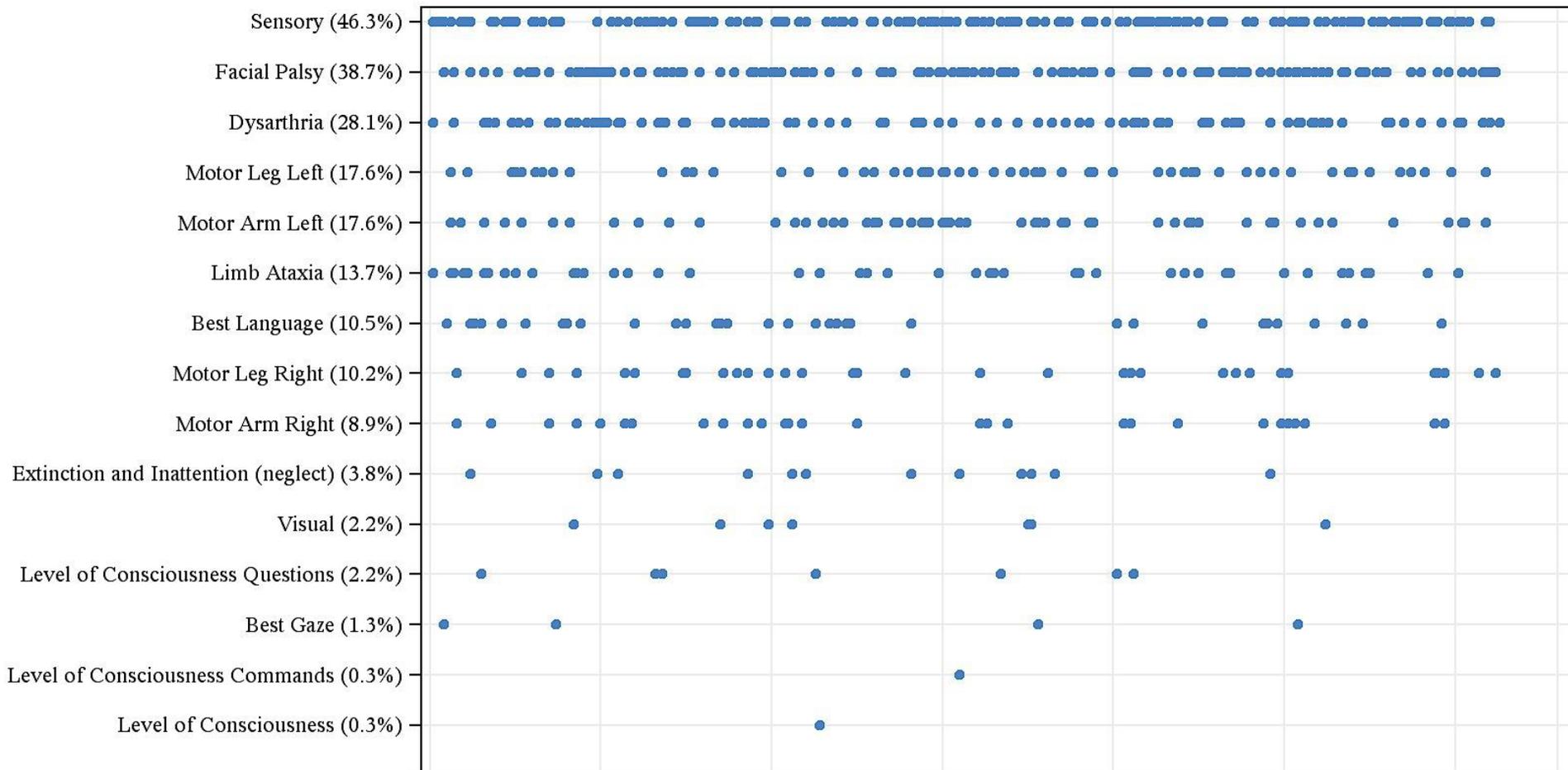
Visual or sensory extinction (≥ 1 on NIHSS question 11), or

Any weakness limiting sustained effort against gravity (≥ 2 on NIHSS question 5 or 6),

Any deficits that lead to a total NIHSS > 5 , or

Any remaining deficit considered potentially disabling in the view of the patient and the treating practitioner. Clinical judgment is required.

Neurological deficits by NIHSS in PRISMS



Decision to treat with alteplase in Mild Stroke

Survey vignettes (15/person):
156 respondents: 80% neurol, 20% EM

Four variables accounted for 15% of
the variance

*Decision making in treatment of mild
stroke needs to be further explored*

Factor	Mean	SD
Previous intracerebral hemorrhage		
Within 6 mo	0.23	0.28
≥6 mo	0.30	0.32
None	0.47	0.35
Recent anticoagulation use		
Within 48 h	0.21	0.27
≥48 h ago	0.36	0.33
None	0.44	0.36
National Institutes of Health Stroke Scale		
1	0.24	0.30
2	0.31	0.32
3	0.34	0.33
4	0.37	0.35
5	0.41	0.35
Previous ischemic stroke		
within 6 wk	0.25	0.29
≥6 wk ago	0.35	0.34
None	0.39	0.35



BE A PART OF STROKE CARE HISTORY

heart.org/MaRISS

MaRISS

Mild and Rapidly Improving Stroke Study



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

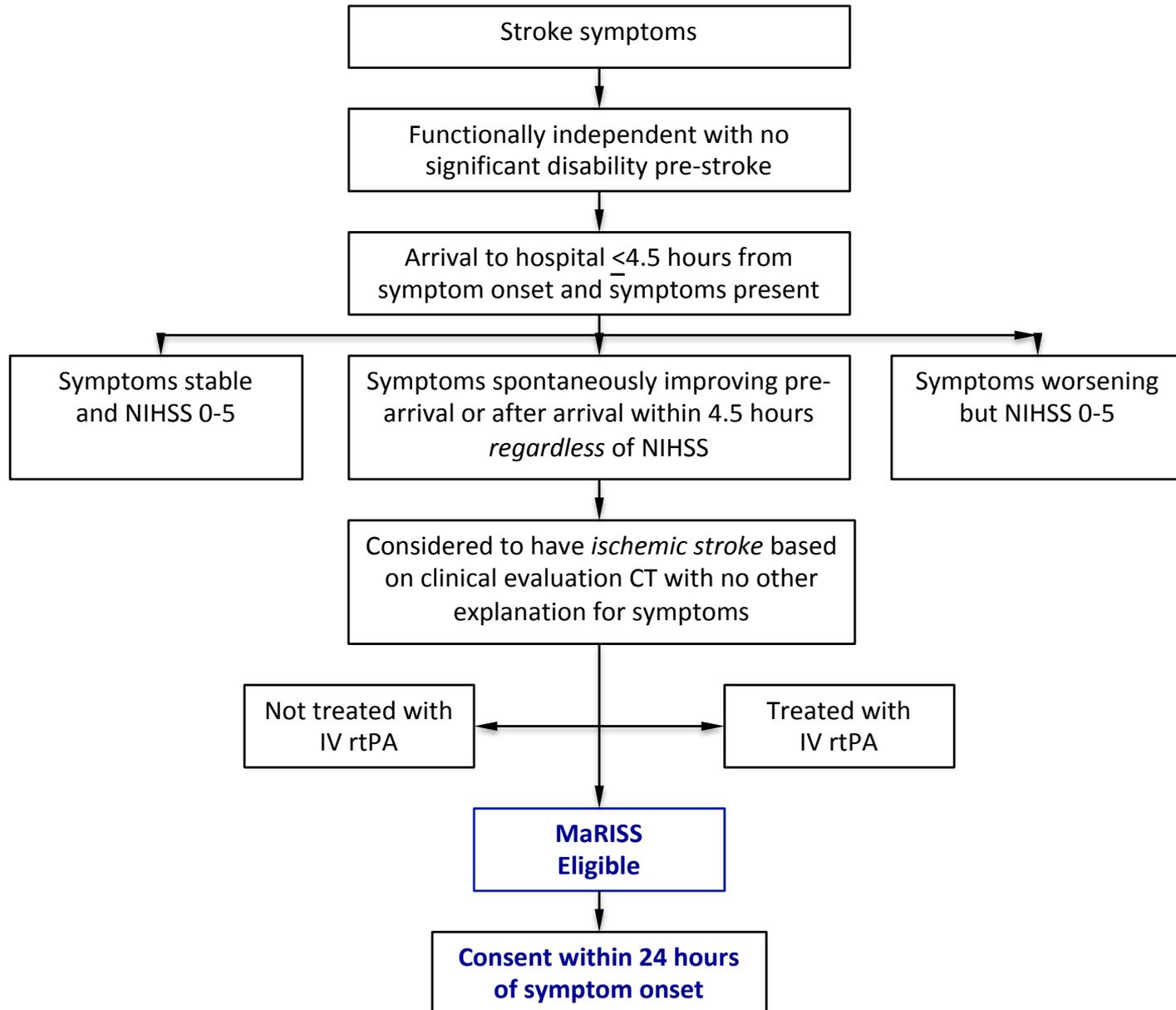
MaRISS Goal and Aims

Overall Goal: Elucidate long-term outcomes in mild and rapidly improving stroke and examine the association with tPA treatment

- Determine the 90-day outcomes
- Determine the predictors outcomes
- Evaluate safety and efficacy outcomes of thrombolysis after adjusting for treatment predictors.

MaRISS

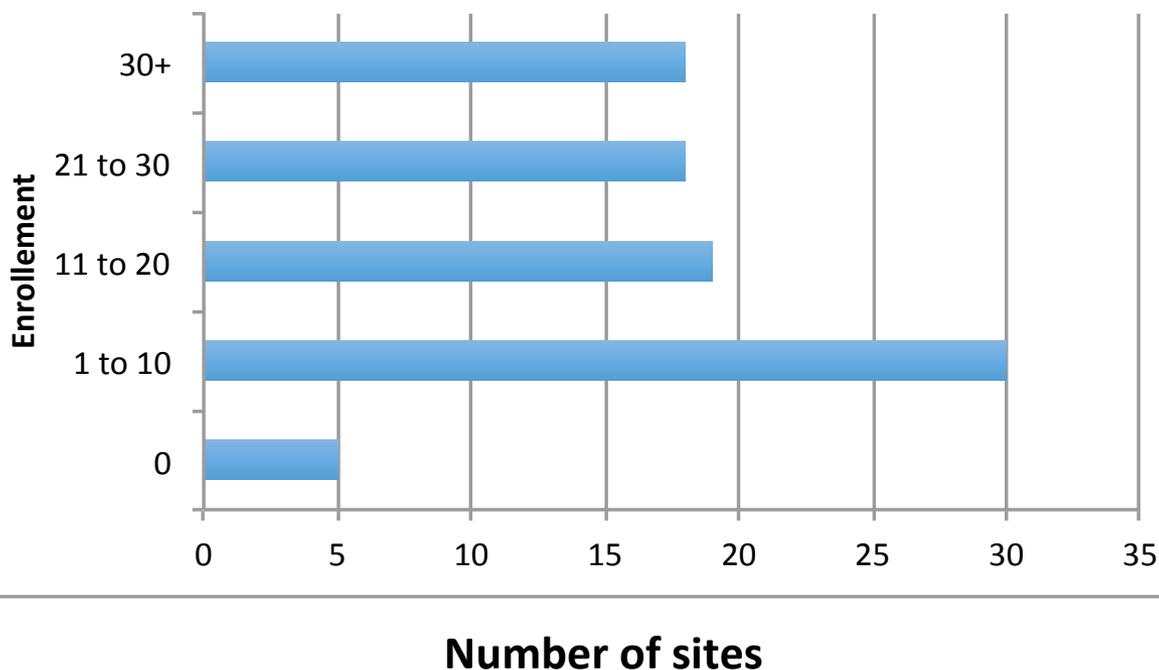
Mild and Rapidly Improving Stroke Study



MaRISS Hospitals

Top 10

MaRISS Site Enrollment



Rhode Island Hospital
Mercy Hospital-Oklahoma
Los Angeles Medical Center/ Kaiser Permanente
Ohio State-Wexner Medical Center
University of Rochester - Strong Memorial
St. Luke's Hospital of Kansas City
Methodist Hospital, Merrillville
Forsyth Memorial Hospital- Novant Health
DLP Conemaugh Memorial Medical Center
Faxton St.Luke's Healthcare

97 active sites

MaRISS Recruitment

- **1,873** enrolled, **1,662** participants in database
 - Proportion treated with alteplase: 56%
 - 45% in ED
 - 11% at transferring facility
 - 45% Female
 - 77% White
 - 12% Black
 - 6% Hispanic

Stroke Diagnosis and Mechanism

Final Diagnosis (N=1623)	
Ischemic Stroke	84%
TIA	9%
SAH/ICH	0.2%
Non-stroke	6%

TOAST (N=1483)	
Large Artery	12%
Cardioembolism	22%
Small vessel occlusion	27%
Other determined	8%
Undetermined	31%

As of 9/19/2018

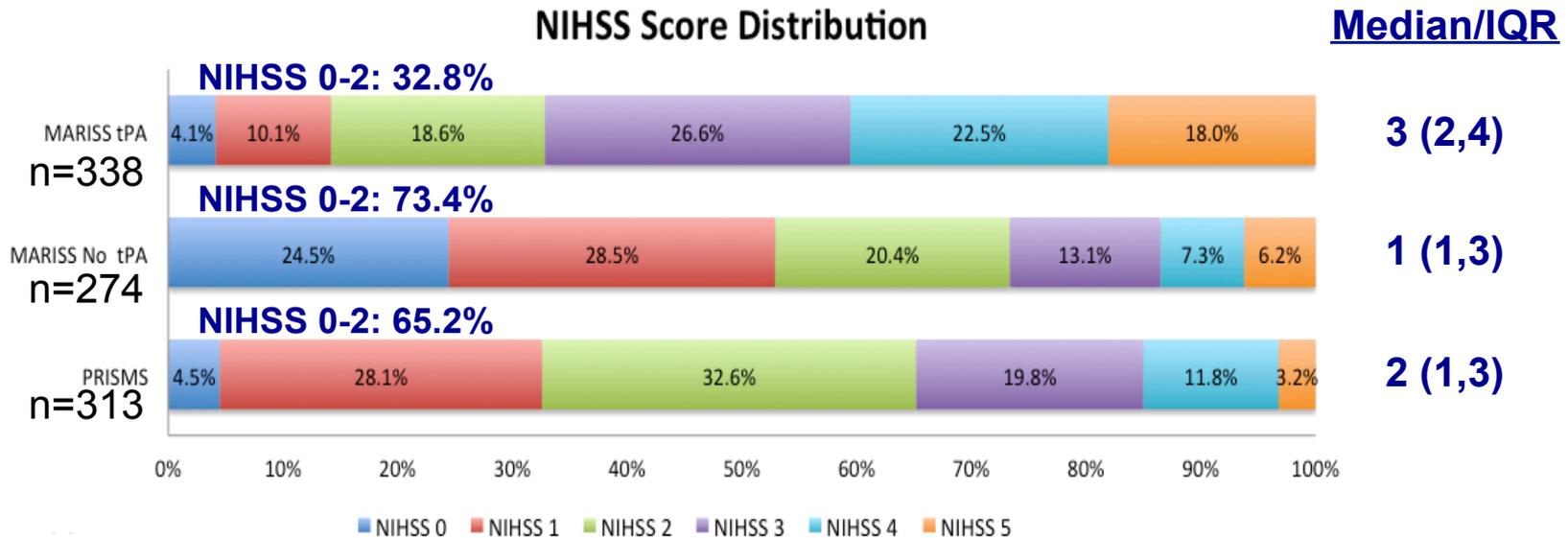
MaRISS participant characteristics

	Total N=1507	No tPA n=651 (43%)	tPA n=856 (57%)
NIHSS 0-5 (% ,n)	93% (n=1398)	45% (n=623)	55% (n=775)
Mean NIHSS	2.3	1.7	2.8
NIHSS >5 (% ,n)	7% (n=109)	26% (n=28)	74% (n=81)
Mean NIHSS	9.9	8.4	10.5

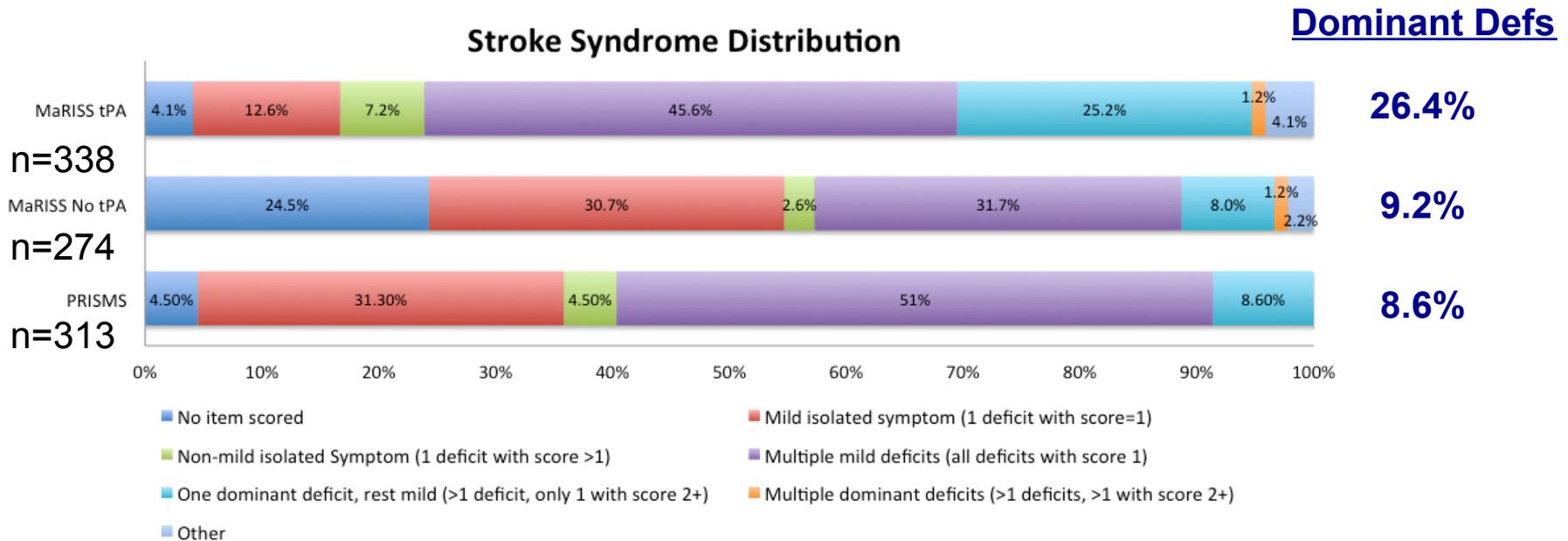
MaRISS outcome completion

mRS	30 days	90 days	30 & 90 d
Expected	1394	1344	1394
Completed	1264	1127	1308
Not reached	120	198	86 (6%)
Missing/awaiting answer	10	19	

Symptom Severity in MaRISS vs. PRISMS



Syndrome Severity in MaRISS vs. PRISMS



LVO in Mild Stroke

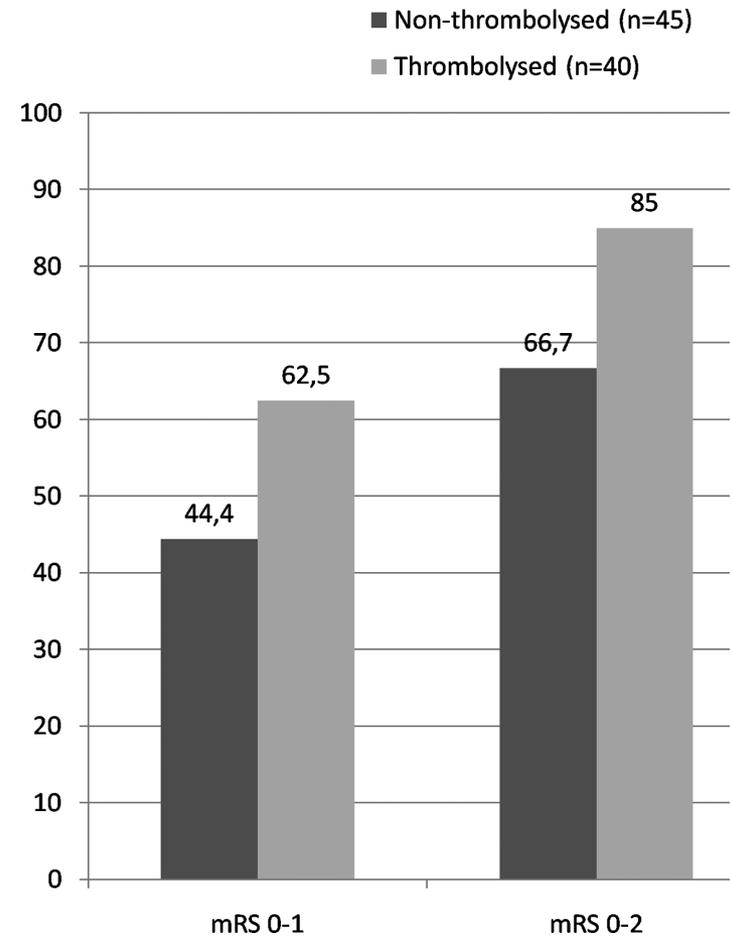
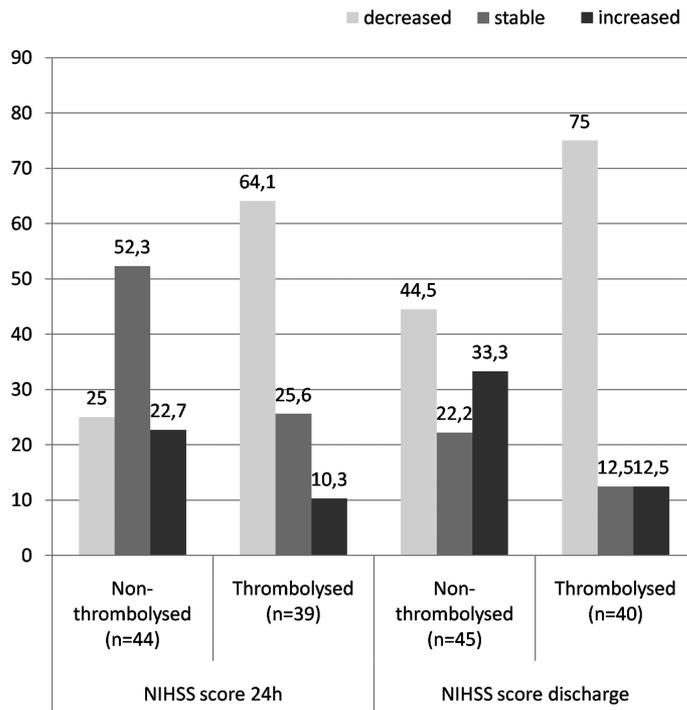
- 181 with anterior circulation stroke, NIHSS 0-5, and acute vessel imaging in institutional registry
- **30% LVO** with ICA, M1 or M2 occlusion
 - 40 IV rtPA alone, mRS 0-1 in 55%
 - 8 immediate EVT (5 with IV rtPA), mRS 0-1 in 75%
 - 6 IV rtPA and delayed EVT, mRS 0-1 in 33%

Early and delayed outcomes in MS with LVO

88 cases with NIHSS 0-5, LVO ICA/M1

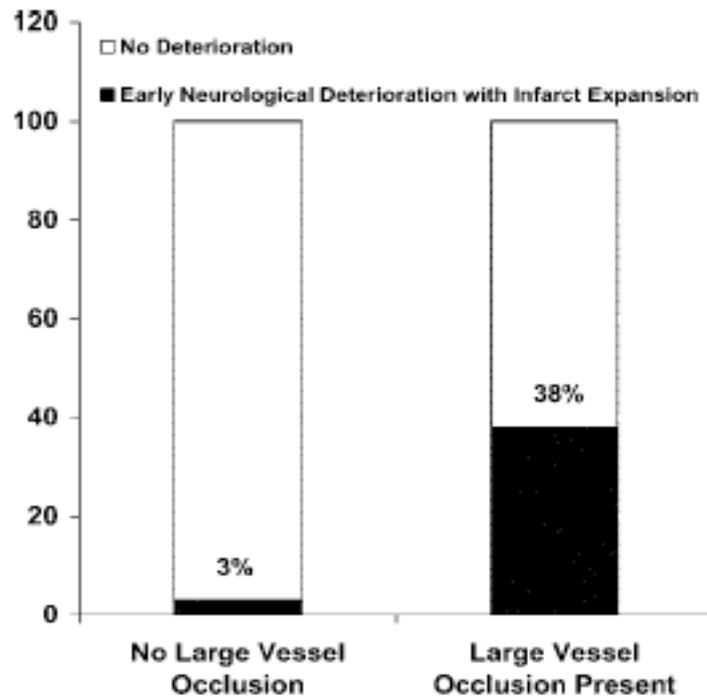
In untreated cases

- NIHSS worsened in 23% at 24h
- NIHSS worsened in 33% at d/c
- 66% mRS ≥ 2 at 3 months

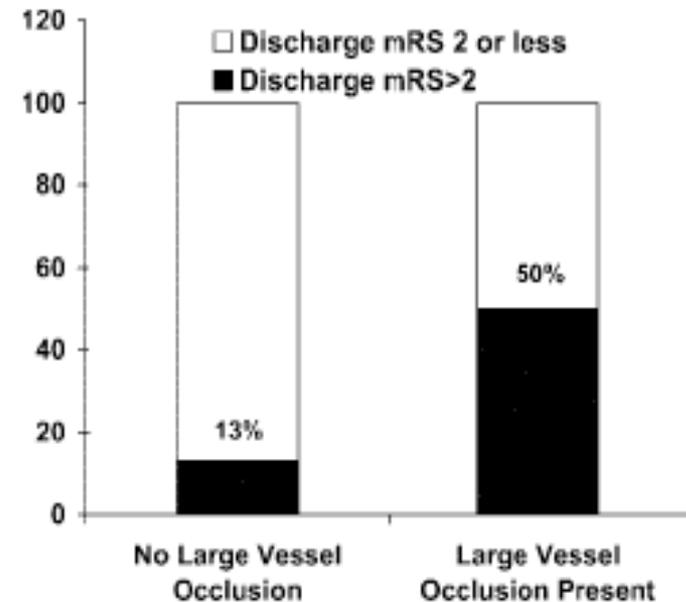


Persistent Intracranial Occlusion Predicts of Infarct Progression in TIA/Minor Stroke

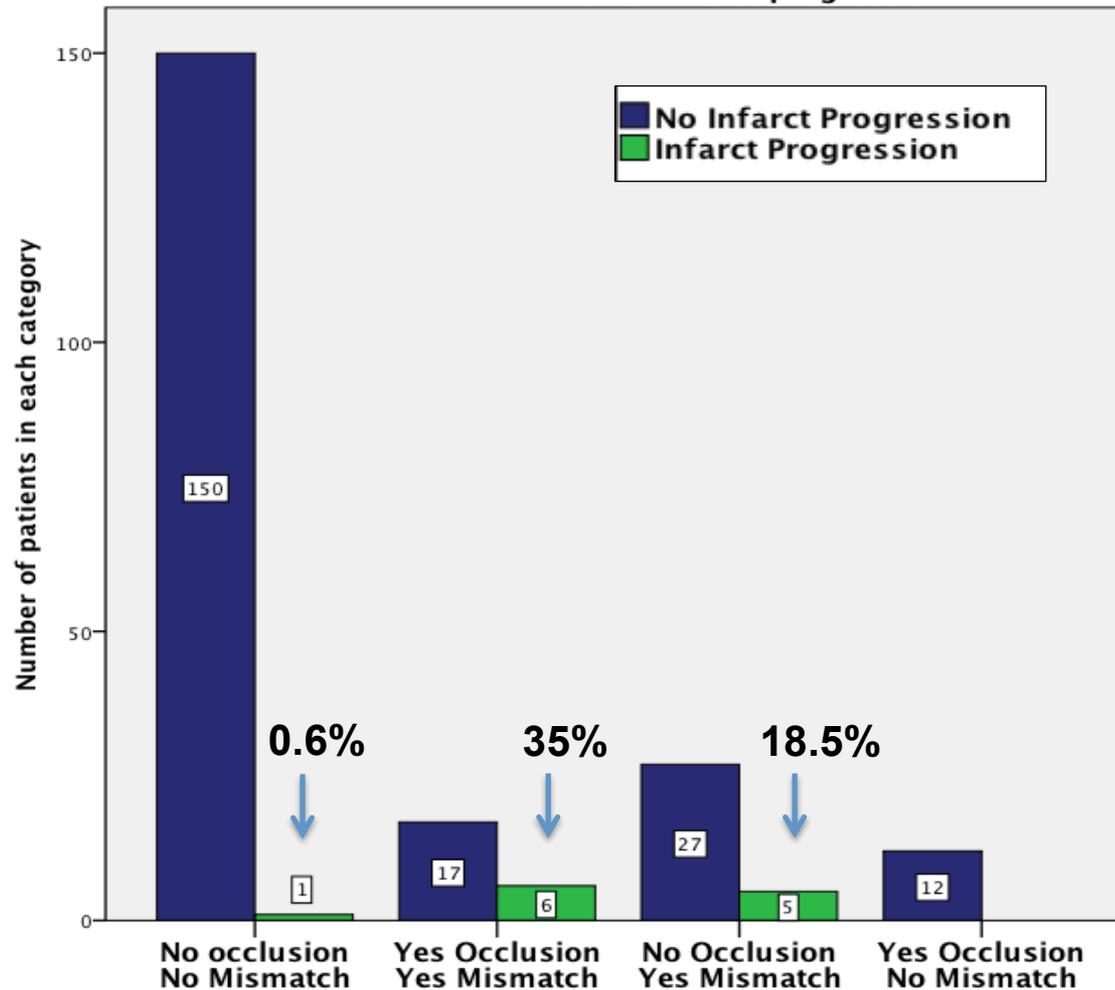
Early Deterioration 10%



Unfavorable Outcome at Discharge 20%

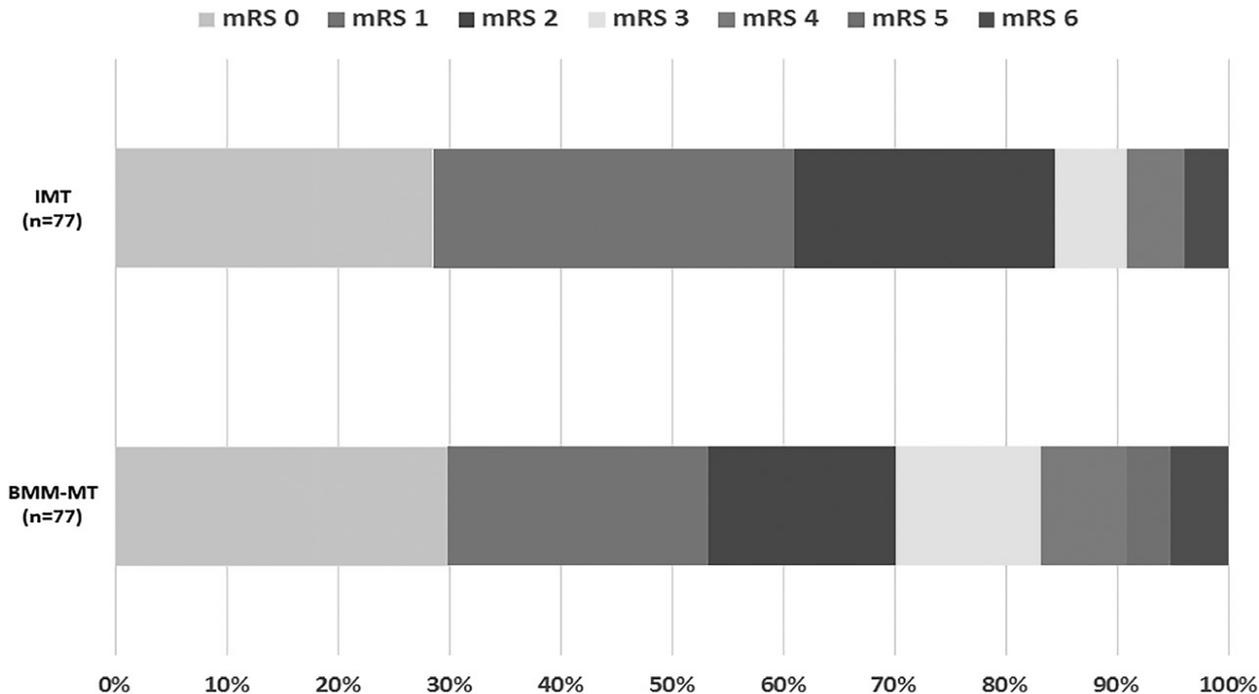


Infarct Progression in TIA/Minor Stroke correlates with perfusion deficit



EVT in Mild Stroke

- Retrospective analysis, EVT in NIHSS 0-5: immediate vs. delayed EVT
- N=300, 80 immediate EVT, 220 delayed EVT, 77 matched for site occlusion, NIHSS
- Outcome mRS 0-2: 85% vs. 70% (aOR 3.1, 95%CI 1.4,6.9) for immediate EVT (overall and for matched cohort).

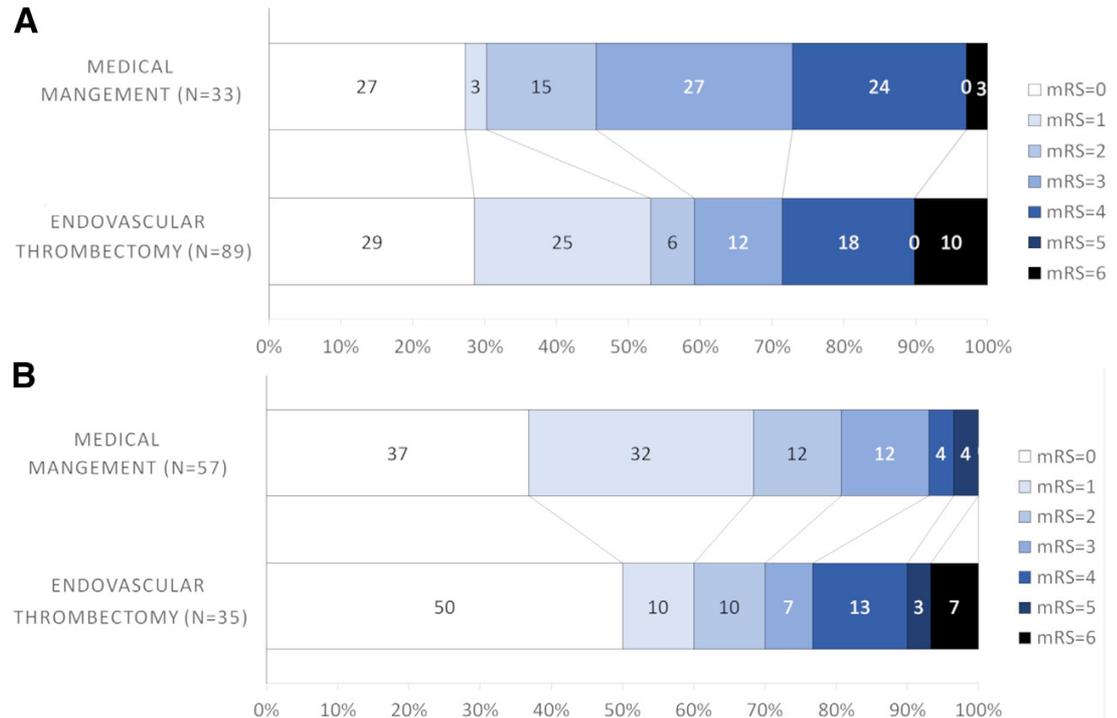


EVT in Mild Stroke

- Retrospective analysis, EVT in NIHSS 0-5: EVT vs. medical management
- N=214, 124 EVT, 90 MM, 31% in each group IV rtPA
- EVT group higher NIHSS (median 4 vs. 3) with more ICA/MI (72% vs. 37%); 62 pairs matched.
- Outcome mRS 0-2: 63% vs. 68% (aOR 0.90, 95%CI 0.43,1.88) for EVT (overall and for matched cohort).

Excellent outcome (mRS 01) in proximal occlusion ICA/M1: 53% EVT vs. 30% MM (aOR 2.68; 95% CI, 0.98–7.32)

Excellent outcome (mRS 01) in distal occlusion M2,M3, M4, ACA: 60% EVT vs. 68% MM, ns



EVT in Mild Stroke: Ongoing Studies

ENDO LOW

Cerenovus

- RCT
- NIHSS 0-5, LVO (ICA, M1, M2)
- ASPECTS ≥ 6
- Mismatch if >8 hours

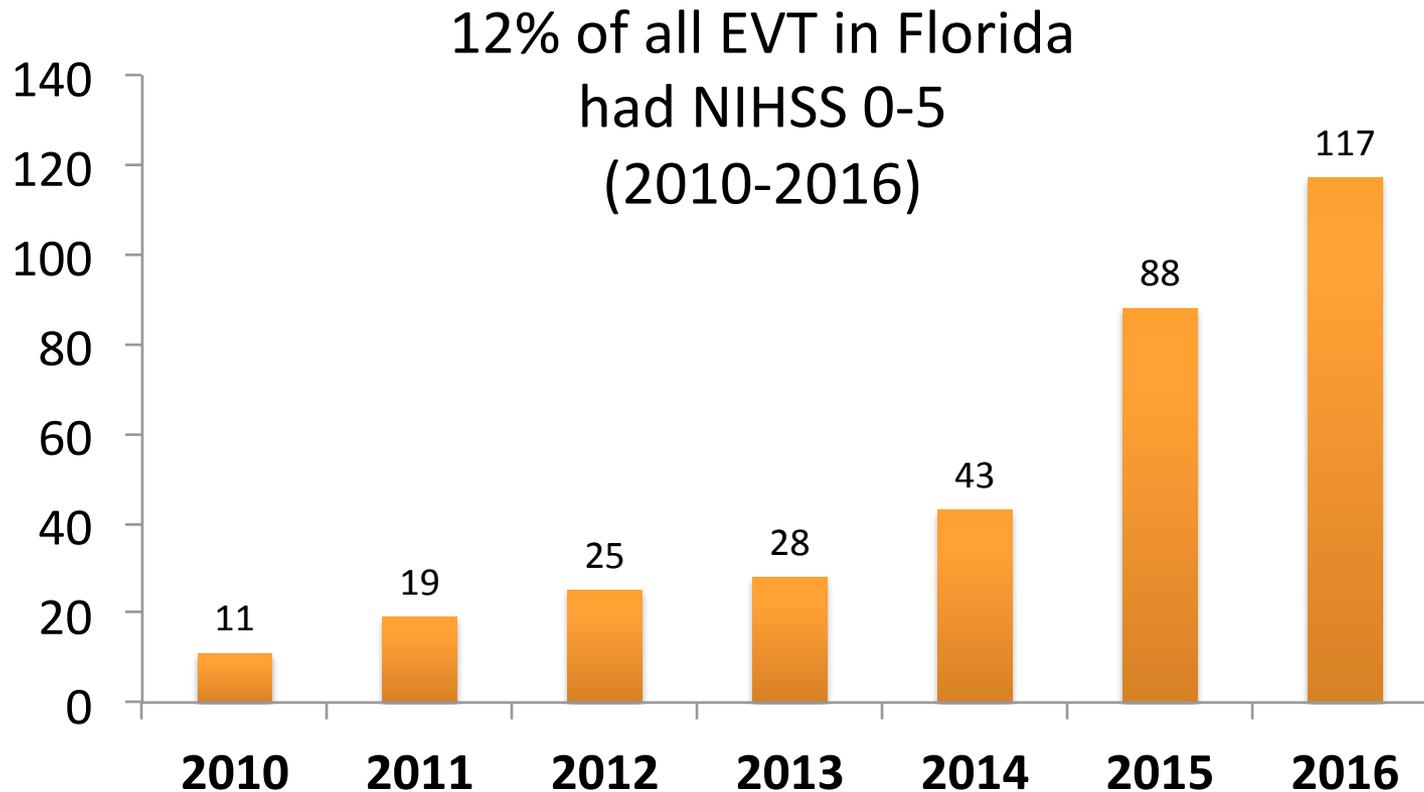
TRIMMIS



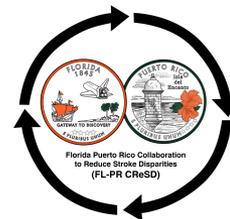
- Pilot study
- NIHSS 0-5, LVO (ICA, M1, M2, A1, V4, BA, P1) with mismatch
- 1° Outcome: sICH, EVT related complications

Trends in EVT use in patients with NIHSS ≤ 5

Florida Stroke Registry



P value for trend < 0.001



Conclusions

- Mild stroke is a common stroke presentation
- Outcomes remain suboptimal in this population
- Some indications of efficacy of thrombolysis in disabling stroke with low NIHSS
- No efficacy of thrombolysis in non-disabling stroke
- Growing interest in endovascular approaches but no evidence
- Detailed multidimensional outcomes and predictors lacking