



IV Thrombolysis Update 2026

The Extended Window

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Disclosures

I have no financial relationships with the developers of any of the products discussed.

Clinical Trials and Studies

- StrokeNET - NINDS
- ASPIRE - NINDS
- DISCOVERY - NINDS
- CAPTIVA – NINDS
- STEP – NINDS
- CLARITY – NINDS
- PICASSO – Mercy Health Ohio

Wake-up Strokes within 4.5 of discovery...

4.6.3. Extended Time Windows for Intravenous Thrombolysis

Recommendations for Extended Time Windows for Intravenous Thrombolysis

Referenced studies that support the recommendations are summarized in the [online data supplement](#).

COR	LOE	Recommendations
2a	B-R	1. In patients with AIS who (a) have unknown time of onset and are within 4.5 hours from symptom recognition and (b) have an MRI-DWI lesion smaller than one-third of the MCA territory and no marked signal change on FLAIR, IVT administered within 4.5 hours of stroke symptom recognition can be beneficial to improve functional outcomes. ¹

The extended window 4.5 – 9 hr; 4.5 – 24 hr...

Recommendations for Extended Time Windows for Intravenous Thrombolysis (Continued)		
COR	LOE	Recommendations
2a	B-R	2. In patients with AIS who have salvageable ischemic penumbra detected on automated perfusion imaging and who (a) awake with stroke symptoms within 9 hours from the midpoint of sleep or (b) are 4.5–9 hours from last known well, IV thrombolysis may be reasonable to improve functional outcomes. ^{2,3}
2b	B-R	3. In patients with AIS due to LVO with salvageable ischemic penumbra, presenting within 4.5 to 24 hours from symptom onset or last known well, and who cannot receive EVT, treatment with IVT directed by individuals with expertise in thrombolytic stroke care may be beneficial to improve functional outcomes. ^{2–5}

Wake-up Strokes within 4.5 of discovery...

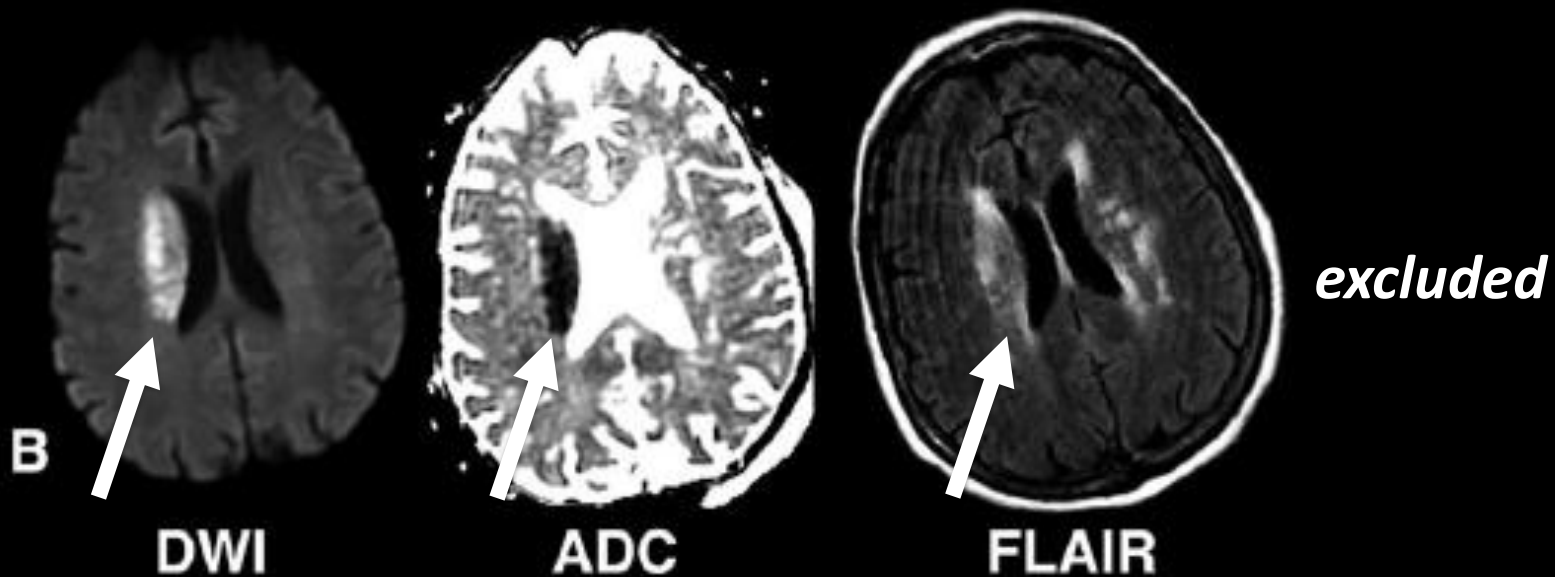
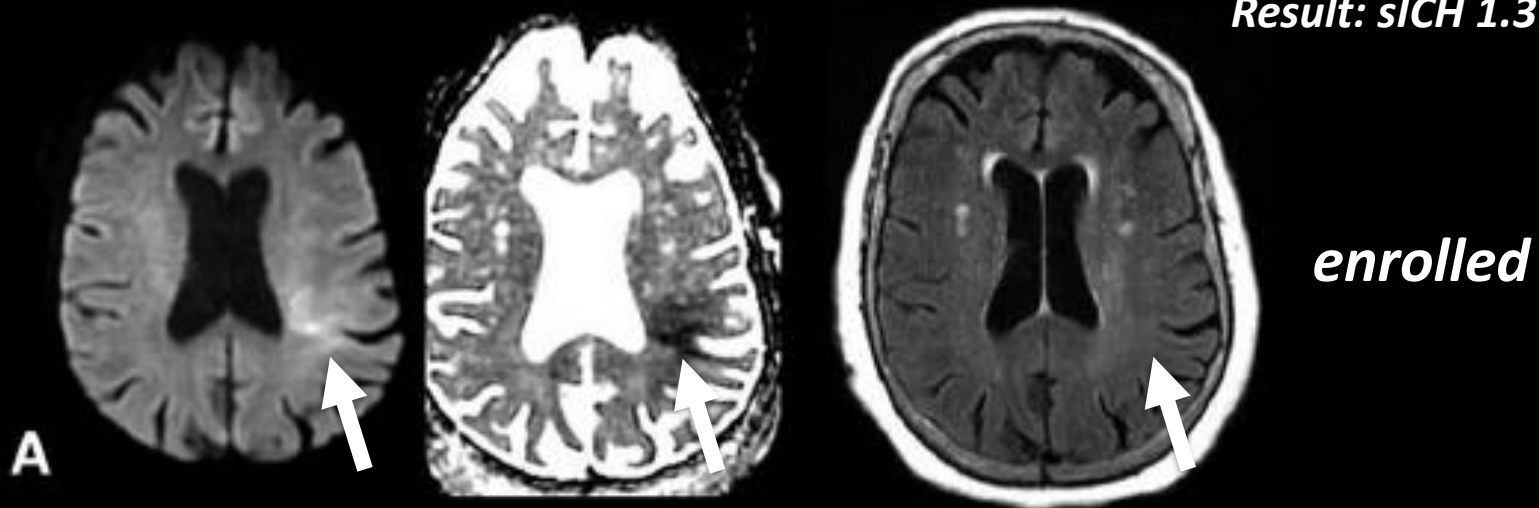
4.6.3. Extended Time Windows for Intravenous Thrombolysis

Recommendations for Extended Time Windows for Intravenous Thrombolysis	
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COR	LOE
1	1
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MR WITNESS

Safety trial: sICH < 5.3%

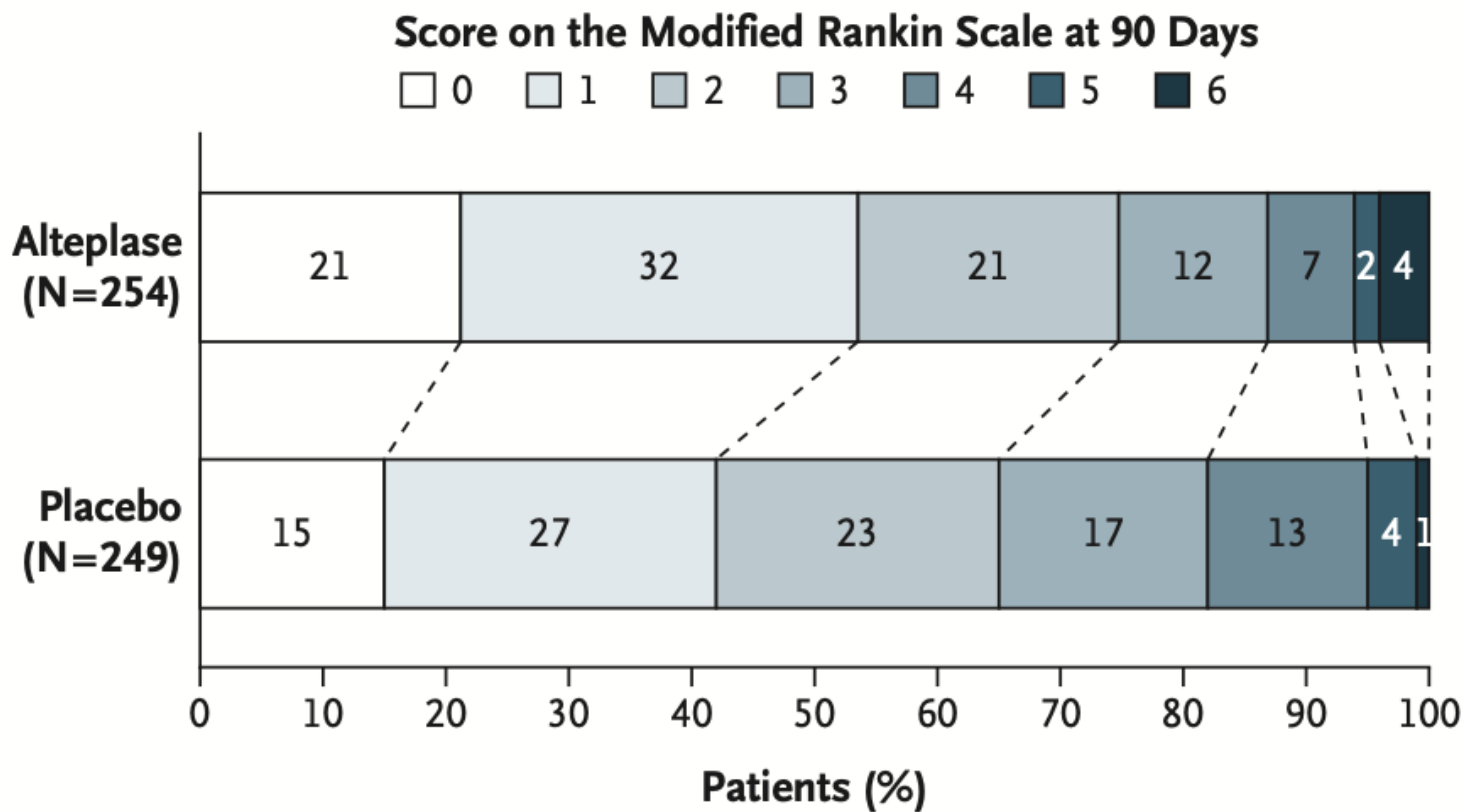
Result: sICH 1.3%



WAKE-UP 2018

- Patients: NIHSS ≤ 25 ; N = 503 (254 v 249)
- LVO/EVT: no LVO if planned EVT
- Window: recognition of stroke symptoms within 4.5 hr of treatment
- Imaging: DWI, FLAIR, SWI*, TOF MRA; positive DWI with “no [clearly] visible change in FLAIR” corresponding; excluded if $> 1/3$ MCA territory on DWI or hemorrhage
- Randomization: ALT v BMT
- Outcome: better 90-d mRS with ALT (mRS 0-1: ALT 53.3% v BMT 41.8%; OR 1.61; P = 0.02)
- Safety: more sICH (PH2): ALT 4.0% v BMT 0.4%; aRR 10.46; CI 1.32-82.77; p = 0.03)

WAKE-UP



THAWS 2020

- Patients: N = 131 (68 v 58)
 - LVO: no LVO if planned EVT
 - Window: recognition of stroke symptoms within 4.5 hr of treatment; LKW < 12 hr before treatment
 - Imaging: DWI, FLAIR, SWI*, TOF MRA; positive DWI with no corresponding FLAIR; ASPECTS ≥ 5
 - Randomization: ALT (**0.6 mg/kg**) v BMT
 - Outcome: no benefit in 90-d mRS with ALT (mRS 0-1: ALT 47.1% v BMT 48.3%; RR 0.97; P = 0.892)
 - Safety: sICH: ALT 1.4% v BMT 0; death at 90 d: 0.03% v 2.8% v 3.3%; NS
- Stopped early for lack of equipoise after publication of WAKE-UP*

TWIST 2023

- Patients: N = 578 (288 v 290); NIHSS ≥ 3 or aphasia
- LVO/EVT: not assessed/no EVT
- Window: recognition of stroke symptoms within 4.5 hr of treatment
- Imaging: **NCCT**: excluding ICH and early infarct changes in $> 1/3$ MCA territory
- Randomization: TNK v BMT
- Outcome: functional mRS: aOR 1.18; 95%CI 0.88-1.58, p = 0.27
- Safety: no difference in sICH or death

Wake-up Strokes within 4.5 of discovery...

4.6.3. Extended Time Windows for Intravenous Thrombolysis

Recommendations for Extended Time Windows for Intravenous Thrombolysis

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COR	LOE	Recommendations
2a	B-R	1. In patients with AIS who (a) have unknown time of onset and are within 4.5 hours from symptom recognition and (b) have an MRI-DWI lesion smaller than one-third of the MCA territory and no marked signal change on FLAIR, IVT administered within 4.5 hours of stroke symptom recognition can be beneficial to improve functional outcomes. ¹

The extended window 4.5 – 9 hr; 4.5 – 24 hr...

Recommendations for Extended Time Windows for Intravenous Thrombolysis (Continued)		
COR	LOE	Recommendations
2a	B-R	2. In patients with AIS who have salvageable ischemic penumbra detected on automated perfusion imaging and who (a) awake with stroke symptoms within 9 hours from the midpoint of sleep or (b) are 4.5–9 hours from last known well, IV thrombolysis may be reasonable to improve functional outcomes. ^{2,3}
2b	B-R	3. In patients with AIS due to LVO with salvageable ischemic penumbra, presenting within 4.5 to 24 hours from symptom onset or last known well, and who cannot receive EVT, treatment with IVT directed by individuals with expertise in thrombolytic stroke care may be beneficial to improve functional outcomes. ^{2–5}

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Thrombolysis Guided by Perfusion Imaging up to 9 Hours after Onset of Stroke

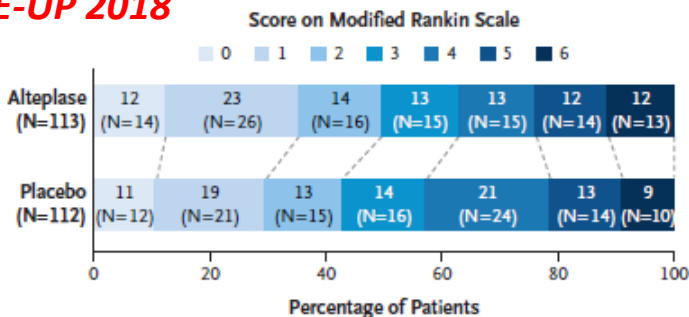
H. Ma, B.C.V. Campbell, M.W. Parsons, L. Churilov, C.R. Levi, C. Hsu, T.J. Kleinig, T. Wijeratne, S. Curtze, H.M. Dewey, F. Miteff, C.-H. Tsai, J.-T. Lee, T.G. Phan, N. Mahant, M.-C. Sun, M. Krause, J. Sturm, R. Grimley, C.-H. Chen, C.-J. Hu, A.A. Wong, D. Field, Y. Sun, P.A. Barber, A. Sabet, J. Jannes, J.-S. Jeng, B. Clissold, R. Markus, C.-H. Lin, L.-M. Lien, C.F. Bladin, S. Christensen, N. Yassi, G. Sharma, A. Bivard, P.M. Desmond, B. Yan, P.J. Mitchell, V. Thijs, L. Carey, A. Meretoja, S.M. Davis, and G.A. Donnan, for the EXTEND Investigators*

EXTEND 2019

- Patients: N = 225 (113 v 112) *Estimated that 77% of patients would now be treated with EVT*
- LVO/EVT: could have LVO but with not planned EVT
- Window: 4.5-9 hr; upon waking, if within 9 hr of midpoint of sleep
- Imaging: CTP or MRP (RAPID) with salvageable penumbra (core: < DWI or 30% rCBF; penumbra TTP > 6s; mismatch ratio ≥ 1.2 ; absolute > 10cc; core < 70cc)
- Randomization: ALT v BMT
- Outcome: better 90-d mRS with ALT (mRS 0-1: ALT 35.4% v BMT 29.5%; aRR 1.44; CI, 1.01-2.06; P = 0.04)
- Safety: sICH ALT 6.2% v BMT 0.9%; RR 7.22; CI, 0.97-53.5; p = 0.05)

*early stop due to loss of
equipoise after publication
of WAKE-UP 2018*

EXTEND



- **NIHSS 4-26**
- **Salvageable, hypoperfused region on CTP or MRP RAPID**
- **Irreversible = DWI diffusion restriction or CBF < 30% normal**
- **Reversible = > 6 sec TTP**

Outcome	Alteplase (N = 113)	Placebo (N = 112)	adj Effect Size (95% CI)	P-Value
<i>Primary Efficacy</i>				
Favorable* at 90d (%)	35.4	29.5	1.44 (1.01 - 2.06)	0.04
<i>Safety</i>				
Death at 90d (%)	11.5	8.9	1.17 (0.57 - 2.40)	0.67
sICH within 36h (%)	6.2	0.9	7.22 (0.97 – 53.54)	0.053

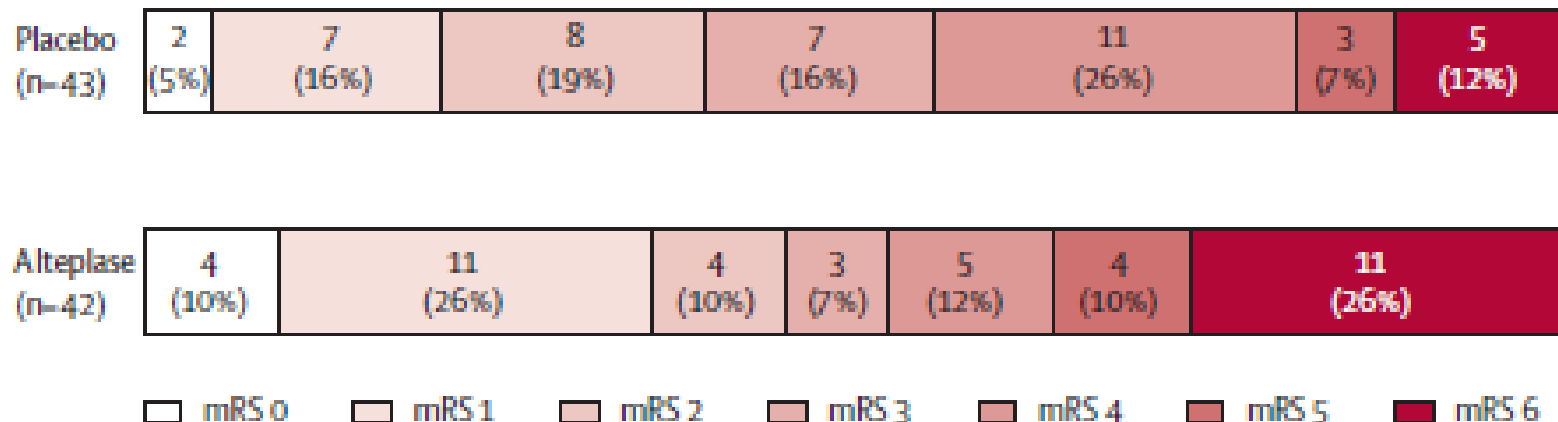
*mRS = 0-1

EPITHET

EPITHET Phase II ALT at 3-6 hr

- N = 101: ALT 52 v placebo 49
- ALT showed better reperfusion
- ALT showed non-significant decrease in infarct growth

Functional outcome in mismatch patients

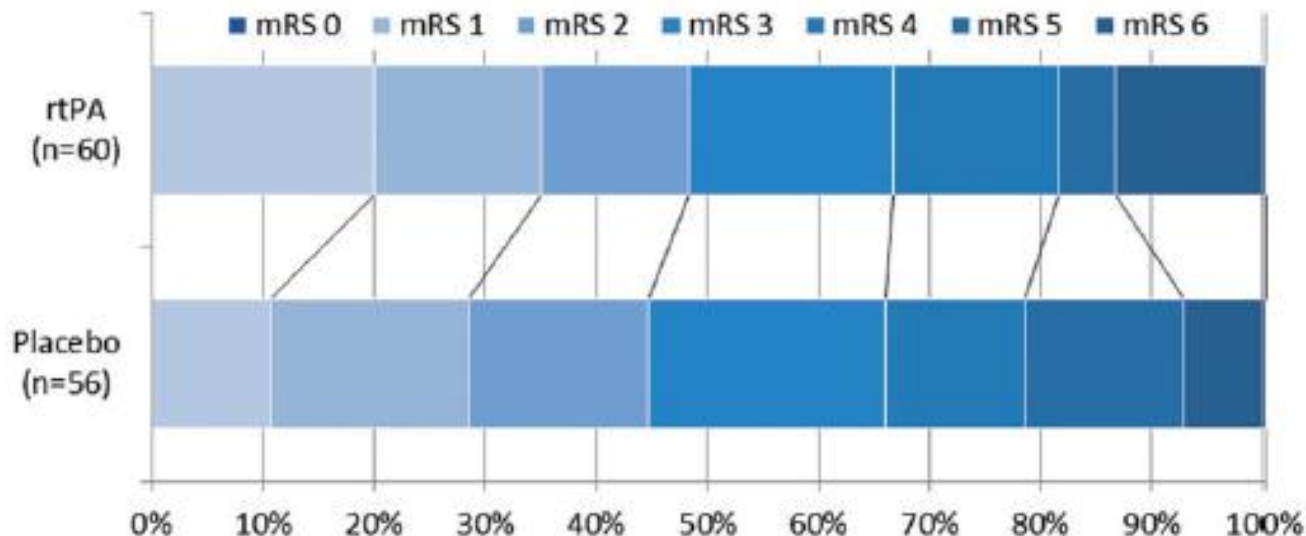


ECASS-4

*Stopped early for
slow recruitment*

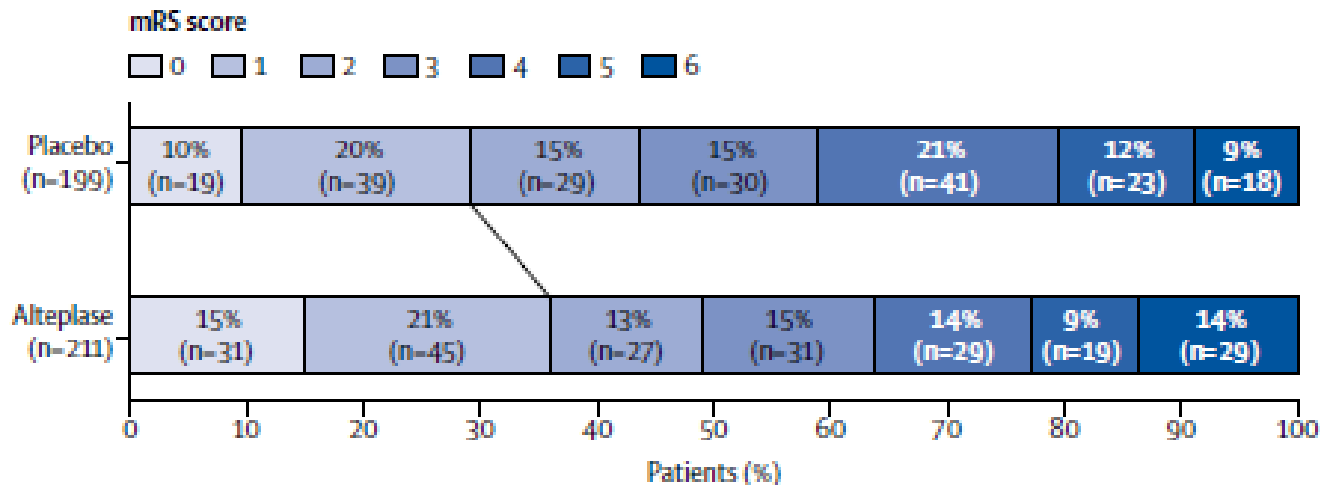
ECASS-4 ALT at 4.5-9 hr

- N = 119: ALT 61 v placebo 58
- No significant difference in mRS at 90 days
 - OR 1.20; 95%CI 0.63-2.27; p = 0.58
- 1 sICH in the ALT group
- Death: ALT 11.5% v placebo 6.8%; p = 0.53



Meta-analysis 2019 of EXTEND, ECASS-4, EPITHET

- > 18 yr
- IV ALT at > 4.5 hr or wake-up stroke
- Perfusion imaging, MRI or CT
- Primary outcome: mRS 0-1 at 90 days; adj for age and stroke severity
- Safety outcomes: death and sICH

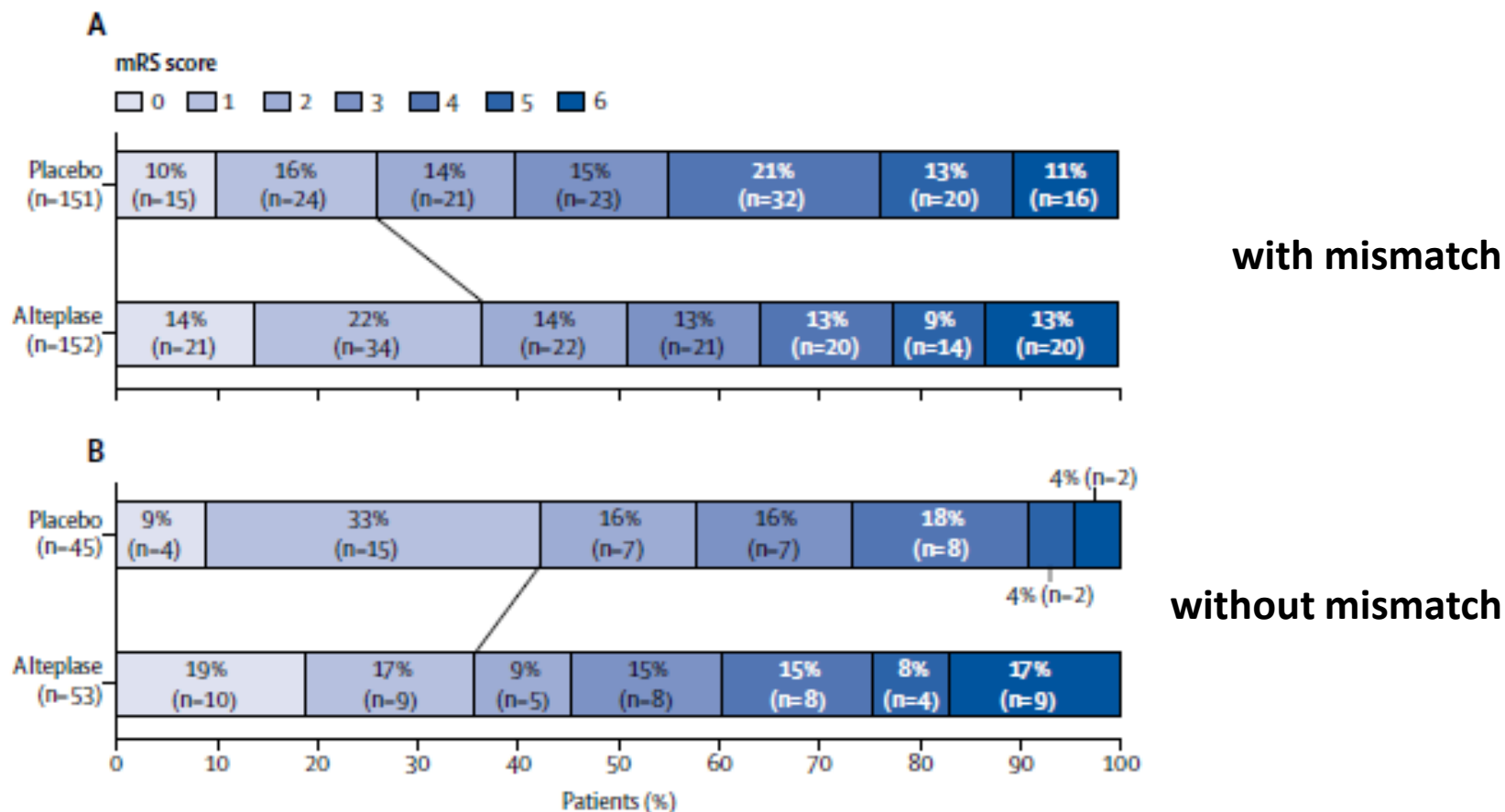


414 patients: ALT 211 v BMT 199

- mRS 0-1: ALT 36% v BMT 29%; adj OR 1.86; 95%CI 1.15-2.99, p = 0.011
- sICH: ALT 5% v BMT 0.5%, adj OR 9.7; 95%CI 1.23-76.55; p = 0.031
- Death: ALT 14% v BMT 9%, 1.55; 95%CI 0.81-2.96, p = 0.66

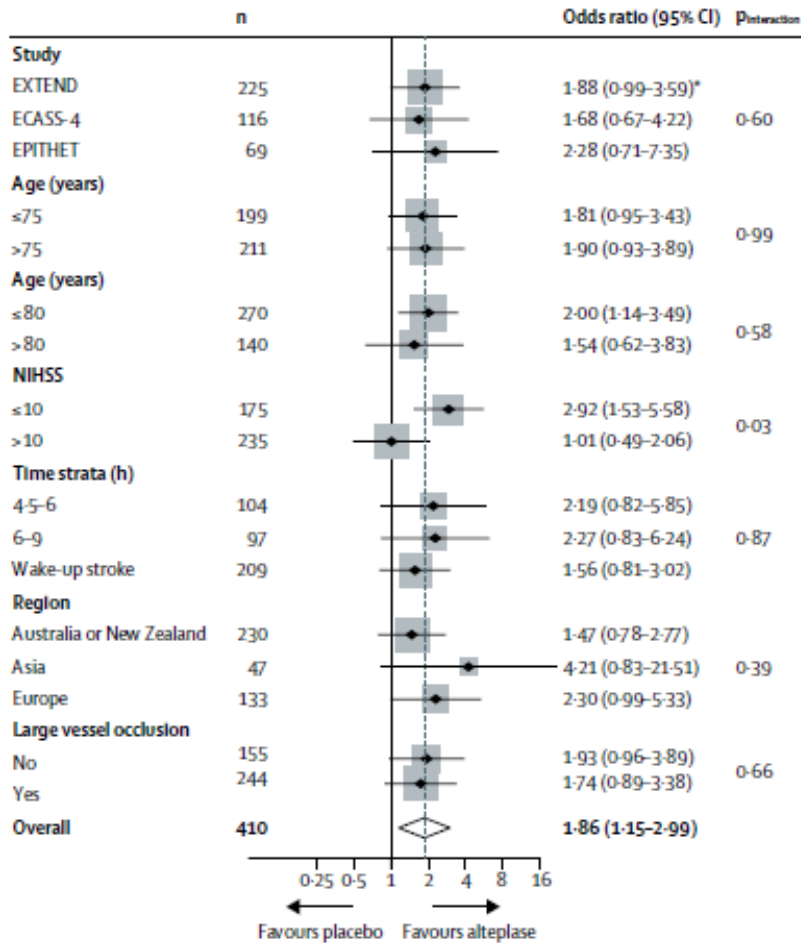
Meta-analysis 2019 of EXTEND, ECASS-4, EPITHET

Benefit depended on the selection of patients with mismatch.

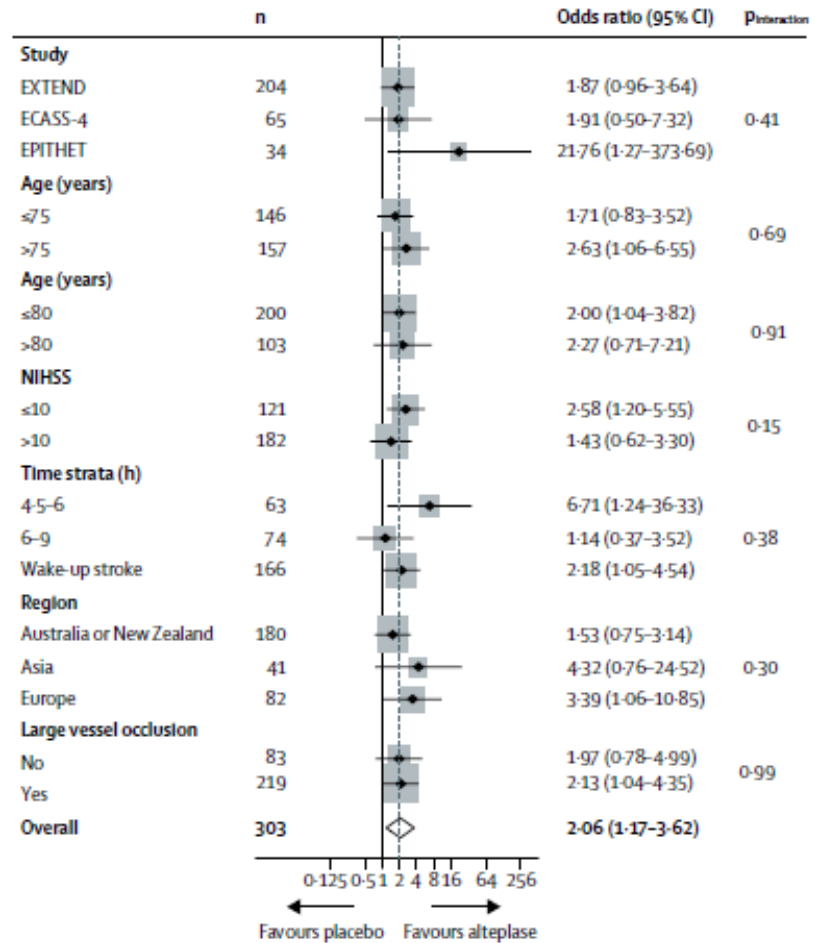


Meta-analysis: EPITHET, ECASS-4, EXTEND

A All patients



B Patients with perfusion mismatch



ORIGINAL ARTICLE

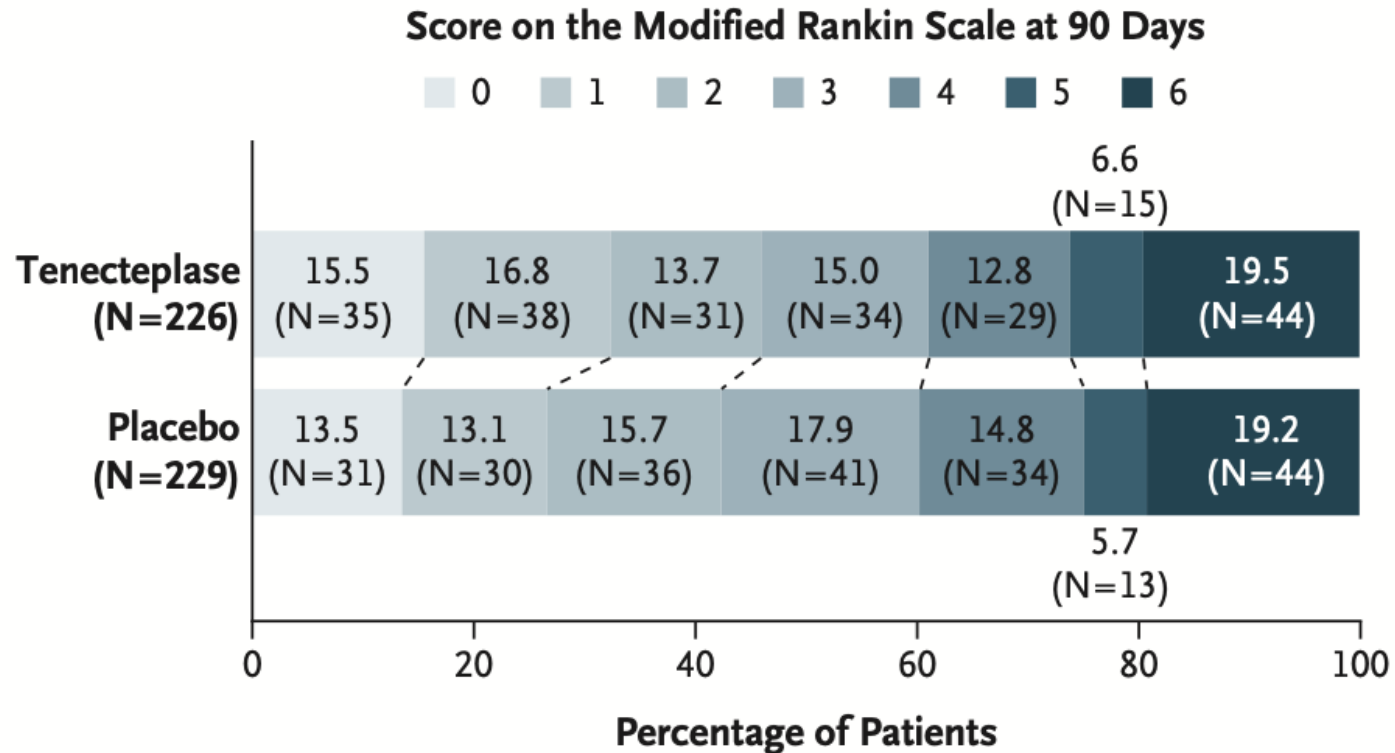
Tenecteplase for Stroke at 4.5 to 24 Hours with Perfusion-Imaging Selection

G.W. Albers, M. Juma, B. Purdon, S.F. Zaidi, C. Streib, A. Shuaib, N. Sangha,
M. Kim, M.T. Froehler, N.E. Schwartz, W.M. Clark, C.E. Kircher, M. Yang,
L. Massaro, X.-Y. Lu, G.A. Rippon, J.P. Broderick, K. Butcher, M.G. Lansberg,
D.S. Liebeskind, A. Nouh, L.H. Schwamm, and B.C.V. Campbell,
for the TIMELESS Investigators*

TIMELESS 2024

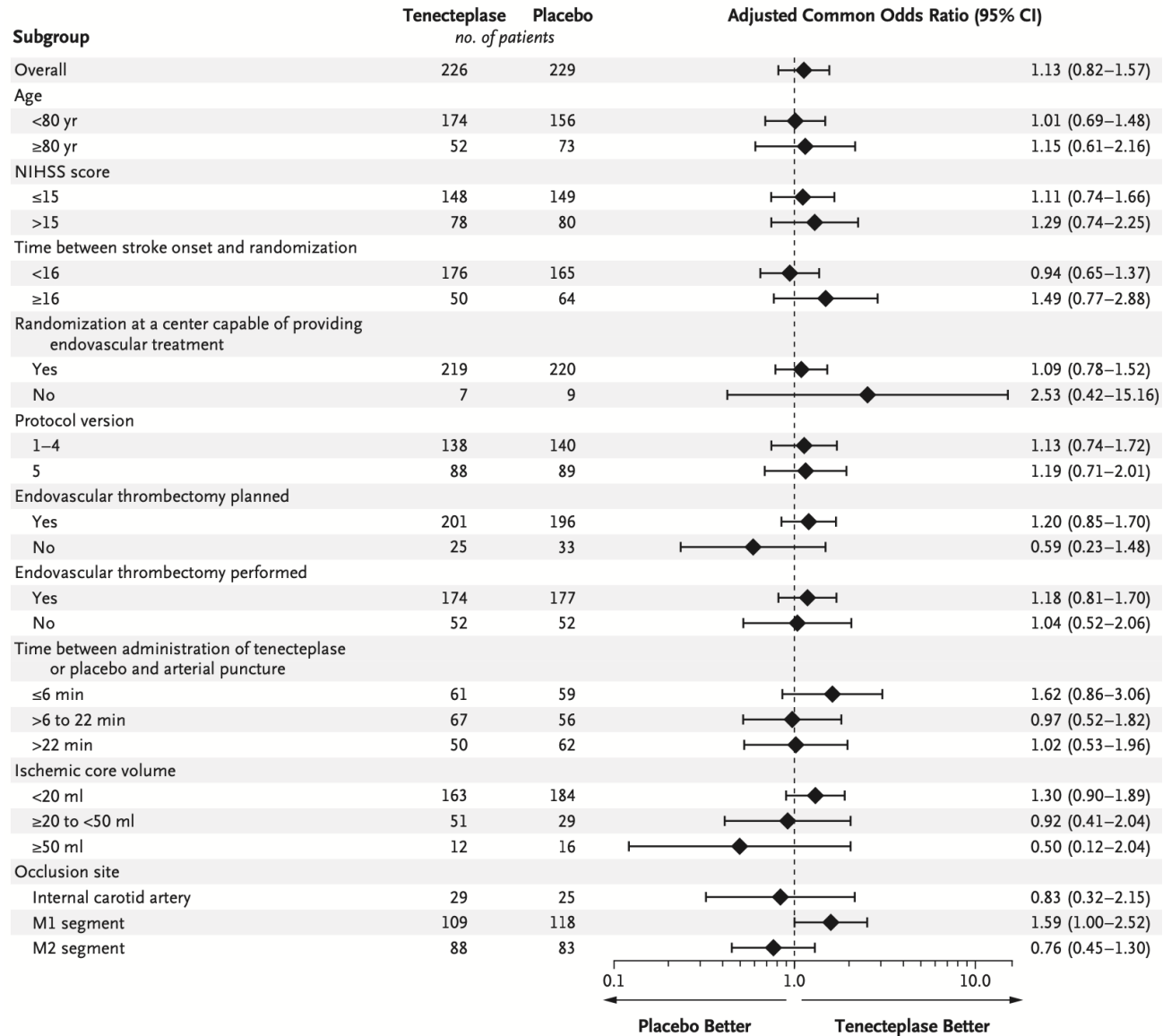
- Patients: N = 458 (228 v 230)
- LVO/EVT: iICA, M1, M2 / **77.3% EVT**
- Window: 4.5 – 24 hr since LKW
- Imaging: CTP or MRP (RAPID) with salvageable penumbra (core: < DWI or 30% rCBF; penumbra TTP > 6s; mismatch ratio ≥ 1.8 ; absolute ≥ 15 cc; core < 70cc)
- Randomization: TNK v BMT before planned EVT
- Outcome: no benefit with TNK: ordinal mRS aOR 1.13; CI, 0.82-1.57; P = 0.4; mRS ≤ 2 : 46.0% v 42.4%; OR 1.18; CI, 0.80-1.74
- Safety: sICH TNK 3.2 v BMT 2.3; NS

TIMELESS



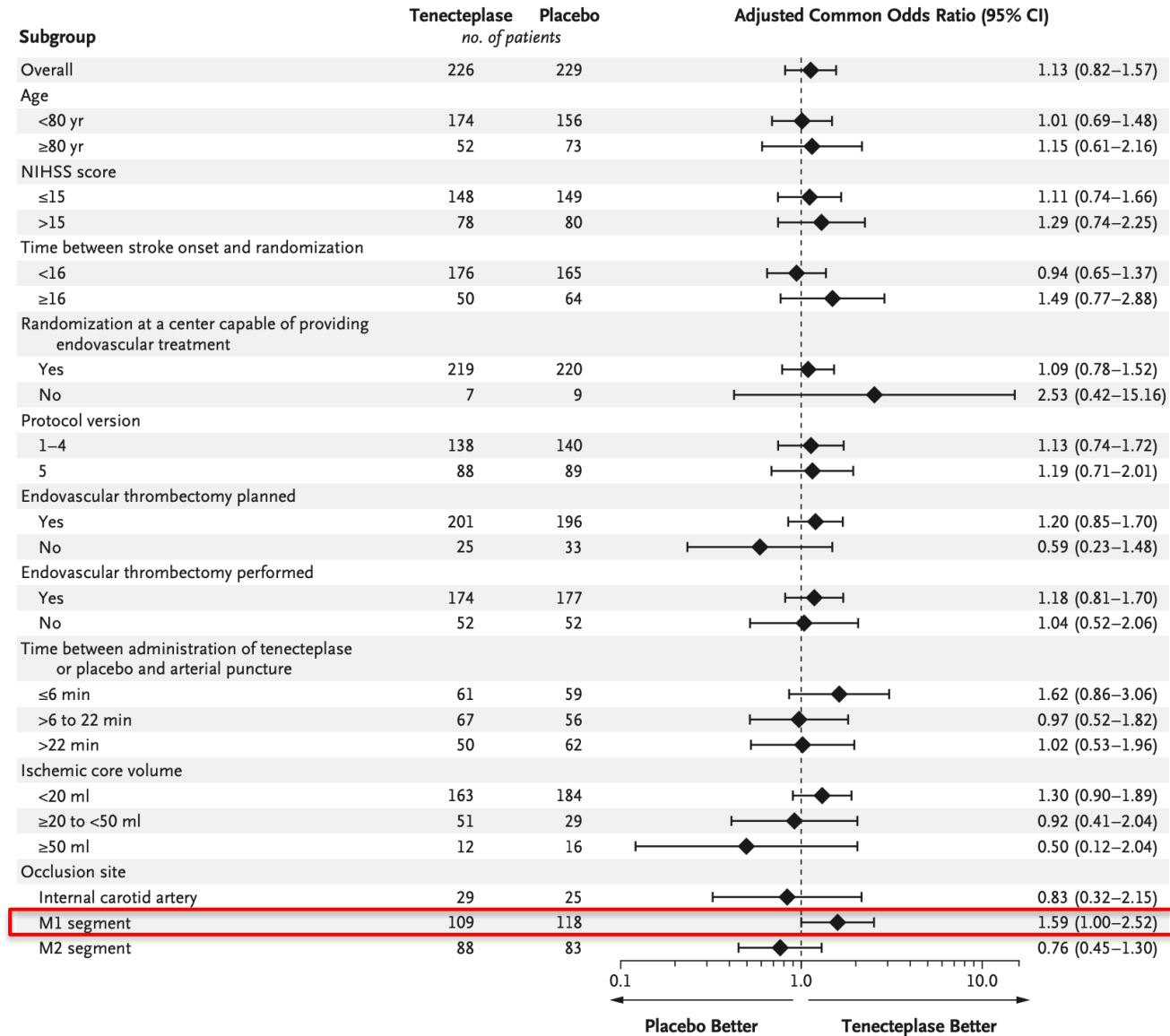
TIMELESS

Subgroups



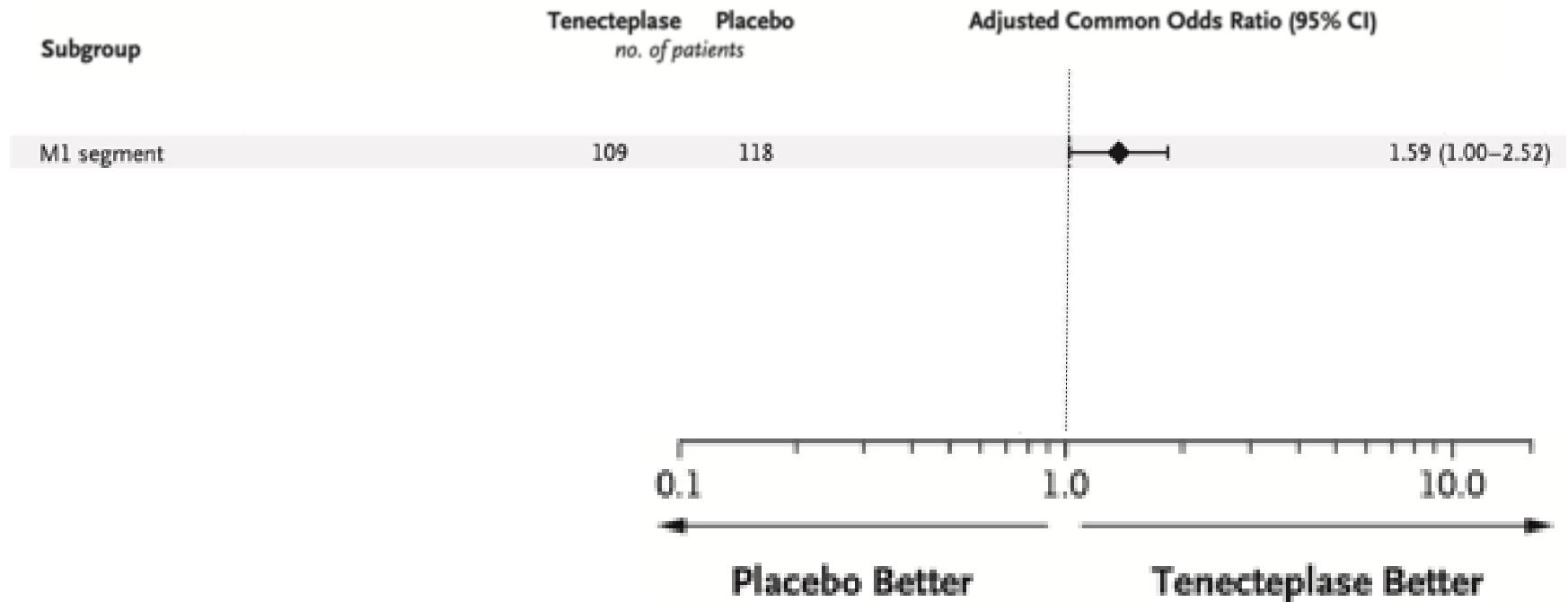
TIMELESS

Subgroups



TIMELESS

Subgroups



Positive findings from TIMELESS

- 1. IV thrombolytics were given up to 24 hr after onset without an increase in brain hemorrhage.*
- 2. In a subgroup analysis of patients with M1 occlusion, 45.9% in the tenecteplase group versus 31.4% in the placebo group achieved functional independence (mRS \leq 2). (OR 2.03, 95%CI, 1.14-3.66).*

TRACE-III

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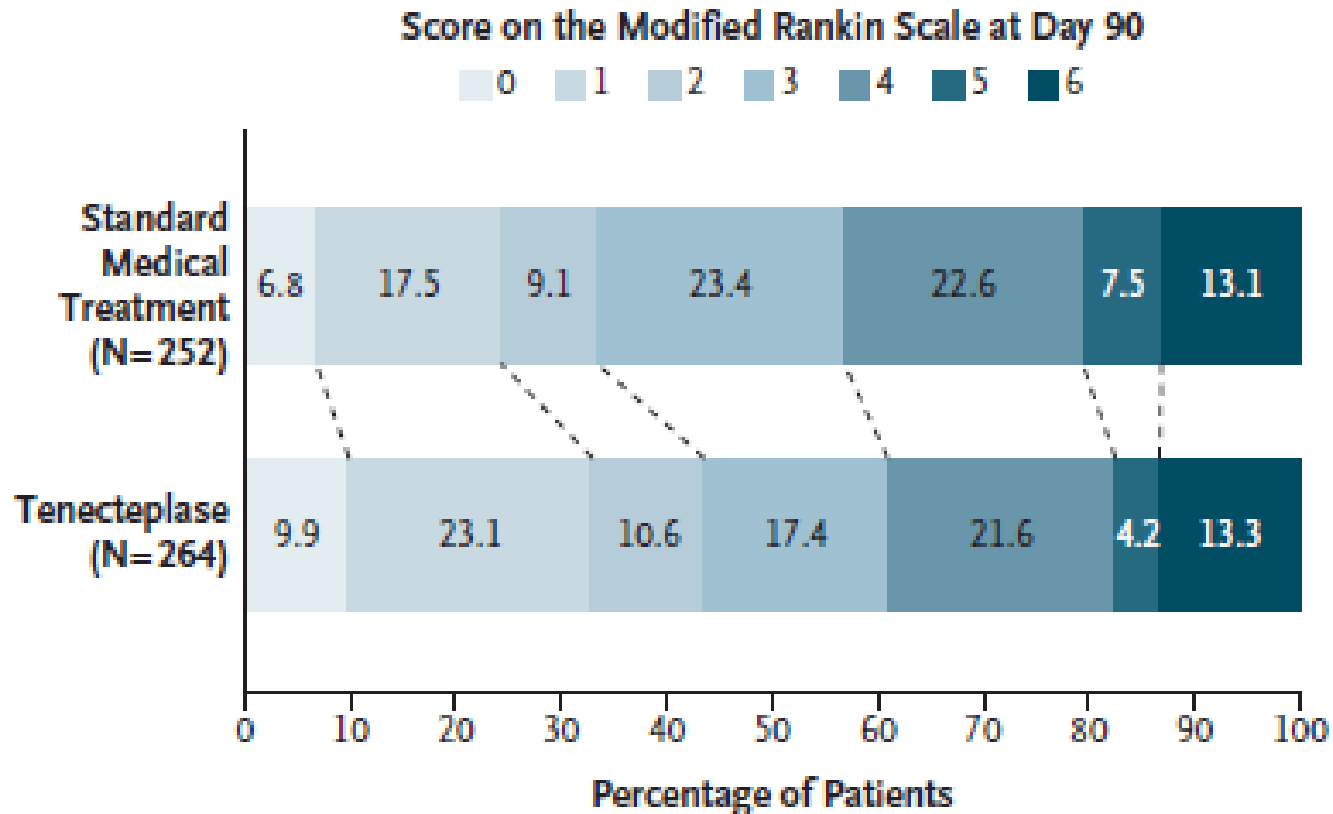
Tenecteplase for Ischemic Stroke at 4.5 to 24 Hours without Thrombectomy

Yunyun Xiong, M.D., Ph.D., Bruce C.V. Campbell, M.B., B.S., Ph.D., Lee H. Schwamm, M.D., Xia Meng, M.D., Ph.D., Aoming Jin, Ph.D., Mark W. Parsons, M.B., B.S., Ph.D., Marc Fisher, M.D., Yong Jiang, Ph.D., Fengyuan Che, M.D., Lihua Wang, M.D., Ph.D., Li Zhou, M.D., Hongguo Dai, M.D., Xintong Liu, M.D., Yuesong Pan, Ph.D., Chunmiao Duan, M.D., Yuming Xu, M.D., Ph.D., Anding Xu, M.D., Ph.D., Lixia Zong, M.D., Ph.D., Zefeng Tan, M.D., Ph.D., Wanxing Ye, Ph.D., Hao Wang, M.D., Ziran Wang, M.D., Manjun Hao, M.D., Zhixin Cao, M.D., Liyuan Wang, M.D., Shuangzhe Wu, M.D., Hao Li, Ph.D., Zixiao Li, M.D., Ph.D., Xingquan Zhao, M.D., Ph.D., and Yongjun Wang, M.D., for the TRACE-III Investigators*

TRACE-III 2024

- Patients: N = 516 (264 v 252)
- LVO/EVT: iICA, M1, M2 / **EVT excluded; < 2%**
- Window: 4.5 – 24 hr since LKW
- Imaging: CTP or MRP with salvageable penumbra (core: < DWI or 30% rCBF; penumbra TTP > 6s; mismatch ratio ≥ 1.8 ; absolute ≥ 15 cc; core < 70cc)
- Randomization: TNK v BMT
- Outcome: mRS 0-1: TNK 33.0% v BMT 24.2%; OR 1.37; 95%CI 1.04-1.81, p = 0.03
- Safety: TNK 3.0% v BMT 0.8%, OR 3.82; 95%CI 0.81-17.87; NS

TRACE-III



516 patients: ALT 264 v placebo 252

- mRS 0-1: TNK 33.0% v BMT 24.2%; OR 1.37; 95%CI 1.04-1.81, $p = 0.03$
- sICH: TNK 3.0% v BMT 0.8%, OR 3.82; 95%CI 0.81-17.87; NS
- Death: TNK 13.3% v BMT 13.1%, OR 1.01; 95%CI 0.65-1.58, NS

CHABLIS-T II 2025

- Patients: N = 224 (111 v 113)
- LVO/EVT: eICA, iICA, M1, M2, A1, A2 / **EVT in 54.9%**
- Window: 4.5 – 24 hr since LKW
- Imaging: CTP or MRP with salvageable penumbra (core: < DWI or < 30% rCBF; penumbra TTP > 3s; mismatch ratio ≥ 1.2 ; absolute ≥ 10 cc; core < 70cc)
- Randomization: TNK v BMT
- Outcome: $\geq 50\%$ restoration of CBF at 24-48h: TNK 33.3% v BMT 10.8%; RR 3.0; 95%CI 1.6-5.7, $p = 0.001$; mRS at 90d NS
- Safety: sICH TNK 5.4% v BMT 4.4%, aRR 1.3; 95%CI 0.4-4.2; $p = 0.7$

CHABLIS-T II

mRS 0-1 at 90 days

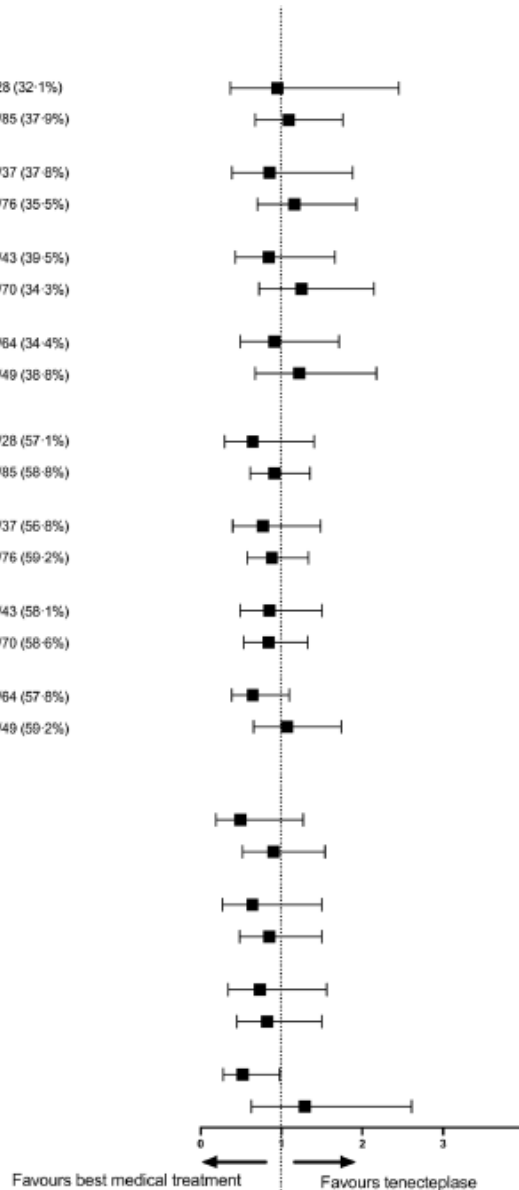
Occlusion Site		
ICA	8/27 (29.6%)	9/28 (32.1%)
Others	35/84 (42.9%)	32/85 (37.9%)
Last known well to randomization		
4-5-9h	11/34 (32.4%)	14/37 (37.8%)
9-24h	33/77 (42.9%)	27/76 (35.5%)
Witnessed Stroke		
Yes	16/43 (37.2%)	17/43 (39.5%)
No	28/68 (41.2%)	24/70 (34.3%)
Endovascular treatment		
Yes	16/58 (27.6%)	22/64 (34.4%)
No	28/53 (52.8%)	19/49 (38.8%)

mRS 0-2 at 90 days

Occlusion Site		
ICA	10/27 (37.0%)	16/28 (57.1%)
Others	46/84 (54.8%)	50/85 (58.8%)
Last known well to randomization		
4-5-9h	15/34 (44.1%)	21/37 (56.8%)
9-24h	41/77 (53.3%)	45/76 (59.2%)
Witnessed Stroke		
Yes	23/43 (53.5%)	25/43 (58.1%)
No	33/68 (48.5%)	41/70 (58.6%)
Endovascular treatment		
Yes	20/58 (34.5%)	37/64 (57.8%)
No	36/53 (67.9%)	29/49 (59.2%)

mRS distribution at 90 days^a

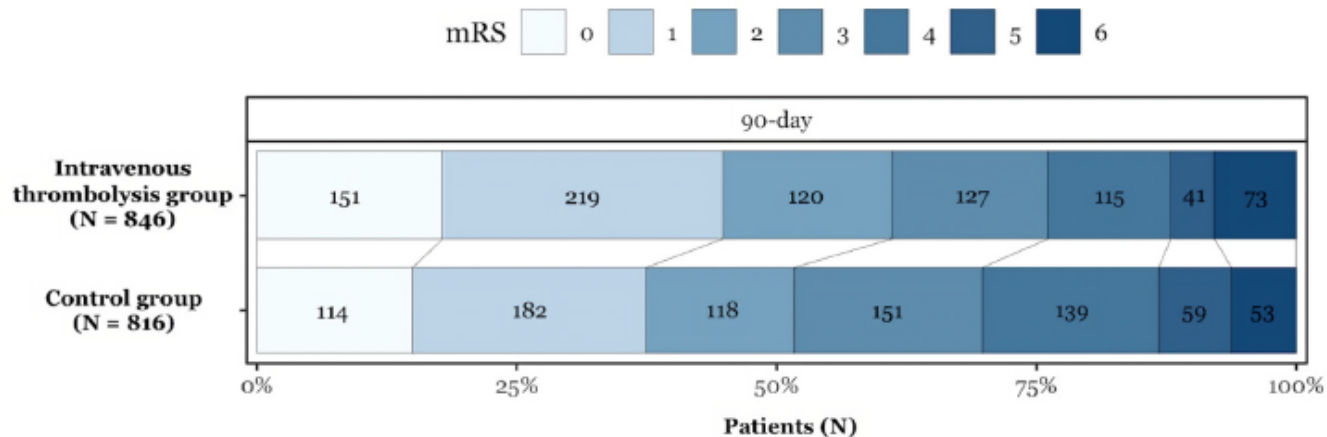
Occlusion Site		
ICA		
Others		
Last known well to randomization		
4-5-9h		
9-24h		
Witnessed Stroke		
Yes		
No		
Endovascular treatment		
Yes		
No		



Meta-analysis 2025

EPITHET, ROSE-TNK, EXIT-BT), WAKE-UP, EXTEND, ECASS-4, THAWS, TRACE-III

- > 18 yr
- IVT at > 4.5 hr or wake-up stroke
- No EVT
- Perfusion imaging, MRI or CT (except EXIT-B and EPITHET)



1662 patients: IVT 846 v placebo 816

- mRS 0-1: IVT 43.9% v BMT 36%; OR 1.43; 95%CI 1.17-1.75, $p = 0.0005$
- sICH: IVt 2.7% v BMT 0.5%, OR 4.25; 95%CI 1.67-10.84; $p = 0.002$
- Death: IVT 8.4% v BMT 6.5%, 1.28; 95%CI 0.87-1.89, $p = 0.21$

<i>Trial</i>	<i>Hypothesis</i>	<i>Selection</i>	<i>Result</i>	<i>Comment</i>
EXTEND	ALT works at 4.5-9h	CTP/MRP	Pos	77% would now get EVT
ECASS-4	ALT works at 4.5-9h	CTP/MRP	Neg	Too small
TIMELESS	TNK before EVT works 4.5-24h	CTP/MRP	Neg	Safe; maybe benefit in subgroup
TRACE-III	TNK w/o EVT works 4.5-24h	CTP/MRP	Pos	Most would get EVT at BMC
CHABLIS-T II	TNK \pm EVT works 4.5-24h	CTP/MRP	Neg	55% EVT; selection not clear
Meta 2019	IVT w/o EVT works > 4.5 h	CTP/MRP	Pos more sICH	Valid for those not getting EVT
Meta 2025	IVT w/o EVT works > 4.5 h	CTP/MRP	Pos more sICH	Valid for those not getting EVT

The extended window 4.5 – 9 hr; 4.5 – 24 hr...

Recommendations for Extended Time Windows for Intravenous Thrombolysis (Continued)		
COR	LOE	Recommendations
2a	B-R	2. In patients with AIS who have salvageable ischemic penumbra detected on automated perfusion imaging and who (a) awake with stroke symptoms within 9 hours from the midpoint of sleep or (b) are 4.5–9 hours from last known well, IV thrombolysis may be reasonable to improve functional outcomes. ^{2,3}
2b	B-R	3. In patients with AIS due to LVO with salvageable ischemic penumbra, presenting within 4.5 to 24 hours from symptom onset or last known well, and who cannot receive EVT, treatment with IVT directed by individuals with expertise in thrombolytic stroke care may be beneficial to improve functional outcomes. ^{2–5}

Preliminary Conclusions

- *Patient with unknown onset time discovered within 4.5 hr of treatment may benefit from IVT.*
- *We need more study of CT-based wake-up protocols.*
- *EVT negates detectable benefit of extended window IVT.*
- *Extended window IVT may benefit patients who cannot get EVT.*
- *Extended-window IVT for those without treatable LVO has not been well studied.*
- *Efficient implementation of extended-window protocols will require the use of tools for the rapid automated analysis of perfusion imaging.*

Post-Guideline Publication

OPTION

JAMA | Original Investigation

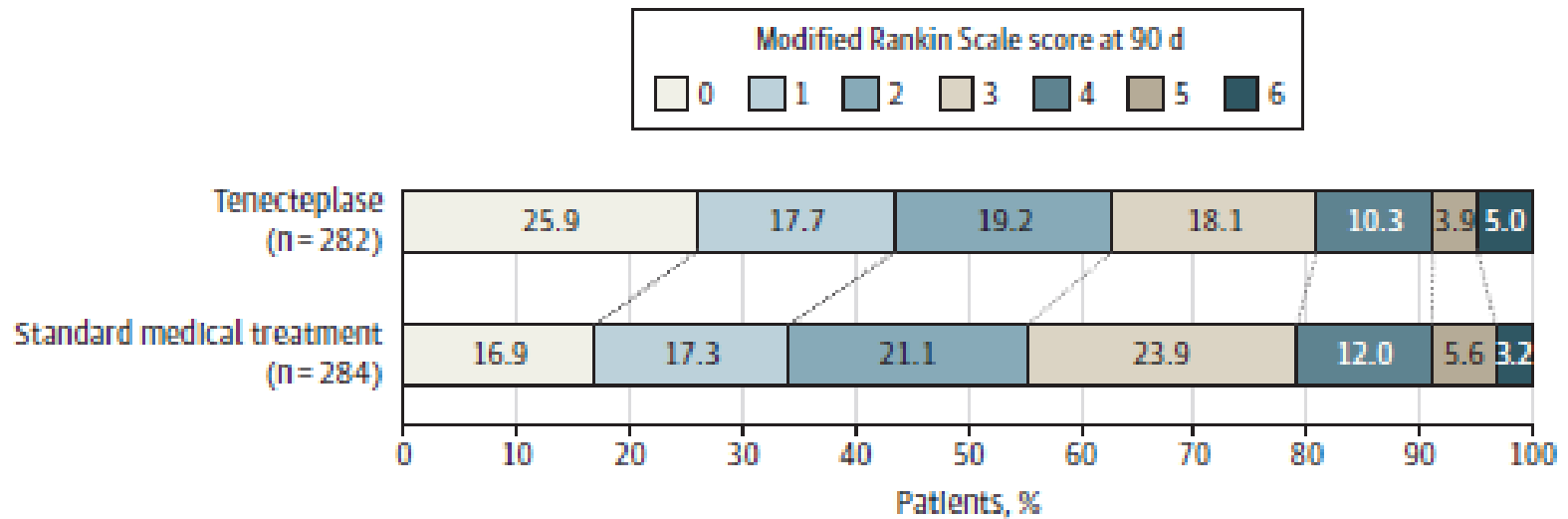
Tenecteplase for Acute Non–Large Vessel Occlusion 4.5 to 24 Hours After Ischemic Stroke The OPTION Randomized Clinical Trial

Gaoting Ma, MD; Ran Mo, MD; Yingting Zuo, PhD; Qingfeng Ma, MD; Guangjian Zhao, MD; Xiaoxi Yao, MS; Ji Liang, MD; Li Zhou, MS; Yong He, MS; Faqing Long, MD; Zhengzhou Yuan, MD; Lei Liu, MS; Guosheng Han, MS; Yan Tan, MS; Zhibing Ai, MD; Chunsheng Cai, MS; Juan Liu, MS; Liyong Zhang, MD; Haihua Yang, MD; Tingyu Yi, MD; Li Li, MD; Yao Fu, MS; Yanxing Zhang, MS; Xiangzhong Shao, MS; Zhipeng Yu, MD; Saizhen Wu, MS; Yanqiu Du, MS; Lingqun Mao, MS; Hongling Guo, MS; Xufeng Chen, MD; Yifei Chen, MD; Qiong Zhao, MS; Liyi Chi, MS; Yi Liu, MD; Haochun Zhang, MS; Guangzong Li, MS; Shujuan Meng, MD; Yifan Wu, MD; Jieying Wu, MD; Ziyang Jiang, MD; Shaoyuan Lei, PhD; Daiquan Gao, MD; Lianmei Zhong, MD; Jens Fiehler, MD; Duolao Wang, PhD; Thanh N. Nguyen, MD; Jeffrey L. Saver, MD; Junwei Hao, MD, PhD;
for the OPTION Investigators

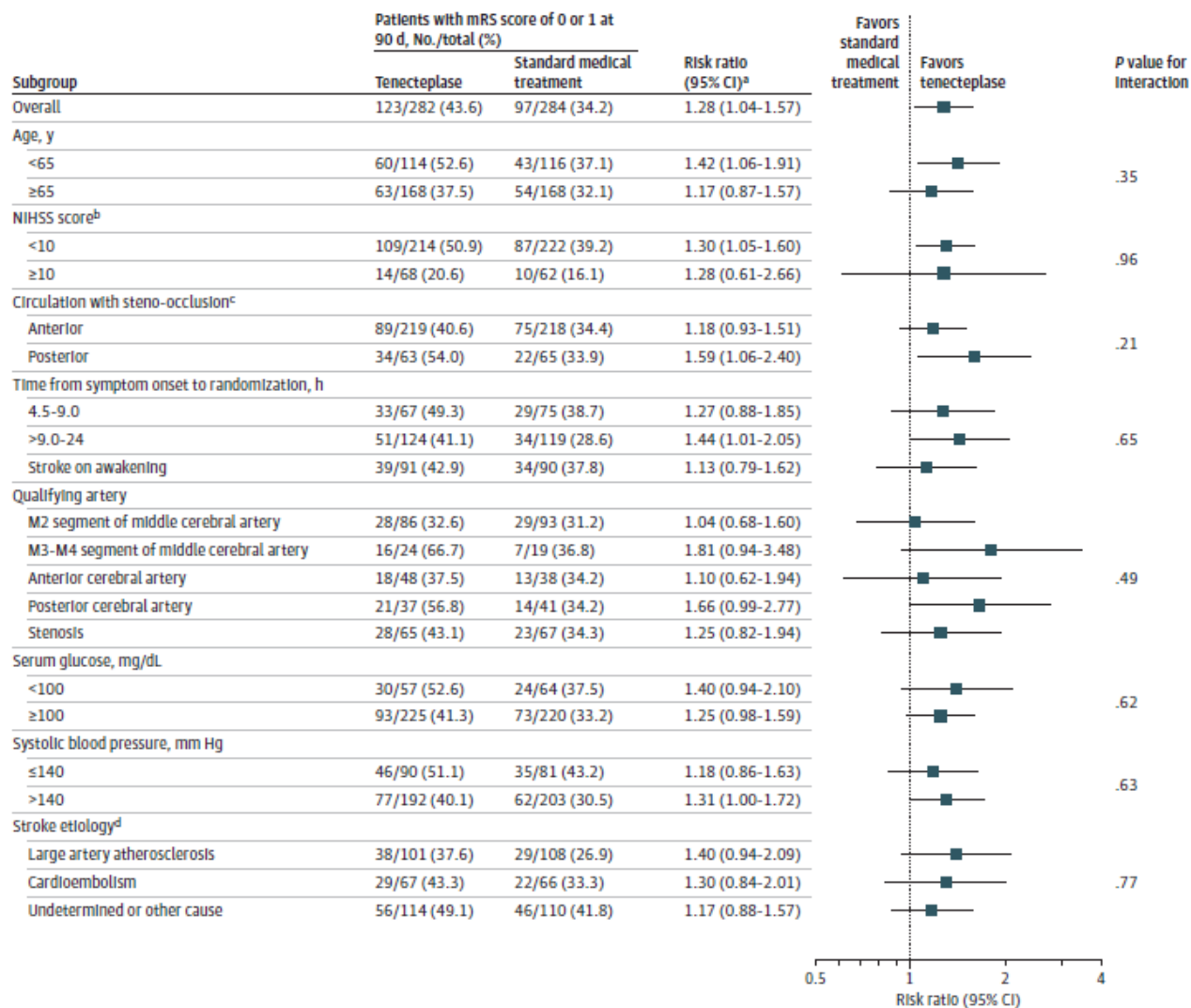
OPTION 2026

- Patients: N = 566 (282 v 284); NIHSS 6-25 or 4-5 with disabling (hemianopia, aphasia, loss of hand function)
- LVO/EVT: **no LVO** (iICA, M1, “vertebrobasilar artery”) / rescue EVT TNK 6 pt BMT 1 pt, after neurologic deterioration
- Window: 4.5 – 24 hr since LKW
- Imaging: CTP with salvageable penumbra (core: < 30% rCBF; penumbra TTP > 6s; mismatch ratio ≥ 1.2 ; absolute $\geq 10\text{cc}$; core < 50cc)
- Randomization: TNK v BMT
- Outcome: mRS 0-1: TNK 43.6% v BMT 34.2%; aRR 1.32; 95%CI 1.08-1.61, p = 0.007
- Safety: sICH at 36 h:TNK 2.8% v BMT 0%, RR 2.85; 95%CI 1.16-5.54; p = 0.004; death at 90 d: 5.0% v 3.2%; RR 1.57; 95%CI 0.69-3.57, p = 0.28

OPTION



OPTION



<i>Trial</i>	<i>Hypothesis</i>	<i>Selection</i>	<i>Result</i>	<i>Comment</i>
EXTEND	ALT works at 4.5-9h	CTP/MRP	Pos	77% would now get EVT
ECASS-4	ALT works at 4.5-9h	CTP/MRP	Neg	Too small
TIMELESS	TNK before EVT works 4.5-24h	CTP/MRP	Neg	Safe; maybe benefit in subgroup
TRACE-III	TNK w/o EVT works 4.5-24h	CTP/MRP	Pos	Most would get EVT at BMC
CHABLIS-T II	TNK \pm EVT works 4.5-24h	CTP/MRP	Neg	55% EVT; selection not clear
Meta 2019	IVT w/o EVT works > 4.5 h	CTP/MRP	Pos more sICH	Valid for those not getting EVT
Meta 2025	IVT w/o EVT works > 4.5 h	CTP/MRP	Pos more sICH	Valid for those not getting EVT
OPTION	TNK works at 4.5-24 h in non-LVO patients	CTP	Pos more ICH	Benefit for non-LVO patients

Conclusions

- *Patient with unknown onset time discovered within 4.5 hr of treatment may benefit from IVT.*
- *We need more study of CT-based wake-up protocols.*
- *EVT negates detectable benefit of extended window IVT.*
- *Extended window IVT may benefit patients who cannot get EVT.*
- ~~*Extended window IVT for those without treatable LVO has not been well studied.*~~ *There is now RCT evidence that extended-window IVT benefits patients without LVO.*
- *Efficient implementation of extended-window protocols will require the use of tools for the rapid automated analysis of perfusion imaging.*