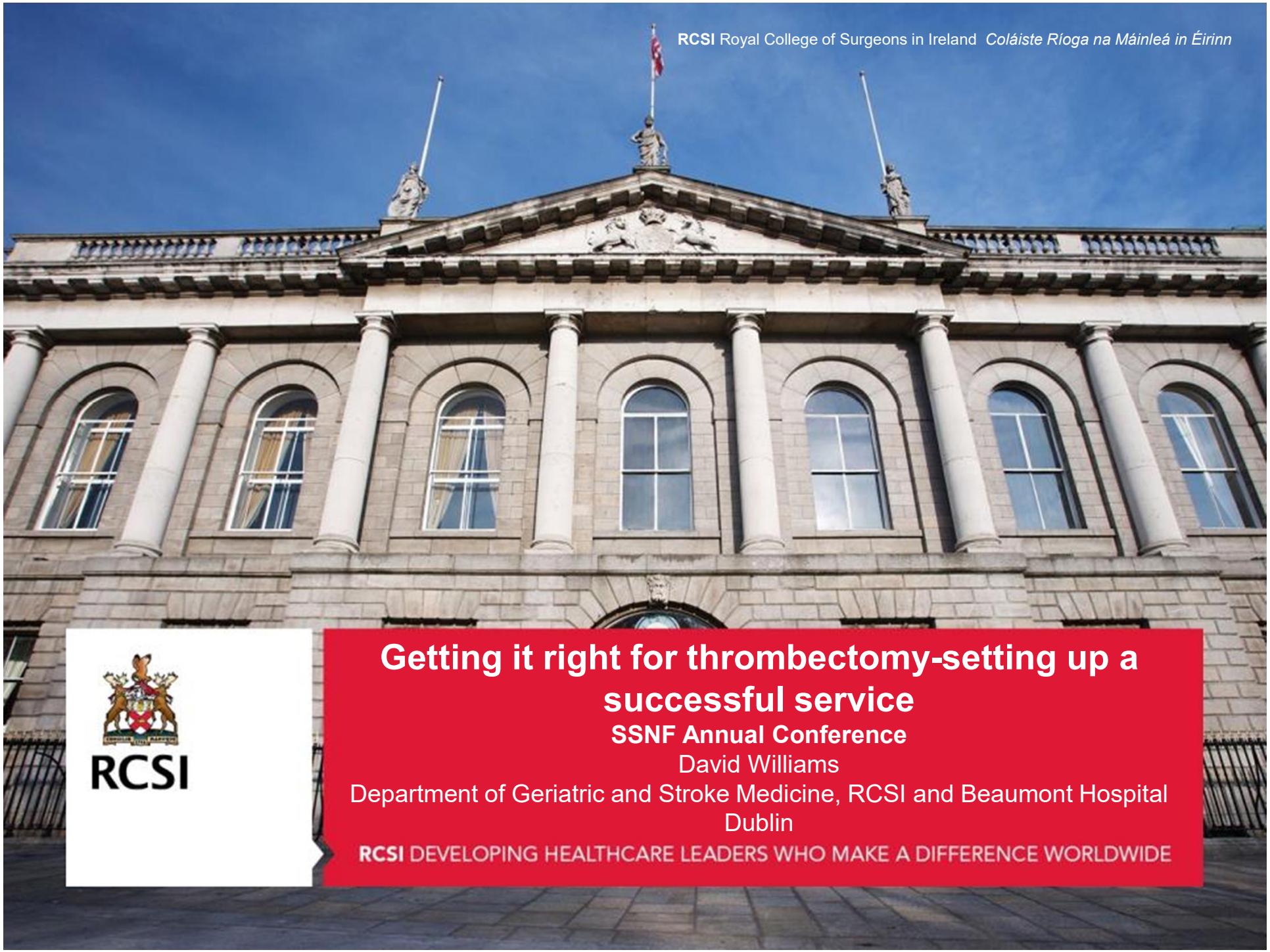
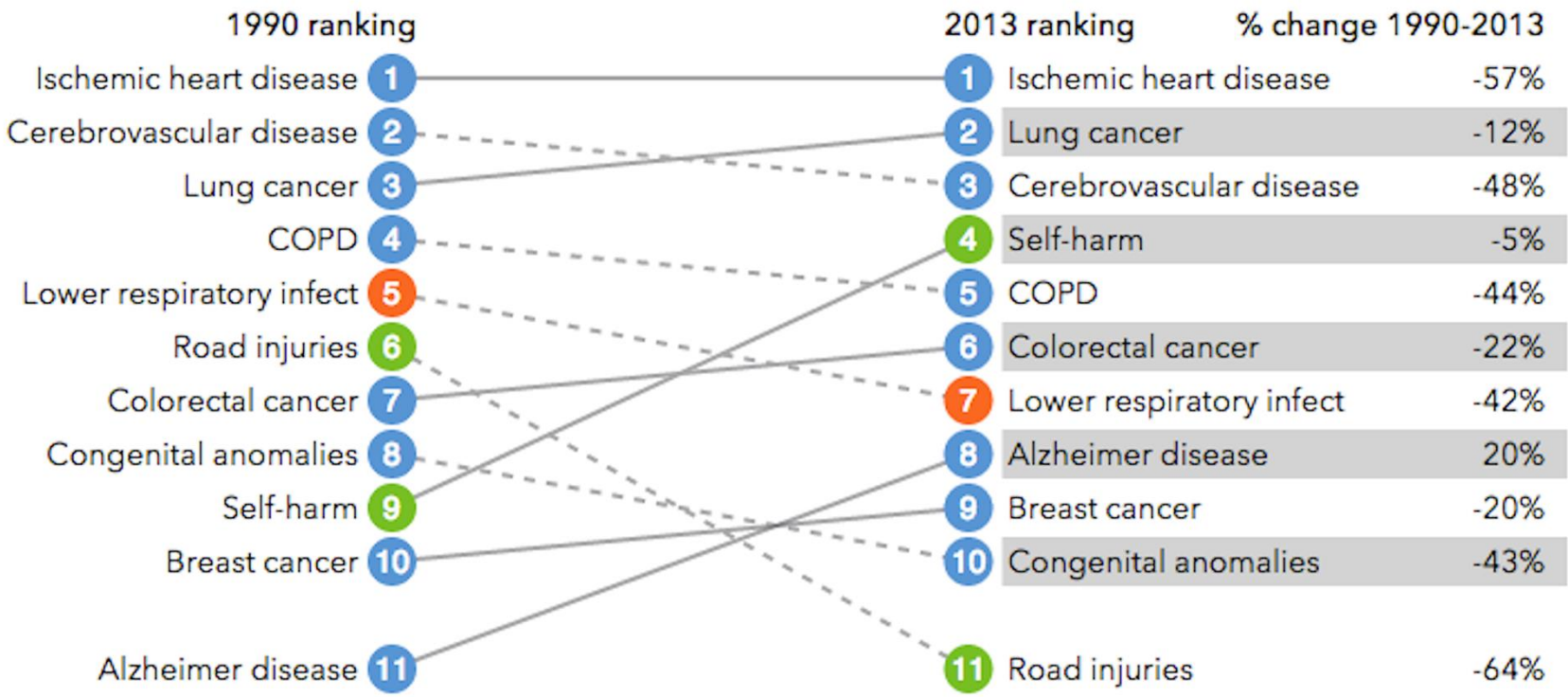

RCSI Royal College of Surgeons in Ireland Coláiste Ríoga na Máinleá in Éirinn
RCSI
Getting it right for thrombectomy-setting up a successful service
SSNF Annual Conference
David Williams
Department of Geriatric and Stroke Medicine, RCSI and Beaumont Hospital Dublin
RCSI DEVELOPING HEALTHCARE LEADERS WHO MAKE A DIFFERENCE WORLDWIDE

LEADING CAUSES OF YLLS TO PREMATURE DEATH, 1990 AND 2013, AND PERCENT CHANGE, 1990-2013

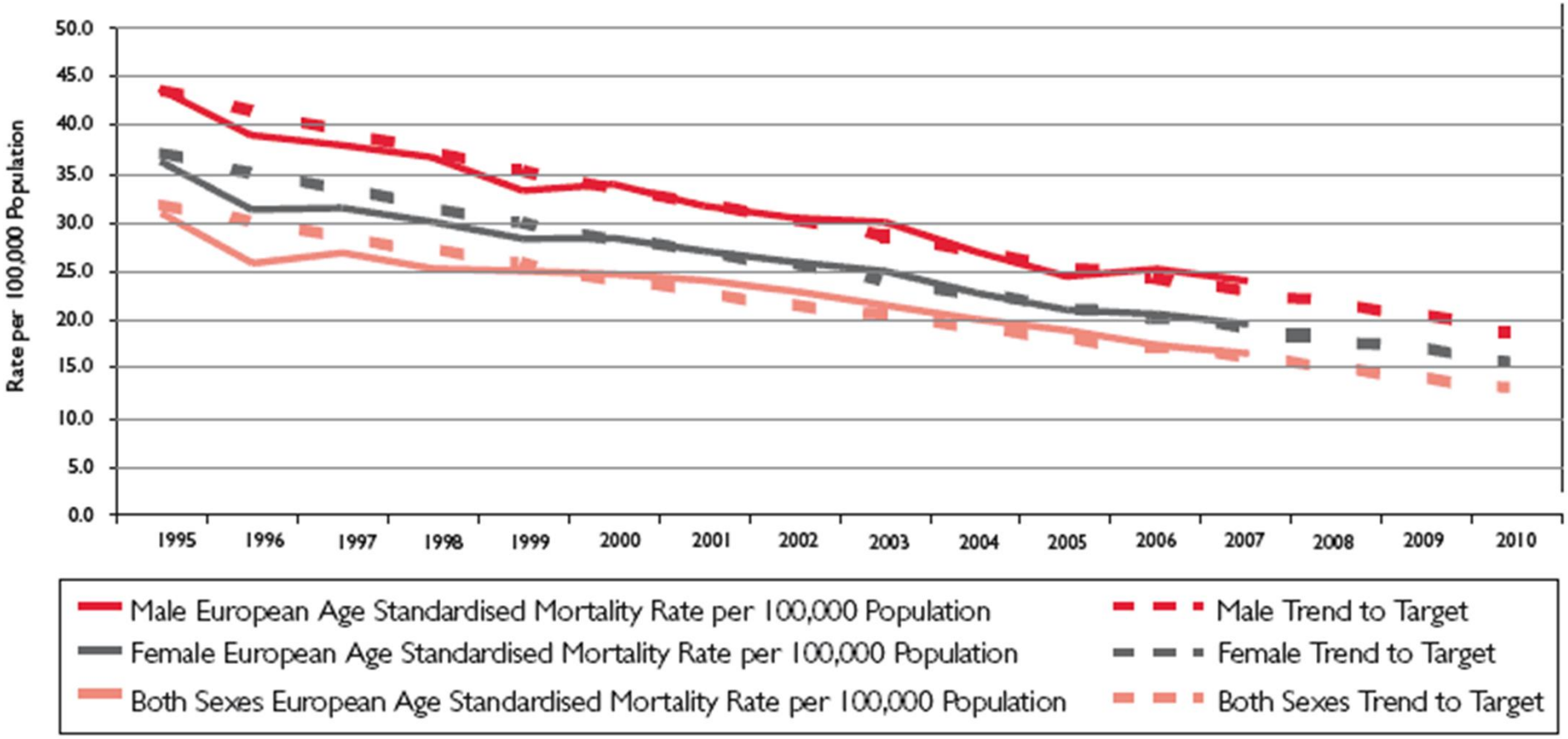
- Communicable, maternal, neonatal, and nutritional diseases
- Non-communicable diseases
- Injuries



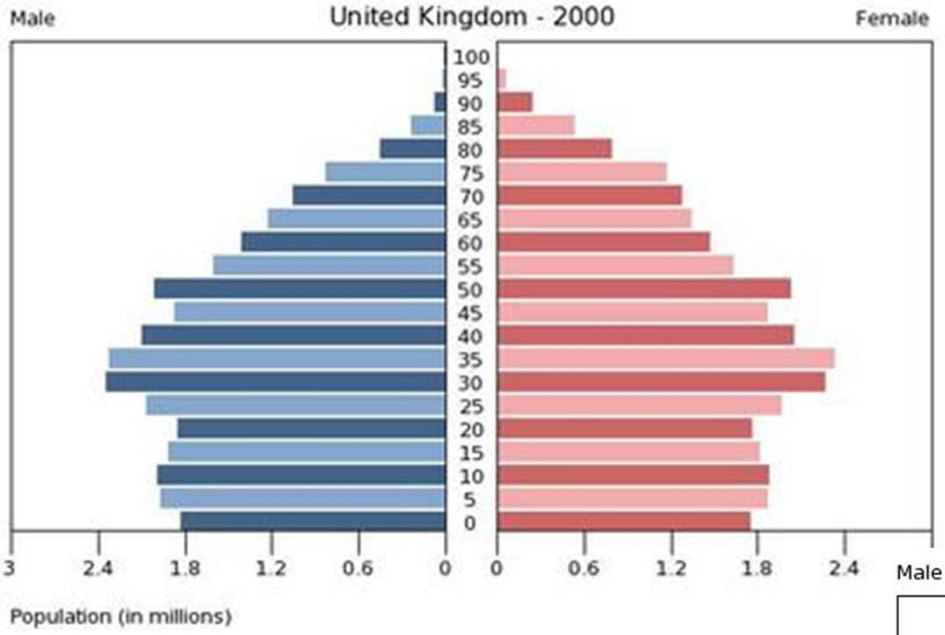
YLLs are years of life lost due to premature mortality.

Rankings are based on YLLs per 100,000, all ages, not age-standardized.

Stroke Mortality



The Demographic Transition



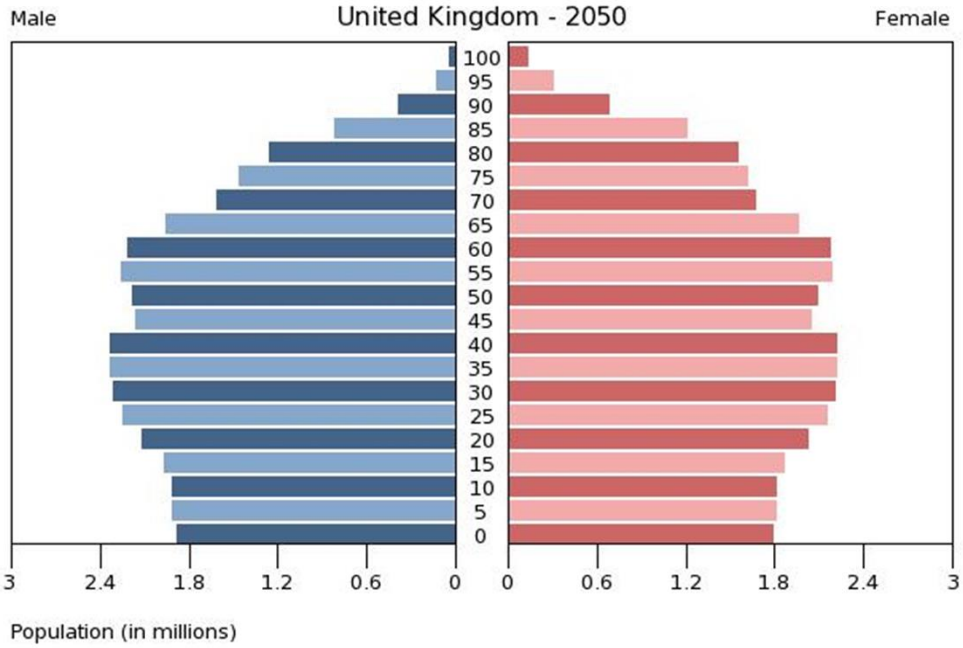
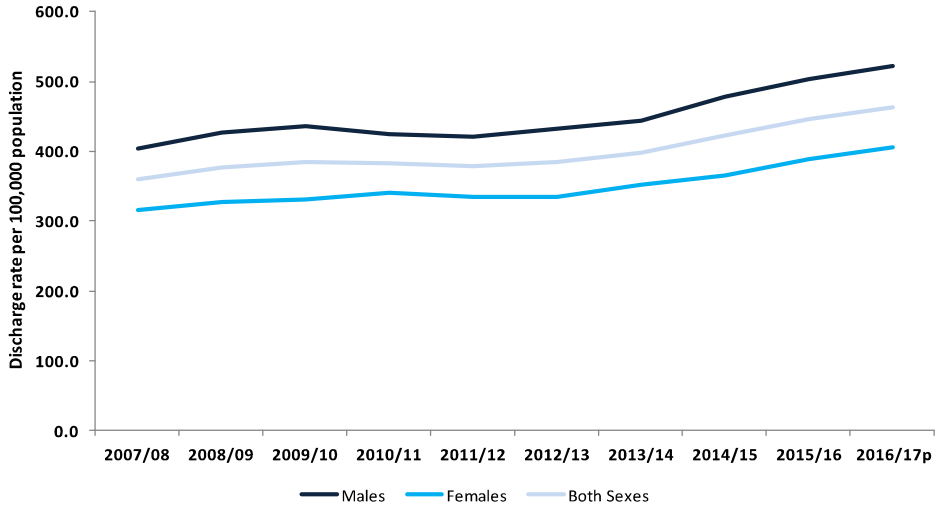


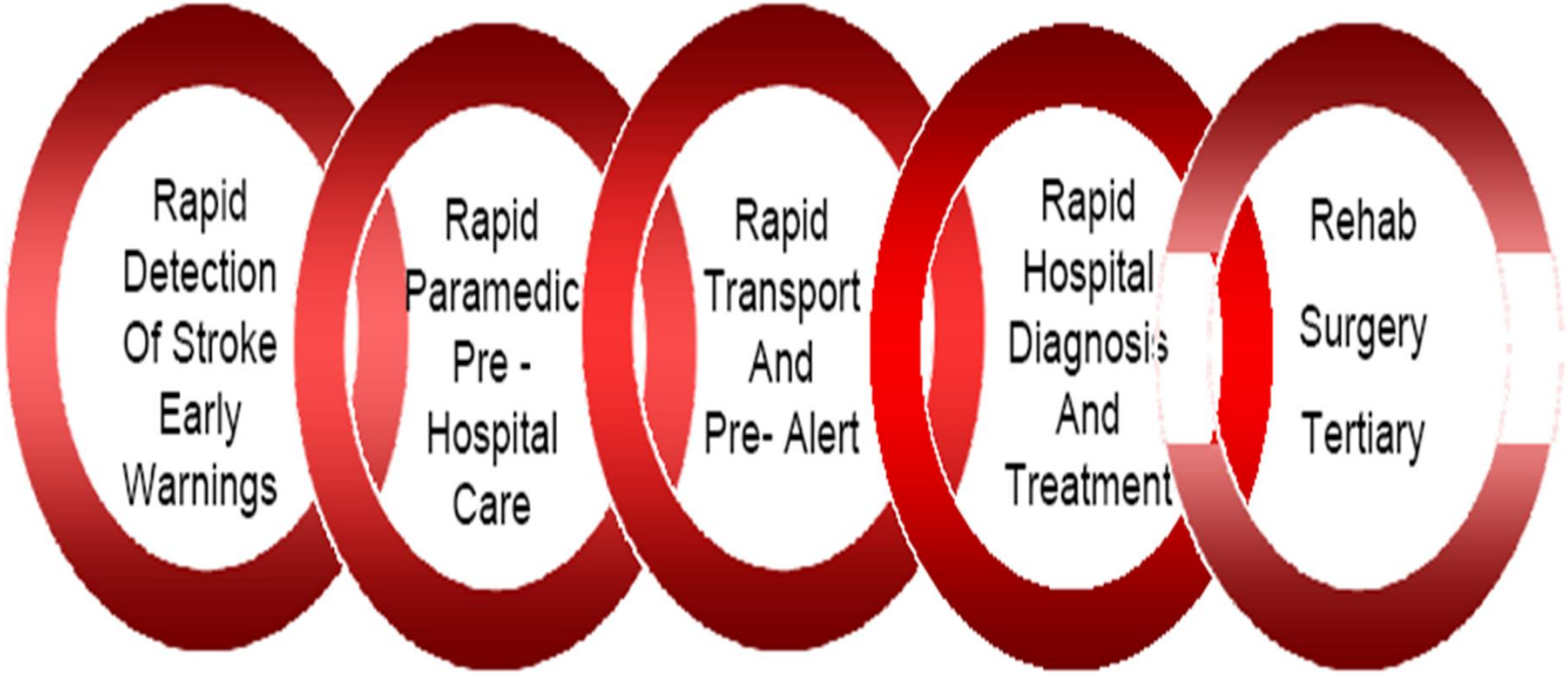
Figure 2: Discharges from hospital with stroke[1];

age and sex adjusted discharge rates per 100,000 population[2]



ISD Scotland Marc

Stroke Chain of Survival



RCSI

Advances in Stroke Care

Oxford Textbook of Medicine, 1983

“ *There is probably little that medical treatment can do to alter the immediate prognosis of stroke. Both fibrinolytic drugs and anti-coagulation increase the risk of intracranial bleeding and should usually not be used.* ”

Research advances

1993	Evidence for Stroke Unit benefits
1994	Carotid Endarterectomy
1997	Aspirin to prevent early recurrent stroke
2003	**Alteplase licensed for treatment acute ischaemic stroke, NICE recommended 2007**
2004	Outpatient therapy services
2005	Early supported discharge services
2007	Hemicraniectomy for malignant MCA infarction
2009	More protection for patients with atrial fibrillation
2015	?

The New England
Journal of Medicine

Volume 333 DECEMBER 14, 1995 Number 24

TISSUE PLASMINOGEN ACTIVATOR FOR ACUTE ISCHEMIC STROKE

THE NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE rt-PA STROKE STUDY GROUP*

Abstract *Background.* Thrombolytic therapy for acute ischemic stroke has been approached cautiously because there were high rates of intracerebral hemorrhage in early clinical trials. We performed a randomized, double-blind trial of intravenous recombinant tissue plasminogen activator (t-PA) for ischemic stroke after recent pilot studies suggested that t-PA was beneficial when treatment was begun within three hours of the onset of stroke.

Methods. The trial had two parts. Part 1 (in which 291 patients were enrolled) tested whether t-PA had clinical activity, as indicated by an improvement of 4 points over base-line values in the score of the National Institutes of Health stroke scale (NIHSS) or the resolution of the neurologic deficit within 24 hours of the onset of stroke. Part 2 (in which 333 patients were enrolled) used a global test statistic to assess clinical outcome at three months, according to scores on the Barthel index, modified Rankin scale, Glasgow outcome scale, and NIHSS.

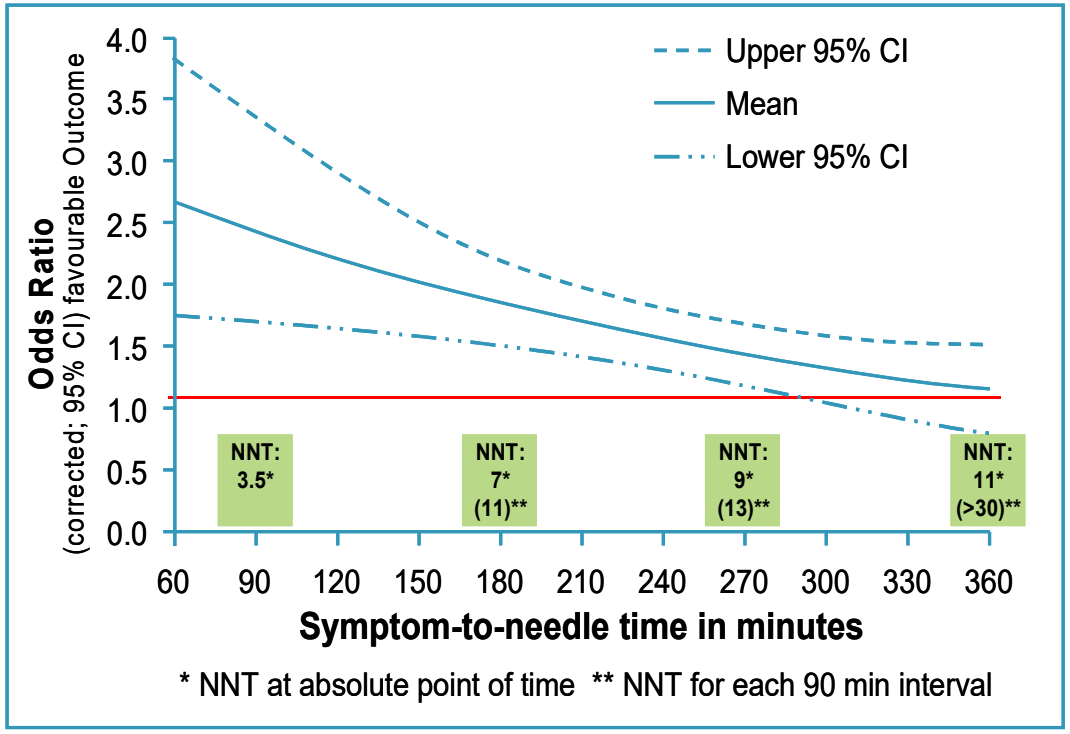
Results. In part 1, there was no significant difference between the group given t-PA and that given placebo in the percentages of patients with neurologic improvement at 24 hours, although a benefit was observed for the t-PA group at three months for all four outcome measures. In part 2, the long-term clinical benefit of t-PA predicted by the results of part 1 was confirmed (global odds ratio for a favorable outcome, 1.7; 95 percent confidence interval, 1.2 to 2.6). As compared with patients given placebo, patients treated with t-PA were at least 30 percent more likely to have minimal or no disability at three months on the assessment scales. Symptomatic intracerebral hemorrhage within 36 hours after the onset of stroke occurred in 6.4 percent of patients given t-PA but only 0.6 percent of patients given placebo ($P<0.001$). Mortality at three months was 17 percent in the t-PA group and 21 percent in the placebo group ($P=0.30$).

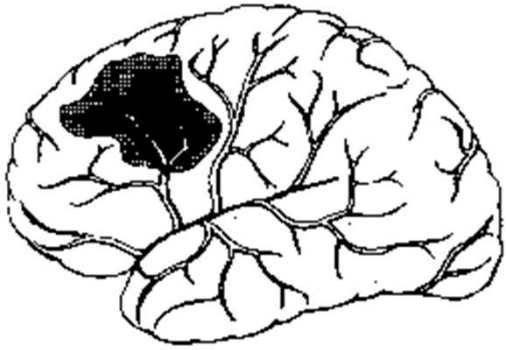
Conclusions. Despite an increased incidence of symptomatic intracerebral hemorrhage, treatment with intravenous t-PA within three hours of the onset of ischemic stroke improved clinical outcome at three months. (N Engl J Med 1995;333:1581-7.)

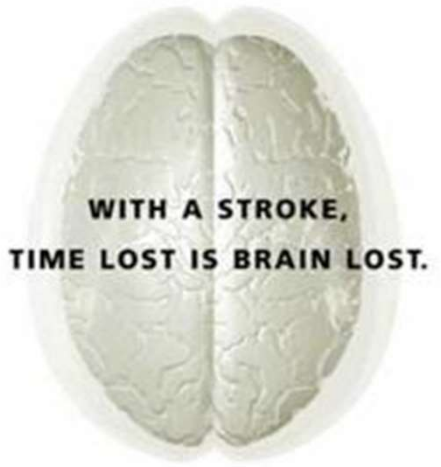
Curiously, the paper that changed Geoff Donnan's practice is the very same one that changed Gord Gubitz's practice. Maybe this is because both subspecialize in stroke, and because for **stroke doctors to come rushing into hospital to give a treatment that might actually work has come as something of a culture shock**. ***Charles Warlow, 2002***

Benefits of tissue Plasminogen Activator (tPA) treatment: time is brain

"The typical patient loses 1.9 million neurons each minute in which stroke is untreated"

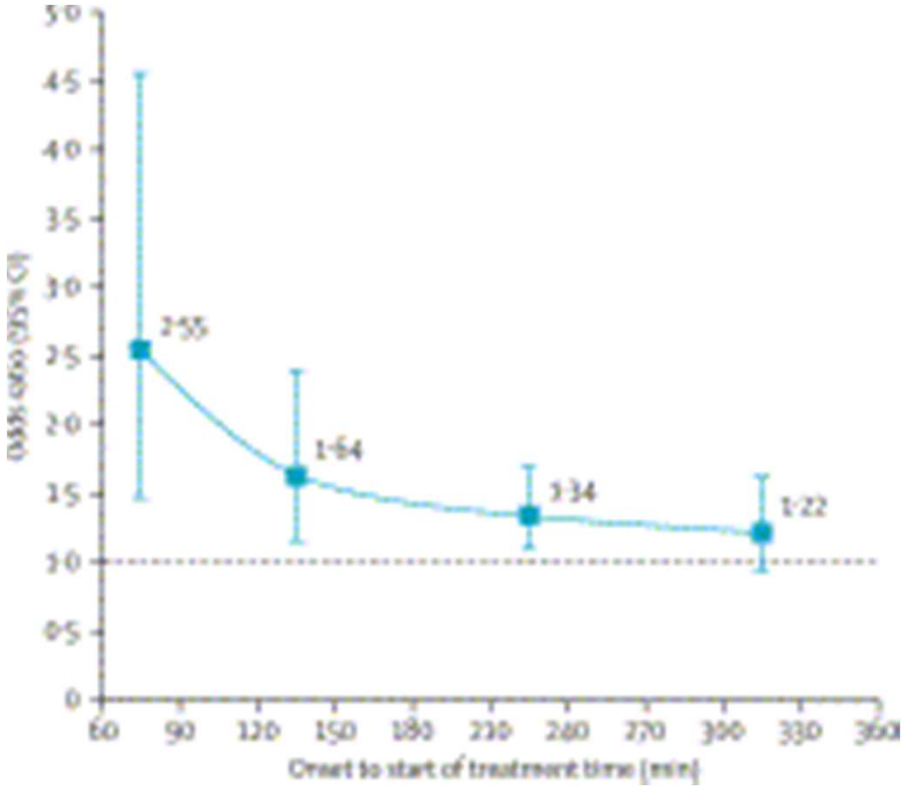




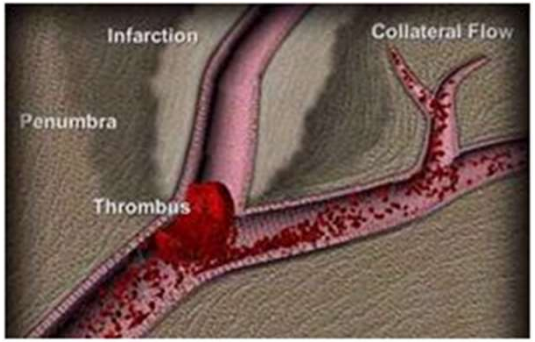


Saver, Stroke 2006

Relationship of stroke onset to start of treatment with excellent functional outcome

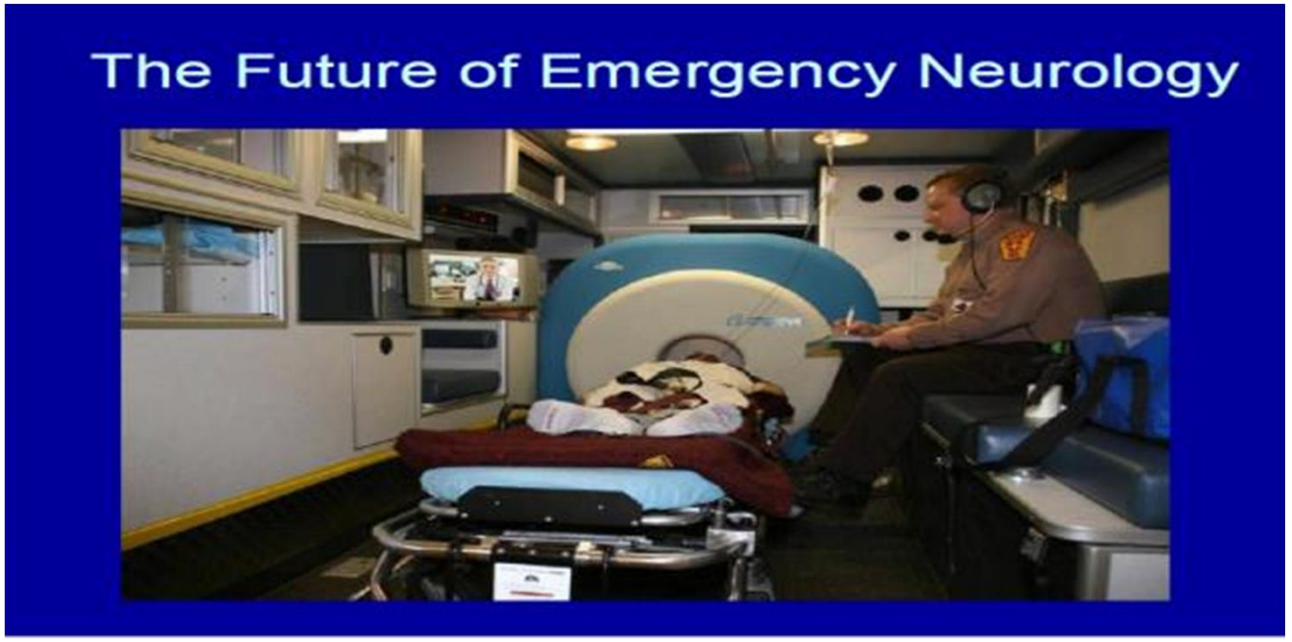


Odds of a favourable outcome drop off by a factor of two in each 90-min period.



Saver J, Levine S, Lancet 375;1667

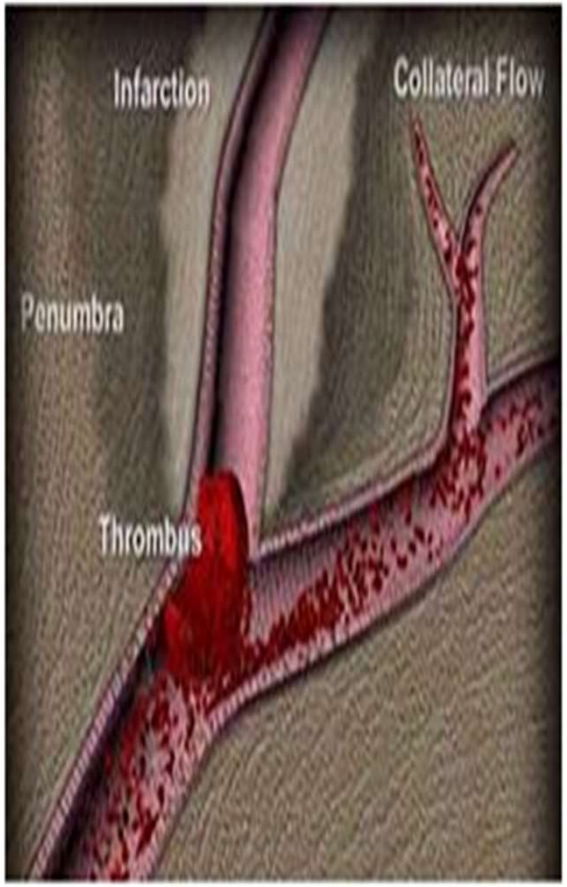
The German Model

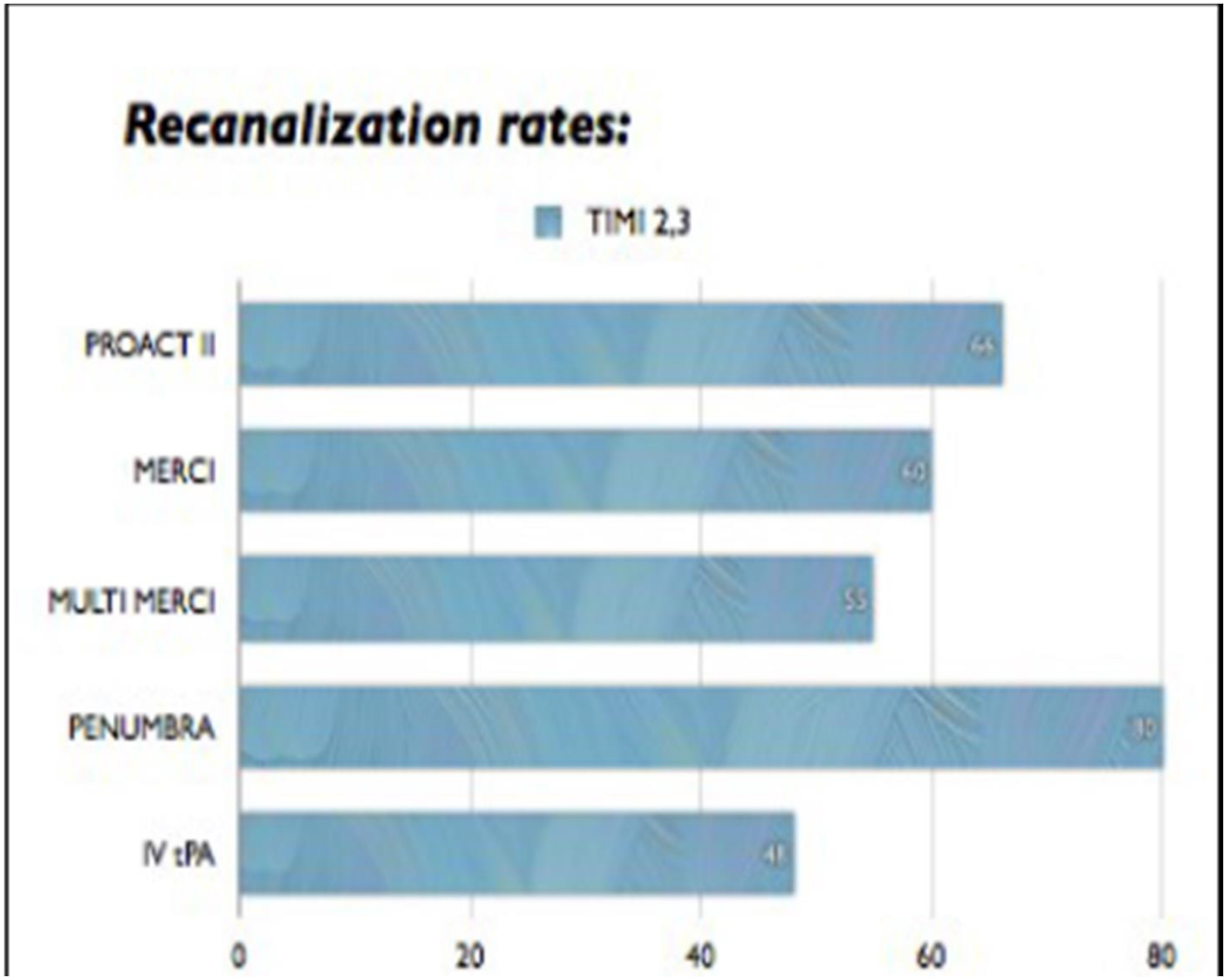


RCSI

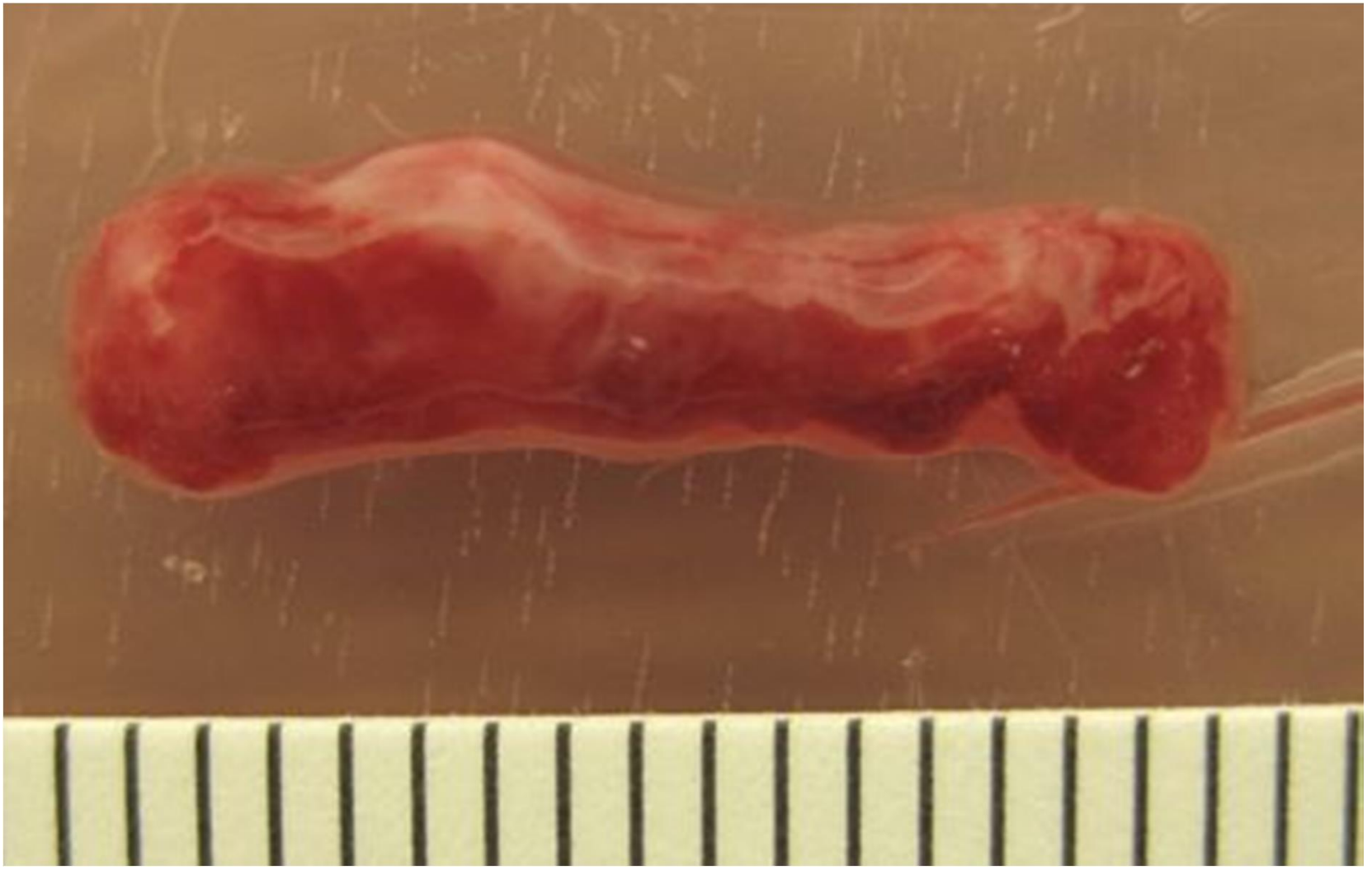
	MSU Group	Control Group	P Value	Difference (95%CI)
Alarm to therapy Decision(min)	35(31-39)	76(63-94)	<0.0001	41(36-48)
Symptom onset to therapy decision(min)	56(43-103)	104(80-156)	<0.0001	43(30-58)
IV tPA rate	12(23%)	8(17%)	0.3	
Alarm to end of CT(min)	34(30-38)	71(62-87)	<0.0001	38(33-43)
Symptom onset to end of CT(min)	56(43-103)	97(74-156)	<0.0001	39(26-52)

Walter S, et al Lancet Neurol. 2012 May;11(5):397-404


Infarction
Collateral Flow
Penumbra
Thrombus


Recanalization rates:
TIMI 2,3
PROACT II
MERCI
MULTI MERCI
PENUMBRA
IV tPA
0
20
40
60
80

Clot Extraction


1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19
Millimetres

A Patient’s Story

ESCAPE

Endovascular treatment for **S**mall **C**ore and **A**nterior circulation **P**roximal occlusion with **E**mphasis on minimizing CT to recanalization times

John Thornton[1], David Williams[1,2]on behalf of the ESCAPE Trial Investigators

Beaumont Hospital[1],RCSI[2]

Principal Investigators:
Michael D Hill
Mayank Goyal
Andrew M Demchuk

N Engl J Med 2015;372:1019-1030

ESCAPE Concept

Question: "Do I take this patient for endovascular treatment (thrombectomy)?"

1. Sequential patient randomization
2. Fast and simple imaging paradigm
3. Quick workflow – parallel processing
4. Effective technology & technique to get TICI 2b/3 reperfusion

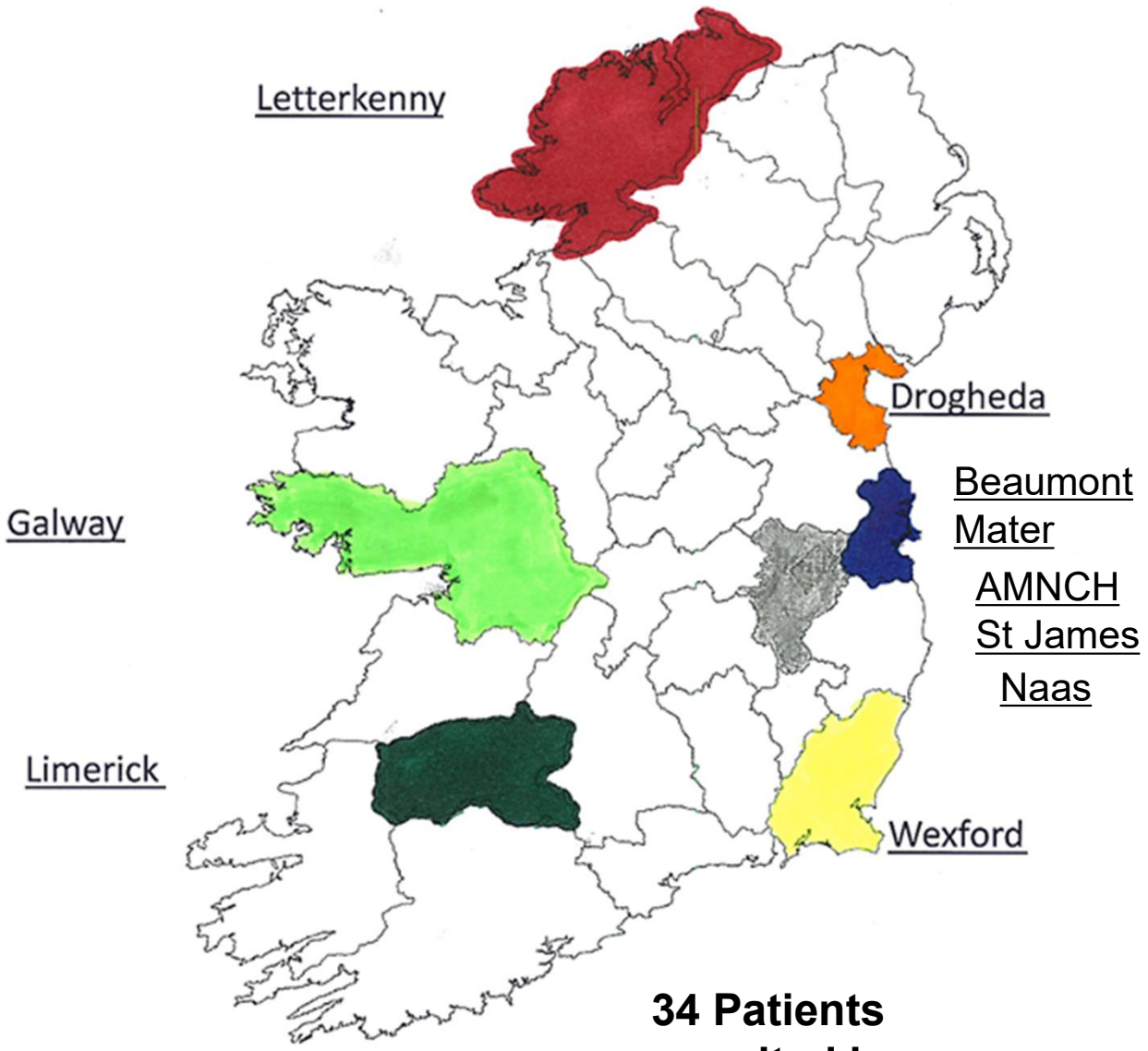
N Engl J Med 2015;372:1019-1030

Methods

- 22 centres in Canada (11), US (6), Korea (3), UK (1), Ireland (1)
- tPA given when patient eligible (no waiting for tPA response)
- Imaging must have shown: small core, proximal intracranial artery occlusion, moderate-good collaterals using CT, mCTA (use of MRI discouraged)
- Intensive quality improvement program with personalized site visits

N Engl J Med 2015;372:1019-1030

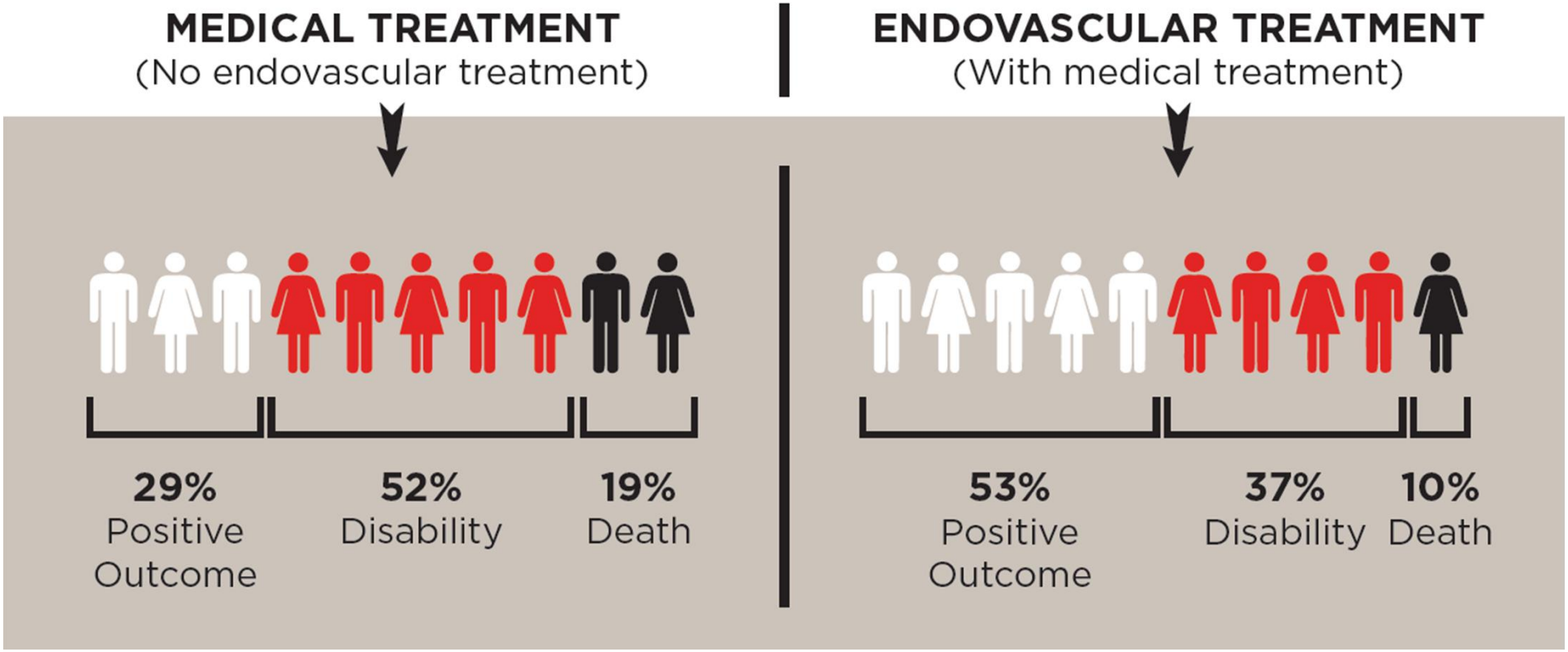
ESCAPE Recruitment Dublin Site



34 Patients recruited in Ireland

N Engl J Med 2015;372:1019-1030

ESCAPE Outcomes



N Engl J Med 2015;372:1019-1030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06-D-30631
06-D-30632

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 1, 2015 VOL. 372 NO. 1

A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke

O.A. Berkhemer, P.S.S. Fransen, D. Beumer, L.A. van den Berg, H.F. Lingsma, A.J. Yoo, W.J. Schonewille, J.A. Vos, P.J. Nederkoorn, M.J.H. Wermer, M.A.A. van Walderveen, J. Staals, J. Hofmeijer, J.A. van Oostayen, G.J. Lycklama à Nijeholt, J. Boiten, P.A. Brouwer, B.J. Emmer, S.F. de Bruijn, L.C. van Dijk, L.J. Kappelle, R.H. Lo, E.J. van Dijk, J. de Vries, P.L.M. de Kort, W.J.J. van Rooij, J.S.P. van den Berg, B.A.A.M. van Hasselt, L.A.M. Aerden, R.J. Dallinga, M.C. Visser, J.C.J. Bot, P.C. Vroomen, O. Eshghi, T.H.C.M.L. Schreuder, R.J.J. Heijboer, K. Keizer, A.V. Tielbeek, H.M. den Hertog, D.G. Gerrits, R.M. van den Berg-Vos, G.B. Karas, E.W. Steyerberg, H.Z. Flach, H.A. Marquering, M.E.S. Sprengers, S.F.M. Jenniskens, L.F.M. Beenen, R. van den Berg, P.J. Koudstaal, W.H. van Zwam, Y.B.W.E.M. Roos, A. van der Lugt, R.J. van Oostenbrugge, C.B.L.M. Majoie, and D.W.J. Dippel, for the MR CLEAN Investigators*

ABSTRACT

BACKGROUND

In patients with acute ischemic stroke caused by a proximal intracranial arterial occlusion, intraarterial treatment is highly effective for emergency revascularization. However, proof of a beneficial effect on functional outcome is lacking.

METHODS

We randomly assigned eligible patients to either intraarterial treatment plus usual care or usual care alone. Eligible patients had a proximal arterial occlusion in the anterior cerebral circulation that was confirmed on vessel imaging and that could be treated intraarterially within 6 hours after symptom onset. The primary outcome was the modified Rankin scale score at 90 days; this categorical scale measures functional outcome, with scores ranging from 0 (no symptoms) to 6 (death). The treatment effect was estimated with ordinal logistic regression as a common odds ratio, adjusted for prespecified prognostic fa[c]tors. The odds ratio measured the likelihood that intraarterial tre[atment] ified Rankin scores, as compared with usual care

RESULTS

We enrolled 500 patients at 16 medical centers in th[e Netherlands]. traarterial treatment and 267 to usual care alone). T[he median] 23 to 96), and 445 patients (89.0%) were treated wit[hin] domization. Retrievable stents were used in 190 of th[ese] intraarterial treatment. The adjusted common odd[s ratio] interval [CI], 1.21 to 2.30). There was an absolute di[fference] (95% CI, 5.9 to 21.2) in the rate of functional indep[endence] 0 to 2) in favor of the intervention (32.6% vs. 19.1%) ences in mortality or the occurrence of symptomatic

CONCLUSIONS

In patients with acute ischemic stroke caused by [a proximal] of the anterior circulation, intraarterial treatment ter stroke onset was effective and safe. (Funded by others; MR CLEAN Netherlands Trial Registry [number] Controlled Trials number, ISRCTN10888758.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Dippel at the Department of Neurology H643, Erasmus MC University Medical Center, PO Box 2040, Rotterdam 3000 CA, the Netherlands, or at d.dippel@erasmusmc.nl.

Drs. Berkhemer, Fransen, and Beumer and Drs. van Zwam, Roos, van der Lugt, van Oostenbrugge, Majoie, and Dippel contributed equally to this article.

*A complete list of investigators in the

N ENGL J MED 372;1 NEJM.ORG JANUARY 1, 2015

ORIGINAL ARTICLE

Thrombectomy within 8 Hours after Symptom Onset in Ischemic Stroke

T.G. Jovin, A. Chamorro, E. Cobo, M.A. de Miquel, C.A. Molina, A. Rovira, L. San Román, J. Serena, S. Abilleira, M. Ribó, M. Millán, X. Urra, P. Cardona, E. López-Cancio, A. Tomasello, C. Castaño, J. Reverte, I. Aja, I. Delgado, H. Quesada, M. Rubiera, M. Hernández-Pérez, M. Goyal, A.M. Demchuk, R. von Kummer, M. Gallofré, and A. Dávalos, for the REVASCAT Trial Investigators*

ABSTRACT

BACKGROUND

We aimed to assess the safety and efficacy of thrombectomy for the treatment of stroke in a trial embedded within a population-based stroke reperfusion registry.

METHODS

During a 3-year period at five centers in Catalonia, Spain, we randomly assigned 206 patients who could be treated within 8 hours after the onset of symptoms of acute ischemic stroke to receive either medical therapy (including intravenous alteplase when eligible) and endovascular therapy with the Solitaire stent retriever (thrombectomy group) or medical therapy alone (control group). All patients had confirmed proximal anterior circulation occlusion and the absence of a large infarct on neuroimaging. In all study patients, the use of alteplase either did not achieve recanalization or was contraindicated. The primary outcome was the severity of global disability at 90 days, as measured on the modified Rankin scale (ranging from 0 [no symptoms] to 6 [death]). Although the maximum planned sample size was 690, enrollment was halted early because of loss of equipoise after positive results for thrombectomy were reported from other similar trials.

RESULTS

Thrombectomy reduced the severity of disability over the range of the modified Rankin scale (adjusted odds ratio for improvement of 1 point, 1.7; 95% confidence interval [CI], 1.06 to 2.8) and led to higher rates of functional independence (a score of 0 to 2) at 90 days (43.7% vs. 28.2%; adjusted odds ratio, 2.1; 95% CI, 1.1 to 4.1). At 90 days, the rates of symptomatic intracranial hemorrhage were 1.9% in both the thrombectomy group and the control group (P=1.00), and rates of death were 18.4% and 15.7%, respectively (P=0.68). Registry data indicated that only eight patients who met the eligibility criteria were treated outside the trial at participating hospitals.

CONCLUSIONS

Among patients with anterior circulation stroke who could be treated within 8 hours after symptom onset, stent retriever thrombectomy reduced the severity of post-stroke disability and increased the rate of functional independence. (Funded by Fundació Institut Català de Neurociències through an unrestricted grant from Covidien and others; REVASCAT ClinicalTrials.gov number, NCT01044251.)

ORIGINAL ARTICLE

Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke

M. Goyal, A.M. Demchuk, B.K. Menon, M. Eesa, J.L. Rempel, J. Thornton, D. Roy, T.G. Jovin, R.A. Willinsky, B.L. Sapkota, D. Dowlatshahi, D.F. Frei, N.R. Kamal, W.J. Montanera, A.Y. Poppe, K.J. Ryckborst, F.L. Silver, A. Shuaib, D. Tampieri, D. Williams, O.Y. Bang, B.W. Baxter, P.A. Burns, H. Choe, J.-H. Heo, C.A. Holmstedt, B. Jankowitz, M. Kelly, G. Linares, J.L. Mandzia, J. Shankar, S.-I. Sohn, R.H. Swartz, P.A. Barber, S.B. Coutts, E.E. Smith, W.F. Morrish, A. Weill, S. Subramaniam, A.P. Mitha, J.H. Wong, M.W. Lowerison, T.T. Sajobi, and M.D. Hill for the ESCAPE Trial Investigators*

ABSTRACT

BACKGROUND

Among patients with a proximal vessel occlusion in the anterior circulation, 60 to 80% of patients die within 90 days after stroke onset or do not regain functional independence despite alteplase treatment. We evaluated rapid endovascular treatment in addition to standard care in patients with acute ischemic stroke with a small infarct core, a proximal intracranial arterial occlusion, and moderate-to-good collateral circulation.

METHODS

We randomly assigned participants to receive standard care (control group) or standard care plus endovascular treatment with the use of available thrombectomy devices (intervention group). Patients with a proximal intracranial occlusion in the anterior circulation were included up to 12 hours after symptom onset. Patients with a large infarct core or poor collateral circulation on computed tomography (CT) and CT angiography were excluded. Workflow times were measured against predetermined targets. The primary outcome was the score on the modified

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Hill at the Calgary Stroke Program, Department of Clinical Neurosciences, Hotchkiss Brain Institute, University of Calgary, Foothills Hospital, Rm. 1242A, 1403 29th Street NW, Calgary, AB T2N 2T9, Canada, or at michael.hill@ucalgary.ca.

Drs. Goyal and Hill contributed equally to this article.

*A complete list of sites and investigators in the Endovascular Treatment for Small Core and Anterior Circulation

ORIGINAL ARTICLE

Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection

B.C.V. Campbell, P.J. Mitchell, T.J. Kleinig, H.M. Dewey, L. Churilov, N. Yassi, B. Yan, R.J. Dowling, M.W. Parsons, T.J. Oxley, T.Y. Wu, M. Brooks, M.A. Simpson, F. Miteff, C.R. Levi, M. Krause, T.J. Harrington, K.C. Faulder, B.S. Steinfort, M. Priglinger, T. Ang, R. Scroop, P.A. Barber, B. McGuinness, T. Wijeratne, T.G. Phan, W. Chong, R.V. Chandra, C.F. Bladin, M. Badve, H. Rice, L. de Villiers, H. Ma, P.M. Desmond, G.A. Donnan, and S.M. Davis, for the EXTEND-IA Investigators*

ABSTRACT

BACKGROUND

Trials of endovascular therapy for ischemic stroke have produced variable results. We conducted this study to test whether more advanced imaging selection, recently developed devices, and earlier intervention improve outcomes.

METHODS

We randomly assigned patients with ischemic stroke who were receiving 0.9 mg of alteplase per kilogram of body weight less than 4.5 hours after the onset of ischemic stroke either to undergo endovascular thrombectomy with the Solitaire FR (Flow Restoration) stent retriever or to continue receiving alteplase alone. All the patients had occlusion of the internal carotid or middle cerebral artery and evidence of salvageable brain tissue and ischemic core of less than 70 ml on computed tomographic (CT) perfusion imaging. The coprimary outcomes were reperfusion at 24 hours and early neurologic improvement (28-point reduction on the National Institutes of Health Stroke Scale or a score of 0 or 1 at day 3). Secondary outcomes included the functional score on the modified Rankin scale at 90 days.

RESULTS

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Campbell at the Department of Neurology, Royal Melbourne Hospital, Grattan St., Parkville, VIC 3050, Australia, or at bruce.campbell@mh.org.au.

*A complete list of investigators in the Extending the Time for Thrombolysis in Emergency Neurological Deficits — Intra-Arterial (EXTEND-IA) trial is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on February 11, 2015, at NEJM.org.

N Engl J Med 2015;372:1009-18.
DOI: 10.1056/NEJMoa1414792

ORIGINAL ARTICLE

Stent-Retriever Thrombectomy after Intravenous t-PA vs. t-PA Alone in Stroke

Jeffrey L. Saver, M.D., Mayank Goyal, M.D., Alain Bonafe, M.D., Hans-Christoph Diener, M.D., Ph.D., Elad I. Levy, M.D., Vitor M. Pereira, M.D., Gregory W. Albers, M.D., Christophe Cognard, M.D., David J. Cohen, M.D., Werner Hacke, M.D., Ph.D., Olav Jansen, M.D., Ph.D., Tudor G. Jovin, M.D., Heinrich P. Mattle, M.D., Raul G. Nogueira, M.D., Adnan H. Siddiqui, M.D., Ph.D., Dileep R. Yavagal, M.D., Blaise W. Baxter, M.D., Thomas G. Devlin, M.D., Ph.D., Demetrius K. Lopes, M.D., Vivek K. Reddy, M.D., Richard du Mesnil de Rochemont, M.D., Oliver C. Singer, M.D., and Reza Jahan, M.D., for the SWIFT PRIME Investigators*

ABSTRACT

BACKGROUND

Among patients with acute ischemic stroke due to occlusions in the proximal anterior intracranial circulation, less than 40% regain functional independence when treated with intravenous tissue plasminogen activator (t-PA) alone. Thrombectomy with the use of a stent retriever, in addition to intravenous t-PA, increases reperfusion rates and may improve long-term functional outcome.

METHODS

We randomly assigned eligible patients with stroke who were receiving or had received intravenous t-PA to continue with t-PA alone (control group) or to undergo endovascular thrombectomy with the use of a stent retriever within 6 hours after symptom onset (intervention group). Patients had confirmed occlusions in the proximal anterior intracranial circulation and an absence of large ischemic core lesions. The primary outcome was the severity of global disability at 90 days, as assessed by means of the modified Rankin scale (with scores ranging from 0 [no symptoms] to 6 [death]).

RESULTS

The study was stopped early because of efficacy. At 49 centers, 196 patients underwere randomization (98 patients in each group). In the intervention group, the median time from qualifying imaging to groin puncture was 57 minutes, and the rate of substantial reperfusion at the end of the procedure was 88%. Thrombectomy with the stent retriever plus intravenous t-PA reduced disability at 90 days over the entire range of scores on the modified Rankin scale (P<0.001). The rate of functional independence (modified Rankin scale score, 0 to 2) was higher in the intervention group than in the control group (60% vs. 35%, P<0.001). There were no significant between-group differences in 90-day mortality (7% vs. 12%, P=0.50) or symptomatic intracranial hemorrhage (0% vs. 3%, P=0.12).

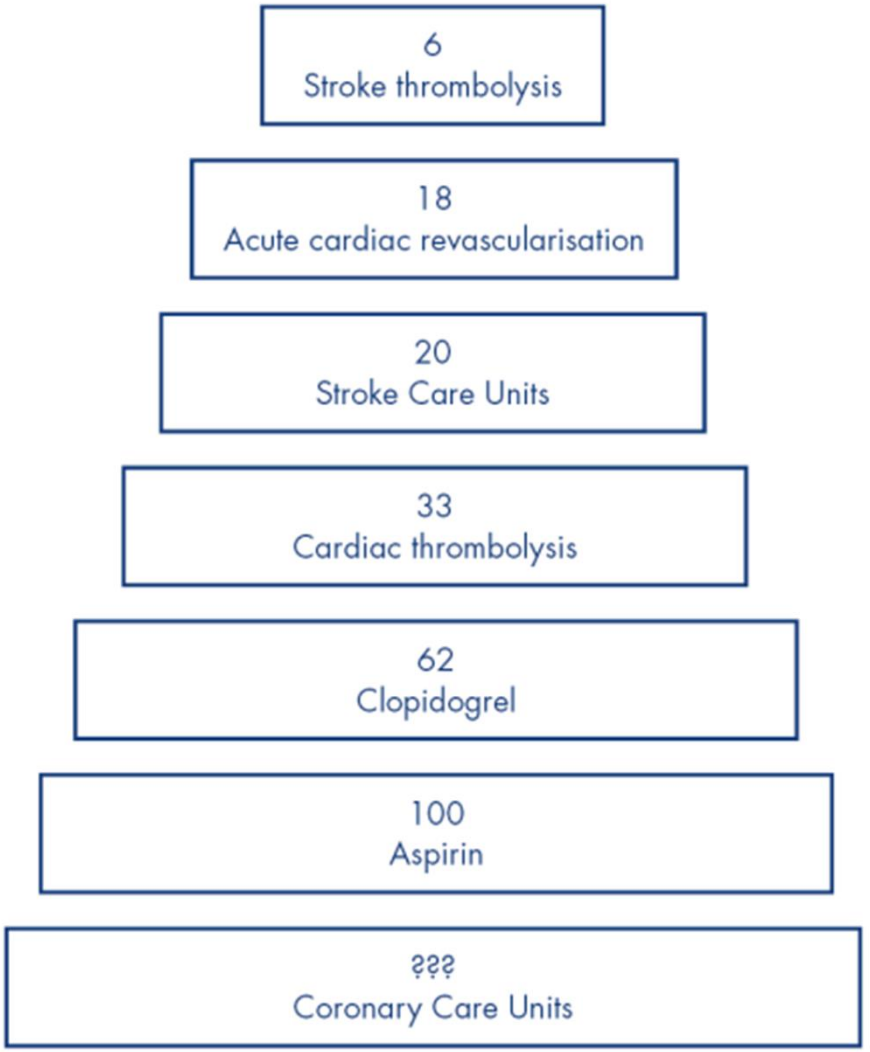
CONCLUSIONS

In patients receiving intravenous t-PA for acute ischemic stroke due to occlusions in the proximal anterior intracranial circulation, thrombectomy with a stent retriever within 6 hours after onset improved functional outcomes at 90 days. (Funded by Covidien; SWIFT PRIME ClinicalTrials.gov number, NCT01657461.)

	MR CLEAN	EXTEND IA	ESCAPE	SWIFT-PRIME	REVASCAT
Sample Size	500	70 (100 Planned)	315 (500 planned)	196 (833 estimated)	206 (690 planned)
Study Characteristics	Endovascular treatment vs best medical mgt, =/- IV tPA	Mechanical clot retrieval after IV tPA vs IV tPA	Mechanical Thrombectomy +/- IVtPA vs best medical Mgt +/- tPA	IV tPA + mechanical clot retrieval vs IV tPA	Mechanical thrombectomy + best medical mgt vs best medical Mgt
OTT	6hrs	6hrs	12hrs	6hrs	8hrs
Primary Outcome	Significant shift towards more favourable mRS(OR 1.67, 95% CI 1.21-2.3)	Higher Median Perfusion (100%vs 37%, p<0.001) Early Neurological improvement (80%vs 37%p<0.001)	Odds of improvement in mRS score by 1 point (OR-3.2, 95% CI 2.0-4.7)	Significant shift in mRS scores towards lover scores in intervention group (p=0.0002)	Odds for improvement by 1 point in mRS at 90d were significantly improved in the intervention group(OR=1.7, 95% CI 1.05-2.8)
Safety	No difference in mean number of serious adverse events	No significant difference between groups in any of the safety outcomes (death, symptomatic ICH or parenchymal haematoma)	Lower risk of death(adj RR=0.5, 95%CI 0.3-0.8) or malignant stroke(adj RR=0.3, 95% CI 0.1-0.8) lower in intervention group with no increase in risk of symptomatic ICH (adj RR=1.2, 95% CI 0.3-4.6) in intervention group	No increased risk of serious adverse events, including symptomatic iCH, parenchymal haematoma and SAH with intervention.	At 90days, the rates of death(18.4%vs 15.5%) and symptomatic ICH(1.9% vs 1.9%) were similar between groups.
NNT	7.4	3.2	4	4	6.5

NNT in context

- RCTs: relatively large treatment effect
- Compares favourably with:
  - Other stroke therapies
  - Established coronary interventions



Further Options for Acute Stroke Management

- Increase the time window for treatment
- Better Patient Selection for acute treatment
- Neuroprotection
- Better Systems of Care
- Acute treatment of TIA/Minor Stroke

A New DAWN

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Thrombectomy 6 to 24 Hours after Stroke with a Mismatch between Deficit and Infarct

R.G. Nogueira, A.P. Jadhav, D.C. Haussen, A. Bonafe, R.F. Budzik, P. Bhuva, D.R. Yavagal, M. Ribo, C. Cognard, R.A. Hanel, C.A. Sila, A.E. Hassan, M. Millan, E.I. Levy, P. Mitchell, M. Chen, J.D. English, Q.A. Shah, F.L. Silver, V.M. Pereira, B.P. Mehta, B.W. Baxter, M.G. Abraham, P. Cardona, E. Veznedaroglu, F.R. Hellinger, L. Feng, J.F. Kirmani, D.K. Lopes, B.T. Jankowitz, M.R. Frankel, V. Costalat, N.A. Vora, A.J. Yoo, A.M. Malik, A.J. Furlan, M. Rubiera, A. Aghaebrahim, J.-M. Olivot, W.G. Tekle, R. Shields, T. Graves, R.J. Lewis, W.S. Smith, D.S. Liebeskind, J.L. Saver, and T.G. Jovin, for the DAWN Trial Investigators*

ABSTRACT

BACKGROUND

The effect of endovascular thrombectomy that is performed more than 6 hours after the onset of ischemic stroke is uncertain. Patients with a clinical deficit that is disproportionately severe relative to the infarct volume may benefit from late thrombectomy.

METHODS

We enrolled patients with occlusion of the intracranial internal carotid artery or proximal middle cerebral artery who had last been known to be well 6 to 24 hours earlier and who had a mismatch between the severity of the clinical deficit and the infarct volume, with mismatch criteria defined according to age (<80 years or ≥80 years). Patients were randomly assigned to thrombectomy plus standard care (the thrombectomy group) or to standard care alone (the control group). The coprimary end points were the mean score for disability on the utility-weighted modified Rankin scale (which ranges from 0 [death] to 10 [no symptoms or disability]) and the rate of functional independence (a score of 0, 1, or 2 on the modified Rankin scale, which ranges from 0 to 6, with higher scores indicating more severe disability) at 90 days.

RESULTS

A total of 206 patients were enrolled; 107 were assigned to the thrombectomy group and 99 to the control group. At 31 months, enrollment in the trial was stopped because of the results of a prespecified interim analysis. The mean score on the utility-weighted modified Rankin scale at 90 days was 5.5 in the thrombectomy group as compared with 3.4 in the control group (adjusted difference [Bayesian analysis], 2.0 points; 95% credible interval, 1.1 to 3.0; posterior probability of superiority, >0.999), and the rate of functional independence at 90 days was 49% in the thrombectomy group as compared with 13% in the control group (adjusted difference, 33 percentage points; 95% credible interval, 24 to 44; posterior probability of superiority, >0.999). The rate of symptomatic intracranial hemorrhage did not differ significantly between the two groups (6% in the thrombectomy group and 3% in the control group, P=0.50), nor did 90-day mortality (19% and 18%, respectively; P=1.00).

CONCLUSIONS

Among patients with acute stroke who had last been known to be well 6 to 24 hours earlier and who had a mismatch between clinical deficit and infarct, outcomes for disability at 90 days were better with thrombectomy plus standard care than with standard care alone. (Funded by Stryker Neurovascular; DAWN ClinicalTrials.gov number, NCT02142283.)

- mRS at 90 days was 5.5 in the thrombectomy group compared with 3.4 in the control group
- Rate of functional independence at 90days was 49% in the thrombectomy group compared with 13% in the control group
- Rate of SICH and mortality did not differ between both groups

thebmj

BMJ 2017;357:j1861 doi: 10.1136/bmj.j1861 (Published 2017 April 13)

NEWS

NHS thrombectomy plan needs more doctors, say stroke experts

Anne Gulland

London

Stroke experts have warned that not enough doctors are trained to carry out mechanical thrombectomy, after NHS England announced that the procedure will be performed on all patients who have had acute ischaemic stroke.

NHS England said that the procedure, which involves removing a blood clot from the brain using a stent, would be introduced in 24 specialist neuroscience centres throughout the country from this year, eventually benefiting around 8000 patients a year.

The Royal College of Physicians first recommended mechanical thrombectomy for patients with acute ischaemic stroke in guidelines last year.[1] A systematic review and meta-analysis in *The BMJ* found that the procedure, if performed within six to eight hours of a stroke occurring, produced functional benefits with no detrimental effects, when compared with medical care alone.[2]

Martin James, associate director of the Royal College of Physicians' stroke programme, said that the plan to commission the procedure was "very welcome indeed" but added, "There remain substantial challenges to its implementation—not least the relatively few doctors trained to perform the procedure, fewer than 100 in the whole UK.

"What we urgently need now is for NHS England to take the lead and invest in the additional capacity of doctors and centres [illegible] estimated 8000 [people] to receive this treatment in coming years."

Nicola Strickland, president of the Royal College of Radiologists, described the procedure as an "amazing, disability sparing treatment" but said that NHS England had not indicated how its plans would be achieved.

She said, "Interventional neuroradiologists are the doctors who perform this intricate and lifesaving procedure. We are already facing a severe shortage of radiologists across the board in this country . . . We need the necessary investment in our workforce to make sure as many patients as possible can benefit from it."

Juliet Bouverie, chief executive of the Stroke Association, described thrombectomy as a "game changer" but added, "Its delivery across England will need significant changes to NHS stroke services, as well as an increase in the number of trained professionals who can carry out the procedure so that as many people as possible can benefit from this powerful new treatment."

Simon Stevens, chief executive of NHS England, said, "This major national upgrade to stroke services puts the NHS at the leading edge of stroke care internationally. It's another practical example of the NHS quietly expanding innovative modern care that will really benefit patients, but which tends to be invisible in the public debate about the NHS."

EDITORIAL

Mechanical thrombectomy services: can the UK meet the challenge?

Andrew Clifton

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Accepted 21 May 2017

In this issue, Werring *et al*[1] have set out the evidence, patient selection and technique of one of the most effective new treatments in stroke medicine, with a 'number needed to treat' of fewer than three for improved functional outcome. The UK's National Institute for Health and Care Excellence (NICE) (February 2016)[2] and the Royal College of Physicians of London (October 2016)[3] have each issued guidelines on its uptake, but these are purely advisory. In April 2017, National Health Service (NHS) England announced that it will commission mechanical thrombectomy. This is likely to be one of the biggest funding commitments that NHS England specialised commissioning has ever made: over £100 million per year when fully implemented, but balanced by massive life-changing patient benefit. NHS England is now working to assess each of England's 24 neuroscience centres to establish the degree of readiness to provide this service.

The challenge will be to deliver the service to our patients safely and effectively. It will be a very major undertaking to provide the additional doctors, nurses, radiographers and other staff to be able neuroscience centres will be the only sites performing these procedures, and whether neurointerventionalists will be supported in some centres by general interventional radiologists, cardiology colleagues or even interventional stroke physicians and neurologists who have undergone appropriate training. The other option would be for some geographical areas to have regional thrombectomy centres staffed by trained non-neurointerventionalists. These logistics are currently being considered.

As Werring *et al* discuss, there are two ways to deliver thrombectomy: either 'drip and ship', or 'mothership' direct transfer to specialist centre. Both may be appropriate, depending on the geographical spread of the local population. However 'drip and ship' has its own challenges: the patient needs a RED category response for transfer from the triaging interventional centre/hyperacute stroke unit to the thrombectomy centre, and this will need to be commissioned. The other major challenge is the investment in training and resources to deliver the immediate imaging in district general hospitals triaging for 'drip and ship'. Currently, there are too few radiogra-

NHS England

Clinical Commissioning Policy Proposition: Mechanical thrombectomy for acute ischaemic stroke


DROM CHA EITHAR
DROMAHAIR
SLIGEACH
12 SLIGO
DRUMKEERAN
BAILE AN TOCHAIR
BALLINTOGHER 3
SLIGEACH
SLIGO 12


51 KILLIMER CAR FERRY
GREGANS
CASTLE HOTEL
RUSHEEN LODGE
B & B
TEA & GARDEN ROOMS
NEWTOWN CASTLE & TRAIL


Oileán Baoi
DURSEY ISLAND
Bealach Bheara
THE BEARA WAY
Mosco
km
MOSCOW 3310
Bealach Bheara
THE BEARA WAY

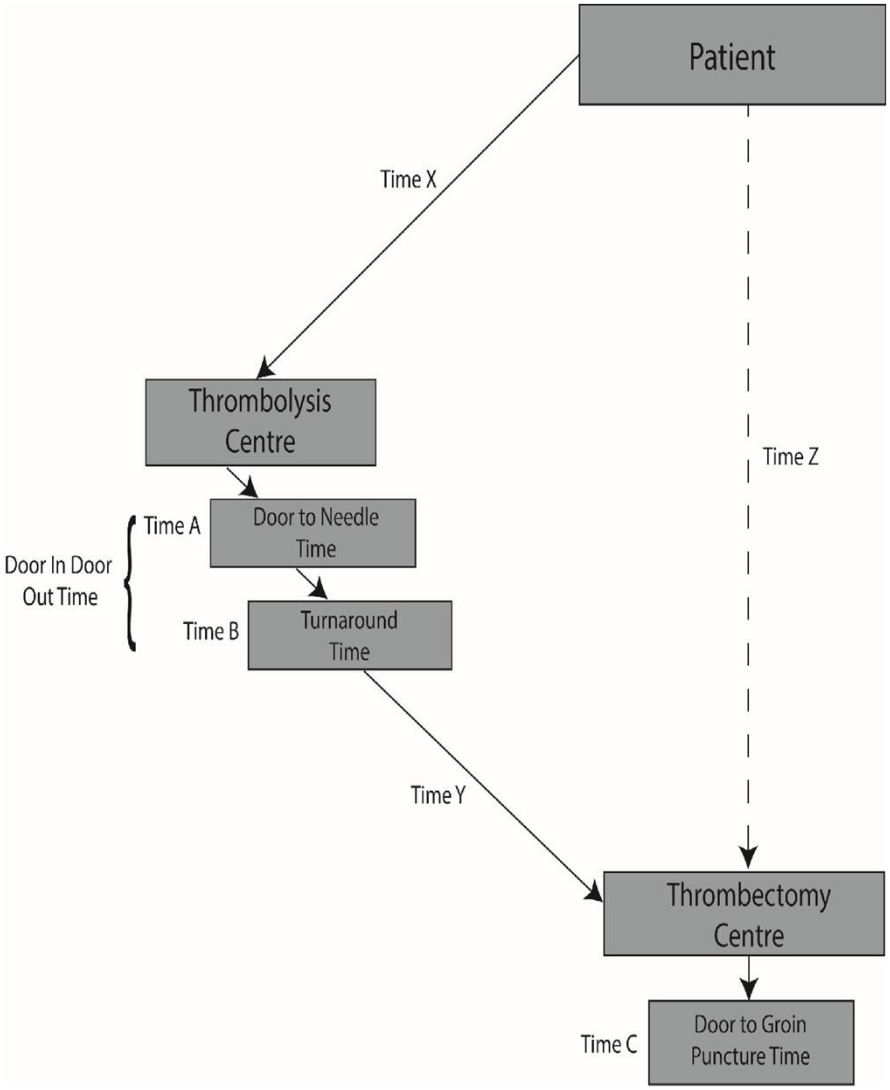
‘Mothership’ vs ‘Drip and Ship’

VS

Drip ‘N Ship Versus Direct to Thrombectomy Centre Conditional Probability Modelling In Ireland

Jessalyn K. Holodinsky, MSc, Alka B. Patel, MGIS PhD, John Thornton, MB FFR RCSI, Noreen Kamal, PhD, Lauren R. Jewett, BSc, Peter J. Kelly, MD MS, Sean Murphy, MD, Ronan Collins, MD, Thomas Walsh, MB BCh, Simon Cronin, MB PhD, Sarah Power, MB PhD, Paul Brennan MRCPI FRCR FFRRCSI MSc, Alan O’Hare MB BCh BAO. MRCPI, MSc, FFRI(RCSI), Dominick J H McCabe PhD, FRCPI, Barry Moynihan, MD, Seamus Looby, MRCPI FFR RCSI, Gerald Wyse, MB BCh BAO MRCPI FRR RCSI, Joan McCormack, RGN MSc, Paul Marsden, BSc, Joseph Harbison, MD, Michael D. Hill, MD MSc, David Williams, MB PhD

Background



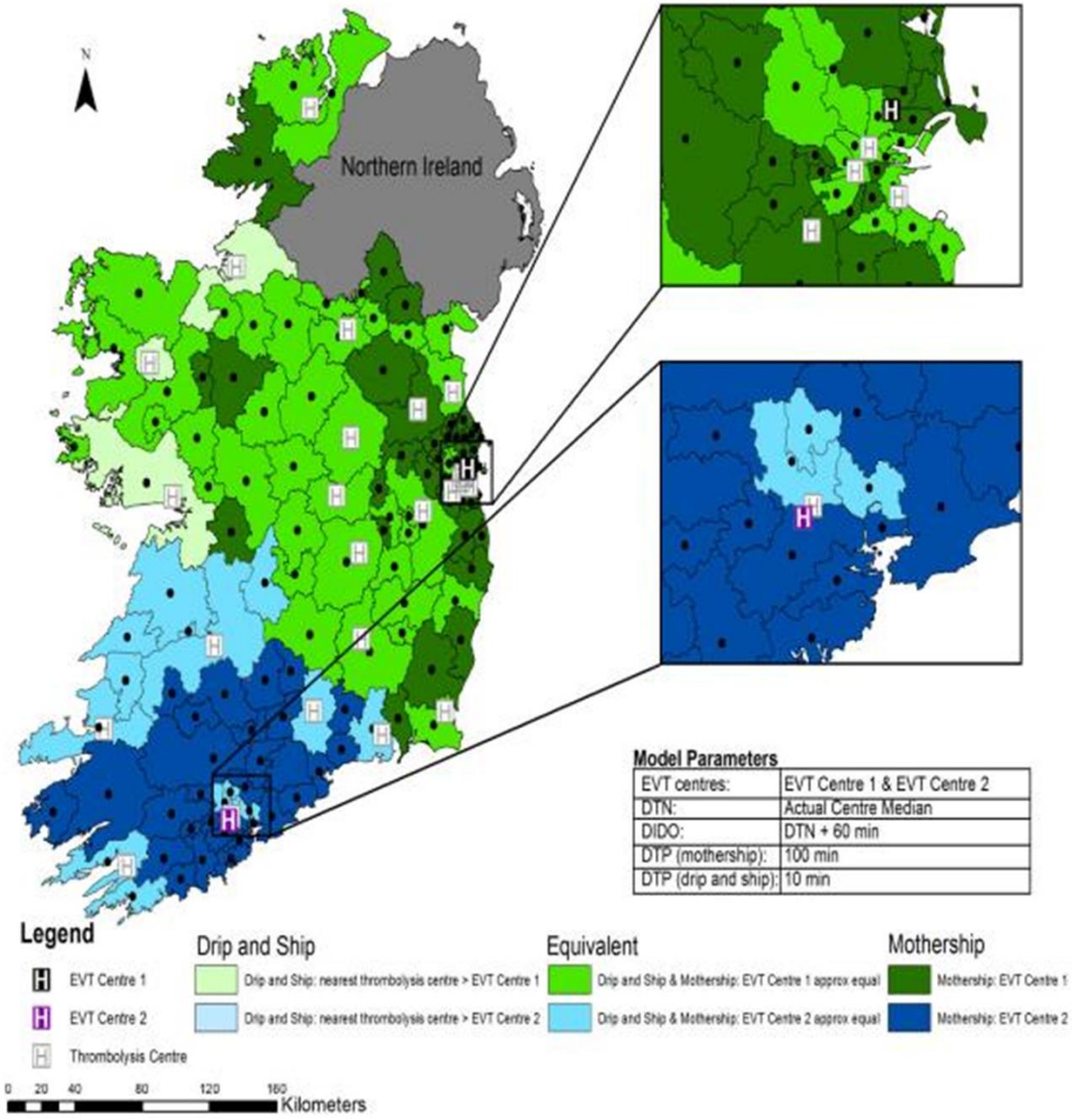
- Endovascular therapy has revolutionized ischemic stroke care
- EVT centers tend to be located in urban areas so quick access isn't available for all patients
- For patients outside EVT centre catchment areas there are two transport options
  - Drip 'n ship (solid line)
  - Mothership (dashed line)

Holodinsky et al. Drip and Ship Versus Direct to Comprehensive Stroke Center: Conditional Probability Modeling. *Stroke*. 2017;48(1):233-238.

Objective

- To apply a previously published conditional probability modelling framework to a defined geographic area in order to predict the best transport option for patients with known large vessel occlusion

Results: Real Treatment Times

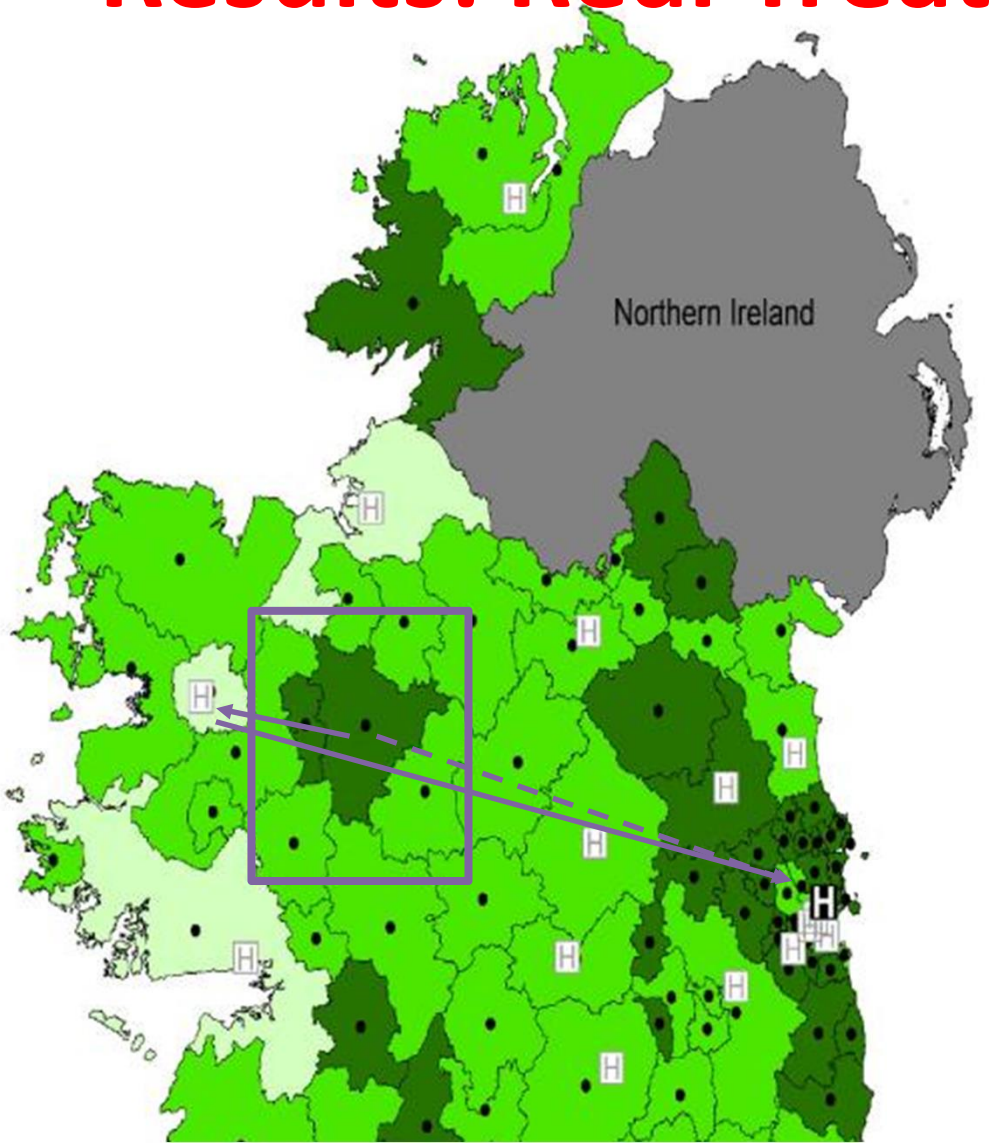


DTN: actual hospital median, ranges from 52 – 137 mins (Irish National Stroke Register)

DIDO: DTN + 60 mins
(Irish National Stroke Register and Beaumont Hospital Thrombectomy Registry)

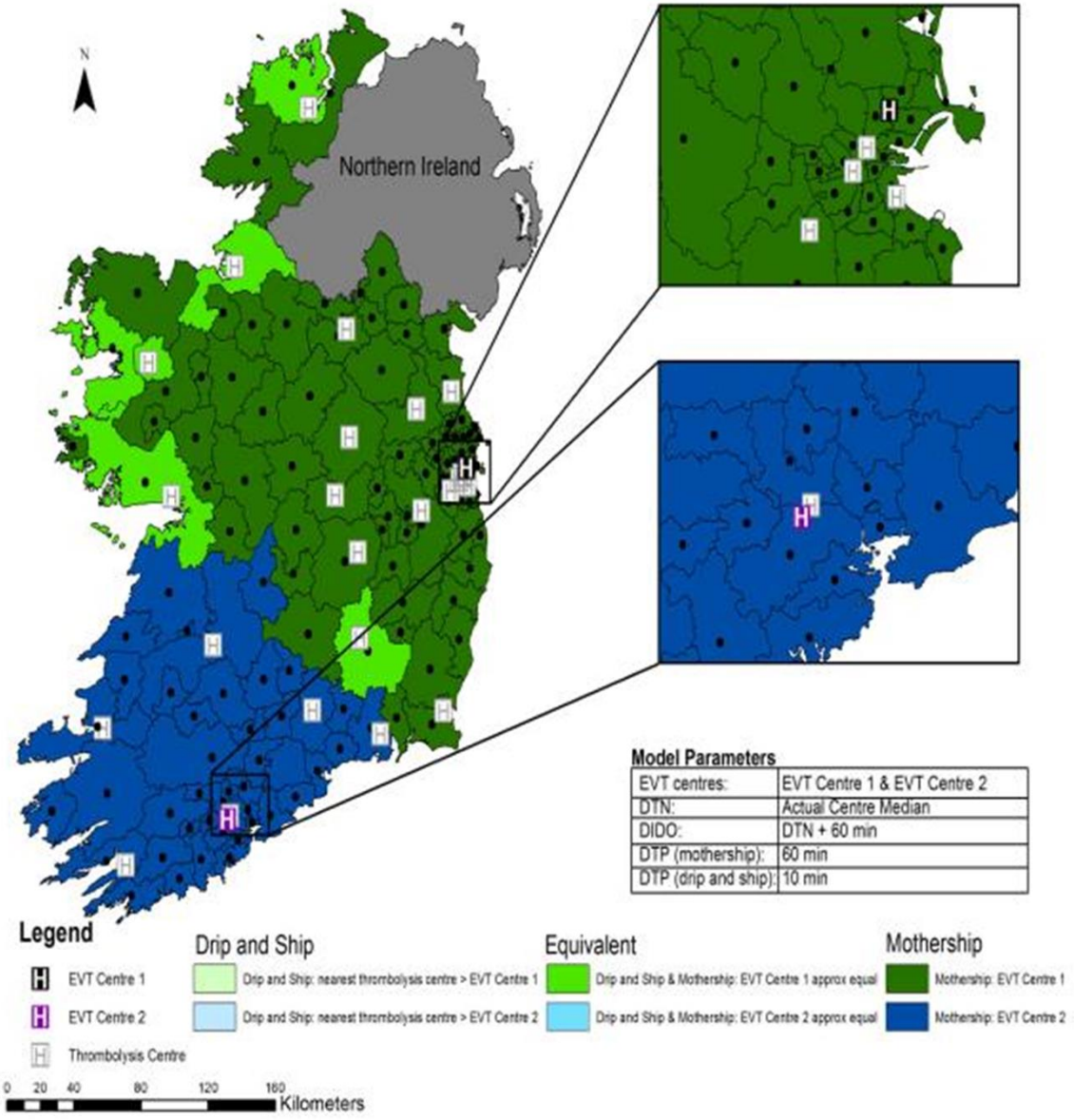
DTP mothership: 100 mins
DTP drip and ship: 10 mins
(Beaumont Hospital Thrombectomy Registry)

Results: Real Treatment Times



- Why are there isolated regions where mothership is the best option?
- In the drip and ship model patients are transported first to their *nearest* thrombolysis centre
- In some cases this involves travel in the opposite direction from the thrombectomy centre
- This “doubling back” never produces the greatest probability of good outcome

Results: What if the Thrombectomy Centre was faster?

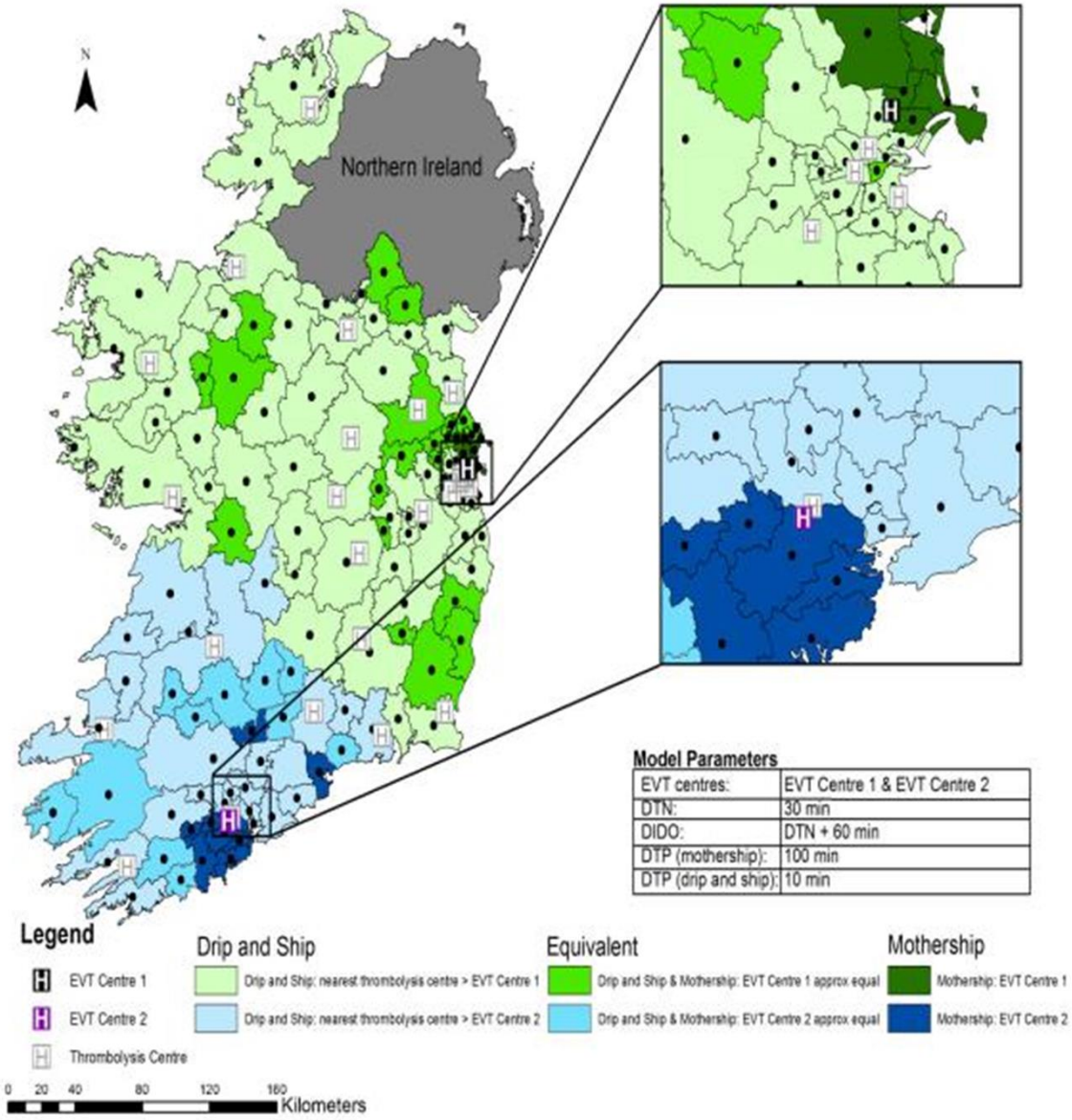


DTN: actual hospital median (ranges from 52 – 137 mins)

DIDO: DTN + 60 mins

DTP mothership: 60 mins
DTP drip and ship: 10 mins

Results: What if the Thrombolysis Centre was faster?



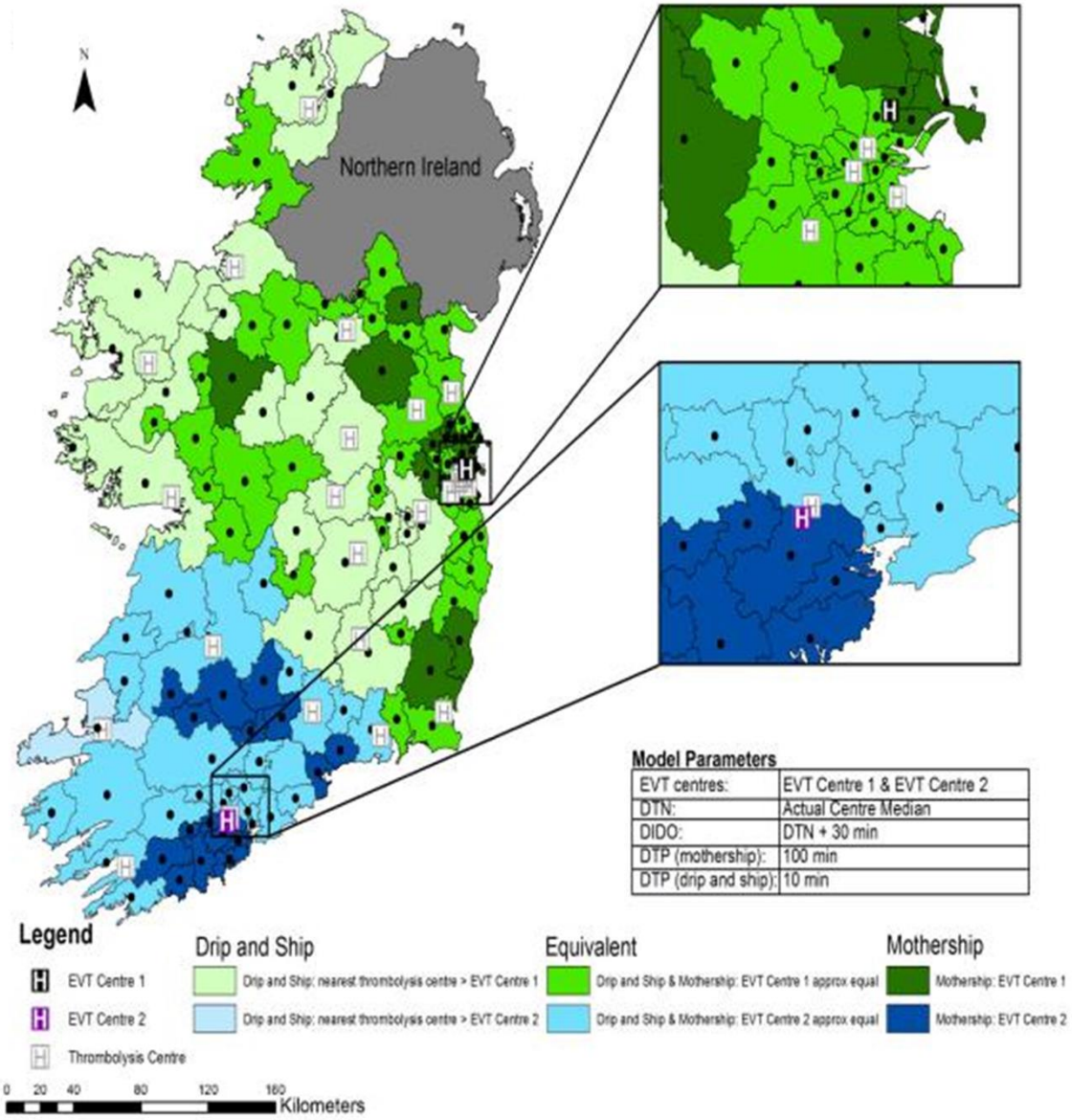
DTN: 30 mins

DIDO: DTN + 60 mins

DTP mothership: 100 mins

DTP drip and ship: 10 mins

Results: What if the Transfer System was faster?



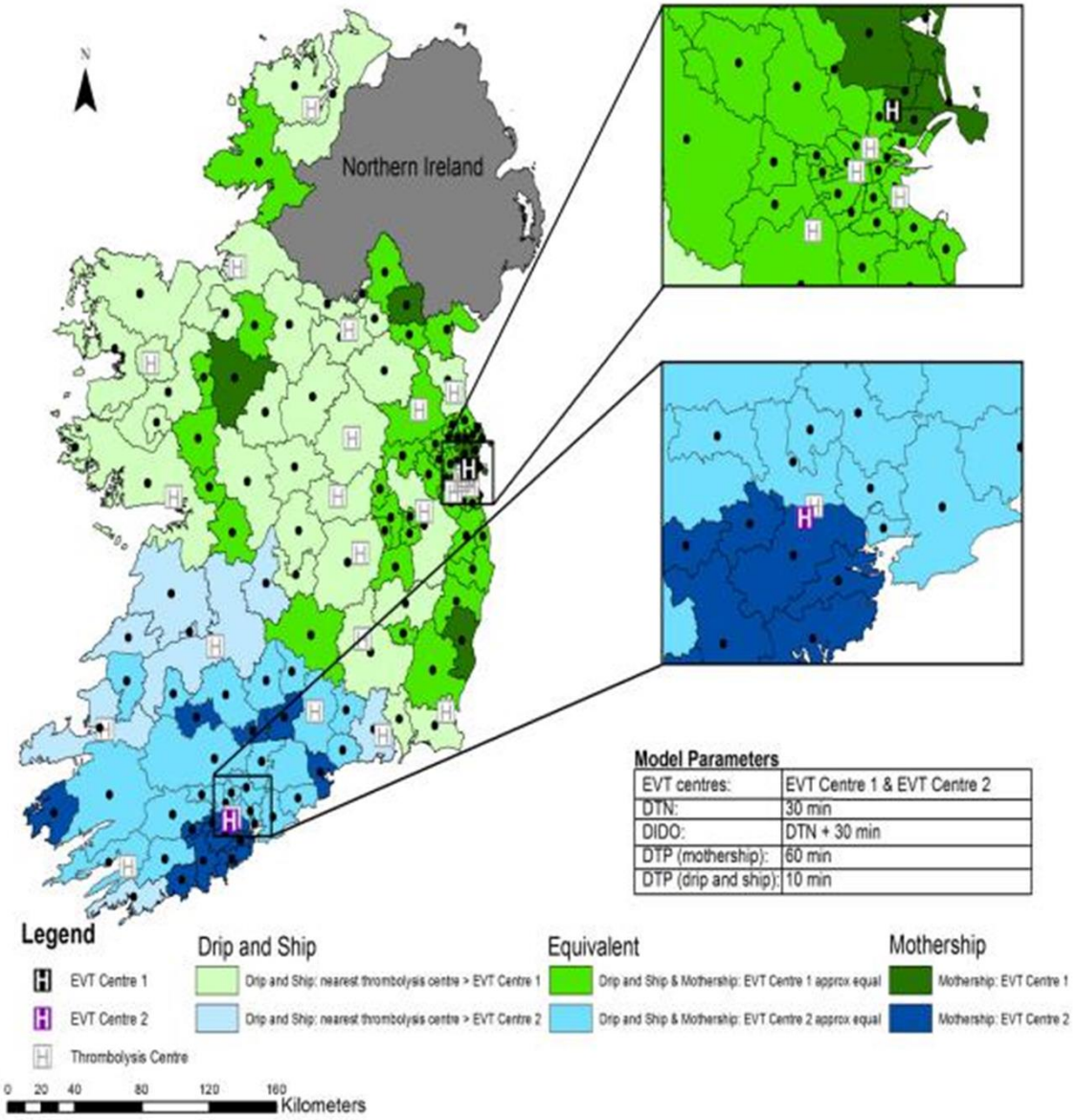
DTN: actual hospital median (ranges from 52 – 137 mins)

DIDO: DTN + 30 mins

DTP mothership: 100 mins

DTP drip and ship: 10 mins

Results: What if all systems were faster?

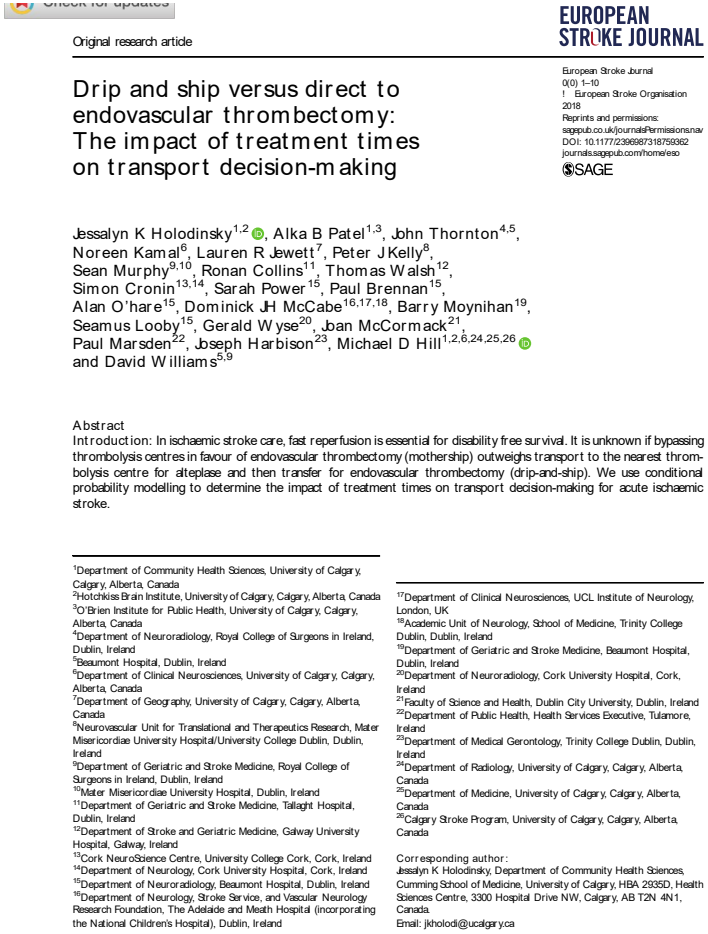


DTN: 30 mins

DIDO: DTN + 30 mins

DTP mothership: 60 mins
DTP drip and ship: 10 mins

Conclusions



Original research article

EUROPEAN STROKE JOURNAL

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Drip and ship versus direct to endovascular thrombectomy: The impact of treatment times on transport decision-making

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Abstract
Introduction: In ischaemic stroke care, fast reperfusion is essential for disability free survival. It is unknown if bypassing thrombolysis centres in favour of endovascular thrombectomy (mothership) outweighs transport to the nearest thrombolysis centre for alteplase and then transfer for endovascular thrombectomy (drip-and-ship). We use conditional probability modelling to determine the impact of treatment times on transport decision-making for acute ischaemic stroke.

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- Conditional probability modelling can be used in a defined geographic area to predict the best transport decisions for patients
- Modelling transport is sensitive to treatment times both at the thrombolysis centre and the thrombectomy centre
- However, other factors such as economics, staffing, and other resources need to be considered as well

‘Drip and Drive’

ORIGINAL RESEARCH

‘Drip-and-drive’: shipping the neurointerventionalist to provide mechanical thrombectomy in primary stroke centers

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ABSTRACT

Background To satisfy the increasing demand of mechanical thrombectomy (MT) for acute ischemic stroke treatment, new organizational concepts for patient care are required. This study evaluates time intervals of acute stroke management in two stroke care models, including one based on transportation of the interventionalist from a comprehensive stroke center (CSC) to treat patients in two primary stroke centers (PSC). We hypothesized that time intervals were not inferior for the ‘drip-and-drive’ concept compared with the traditional ‘drip-and-ship’ concept.

Methods Patients treated with MT at the PSC (‘drip-and-drive’, ‘D+D group’) were compared with patients transferred from PSC to CSC for MT (‘drip-and-ship’, ‘D+S group’) with regard to time delays. Time intervals assessed were: symptom onset to initial CT, to angiography, and to recanalization; time from initial CT to telephone call activation, to arrival, and to angiography; and time from telephone call activation to arrival and from arrival to angiography.

Results 42 patients were treated at the PSC after transfer of the interventionalist, and 32 patients were transferred to the CSC for MT. The groups did not differ with regard to median Onset–CT and CT–Phone times. Significant differences between the groups were found for the primary outcome measure CT–Arrival time (‘D+D group’: median 121 (IQR 108–134) min vs 181 (157–219) min for the ‘D+S group’; P<0.001). Time difference between the groups increased to more than 2 hours for median CT–Angio times (median 123 (IQR 93–147) min vs 252 (228–275) min; P<0.001).

Conclusion Time intervals for the ‘D+D group’ were not inferior to those of the ‘D+S group’. Moreover, under certain conditions, the ‘drip-and-drive’ concept might even be superior.

INTRODUCTION

The publication of major positive randomized trials revealing a significant treatment effect of endovascular recanalization on patient outcome in acute ischemic stroke due to large vessel occlusion[1–5] had a strong impact on stroke management and immediately resulted in new recommendations for acute stroke treatment.[6 7] In Germany, as in many other countries, nationwide stroke units are established even in small and regional hospitals capable of performing acute cranial CT (CCT) and of starting intravenous tissue plasminogen activator immediately, whereas mechanical thrombectomy (MT) is mainly performed at centers with interventional neuroradiologists (INRs), ideally providing 24/7 coverage. Such service requires a certain annual caseload in MT and other intracranial procedures for maintaining skills levels and for justifying the resources, including on-call-services. Accordingly, centralization of stroke care towards comprehensive stroke centers (CSC) has been suggested. However, such re-structuring faces considerable practical, political, budgetary, and psychological challenges, in particular in federal countries such as Germany.

To ensure MT for patients in stroke centers without an INR service, the patient might be transferred to a CSC (‘drip-and-ship’) or the INR might be transferred to the patient at the primary stroke center (PSC). Whereas ‘drip-and-ship’ is already practiced by existing co-operations, such as neurovascular networks,[8] no experience with the relatively new ‘drip-and-drive’ concept has been reported to date.

We present our first year experience with the latter concept. We used time intervals as practical and sensitive performance indicators, and hypothesized that the time intervals may not be significantly inferior for the ‘drip-and-drive’ concept compared with the ‘drip-and-ship’ concept.

METHODS

To provide acute endovascular stroke treatment to the population of two PSCs (hospital A and B) with catchment areas of 180 000 and 200 000 citizens (treating 850–1130 acute ischemic stroke patients each per year), a formal collaboration with our university hospital based CSC was established, including joint processes and matched interventional equipment. As a precondition, technicians and radiologists of the PSCs were introduced to MT procedures and the material used at the CSC, including hands-on courses. INRs from the CSC visited the PSCs to become familiar with the local teams of neurology, radiology, and anesthesiology, as well as with the location and functioning of angiography suites and stroke units. Driving distance between the CSC and the two PSCs is 53 km (hospital A) and 63 km (hospital B). At least seven INRs work at the CSC of whom at least four provide the on-call service at the CSC and a further three INRs cover the on-call service for MT performed at the PSCs.

To cite: Brekenfeld C, Goebell E, Schmidt H, *et al*. *J NeuroIntervent Surg* 2018;**10**:932–936.

- No Difference in median onset-CT and CT-Phone times
- CT-arrival time (121(IQR 108-134)min for ‘D+D’ vs 181(157-219)min for ‘D+S’; P<0.001))
- Time difference between the groups increased to more than 2hrs for median CT-Angio times (median 123(IQR 93-147)min vs 252 (228-275)min;P<0.001)

Conclusions

- Time intervals for the ’D+D group’ were not inferior to those of the ’D+S group’.

- Moreover, under certain conditions, the ’drip-and-drive’ concept might even be superior.

‘Mothership’ vs ‘Drip and Ship’

VS

‘Drip and Drive’

National Thrombectomy Service

- 2018
  - Beaumont Hospital Dublin(331)

    263 Thrombectomies

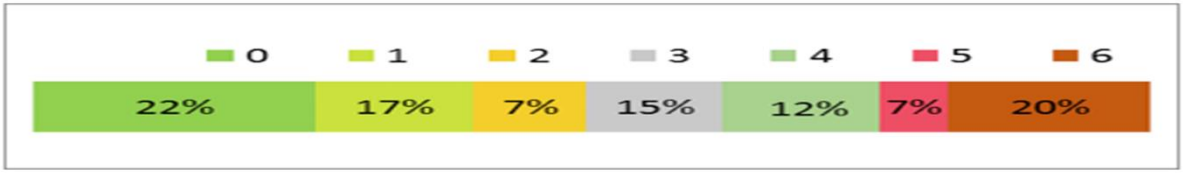
    68 referred but not treated
  - Cork University Hospital (69)

    54 Thrombectomies

    15 referred but not treated

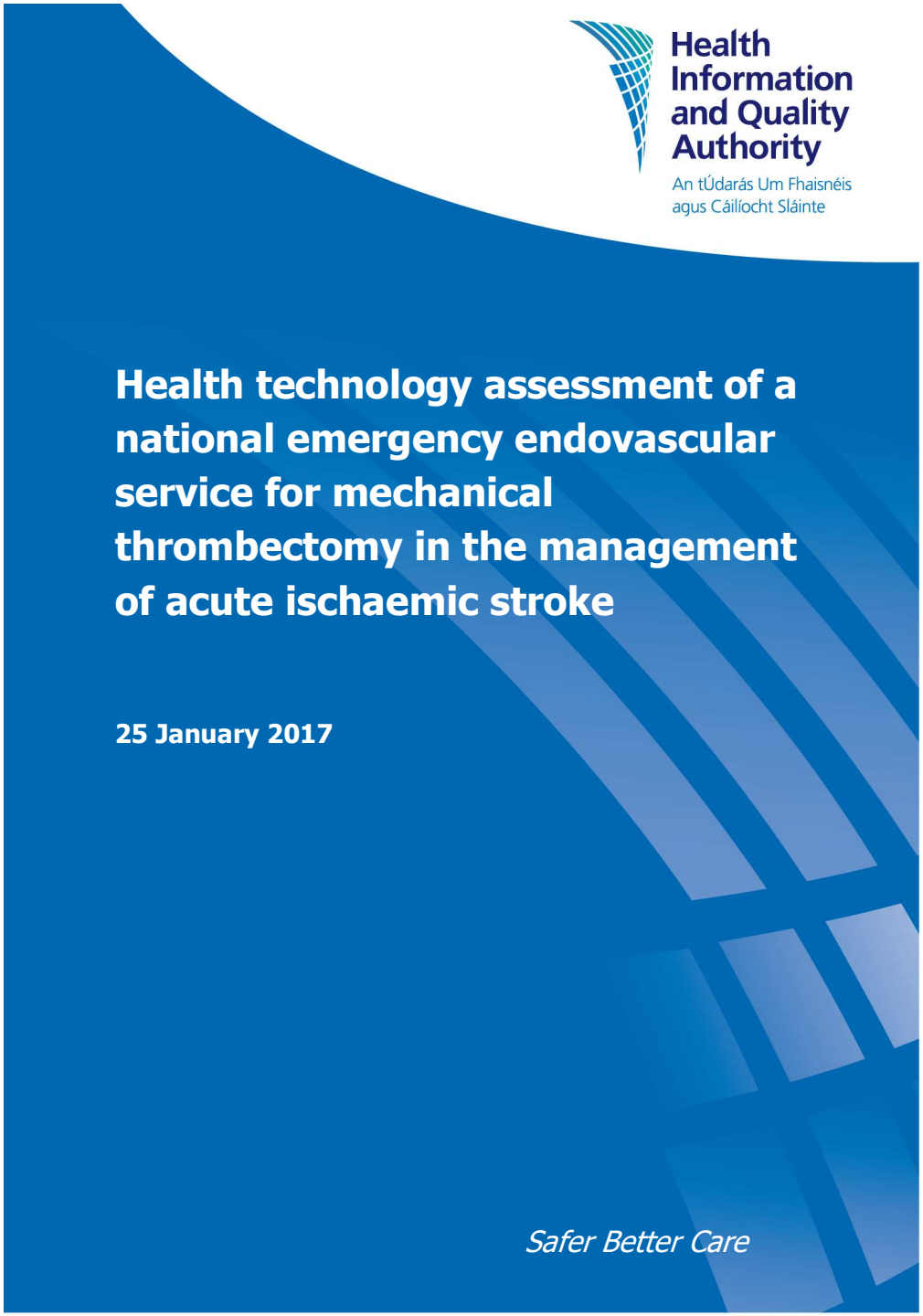
2018 Patient Outcomes

90-Day mRS



Increasing Referral Rate

	2017	2018
Procedures		
Beaumont Hospital	247	263
Cork University Hospital	31	54
Transferred but unsuitable		
Beaumont Hospital	34	68
Cork University Hospital	2	15


Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte
Health technology assessment of a national emergency endovascular service for mechanical thrombectomy in the management of acute ischaemic stroke
25 January 2017
Safer Better Care

Health Information and Quality Authority

An tÚdarás um Fhaisnéis agus Cáilíocht Sláinte

HTA 2017

mechanical thrombectomy

A health technology assessment (HTA) by HIQA recommends a national emergency service providing next generation stroke therapy be established in two hospital sites in Ireland

Burden of ischaemic stroke

4,300

Approximately 4,300 people are admitted to hospital following an acute ischaemic stroke each year.

12.3%

On average, 12.3% of patients hospitalised with acute ischaemic stroke receive clot-busting therapy (thrombolysis).

4% - 5% increase

The total number of stroke cases has been predicted to increase by between 4% - 5% each year from 2015 to 2020.

55% - 57%

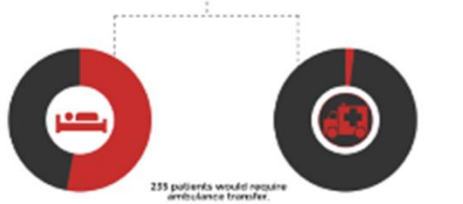
Just over half of strokes occur in men, with just under 30% strokes in men occurring in those under the age of 65.

If introduced

Each year an estimated

268 thrombectomy procedures

in Ireland



57

more patients would regain functional independence after 90 days.

982

ambulance hours transferring patients

Five-year budget impact of a national service is estimated at:

€7.2 million

€3.3 million

Estimated €3.3 million in the first year

€1.0 million

Annual running costs afterwards estimated at €0.8 to €1.2 million

268 patients

based on treating 268 patients each year.


4
Quality Improvement Programme
Save The Brain Campaign
Beaumont Hospital, Dublin

International Recommendations

- Traditionally
  - Door to CT ASAP and within 25 minutes
  - Door to needle ASAP and within 60 minutes

- AHA Door to Needle 45 minutes

- QUICR Door to Needle 30 minutes

October 2016, Beaumont Hospital = 120 minutes

Project Background

Aim

Reduce the door to CT times for possible strokes presenting within 12 hours of onset or unknown onset to **less than 25 minutes** during normal working hours

- Restructuring of the stroke department
- New stroke consultant
- New more ambitious international door to TPA targets
- Door to CT and door to needle times a high priority for department

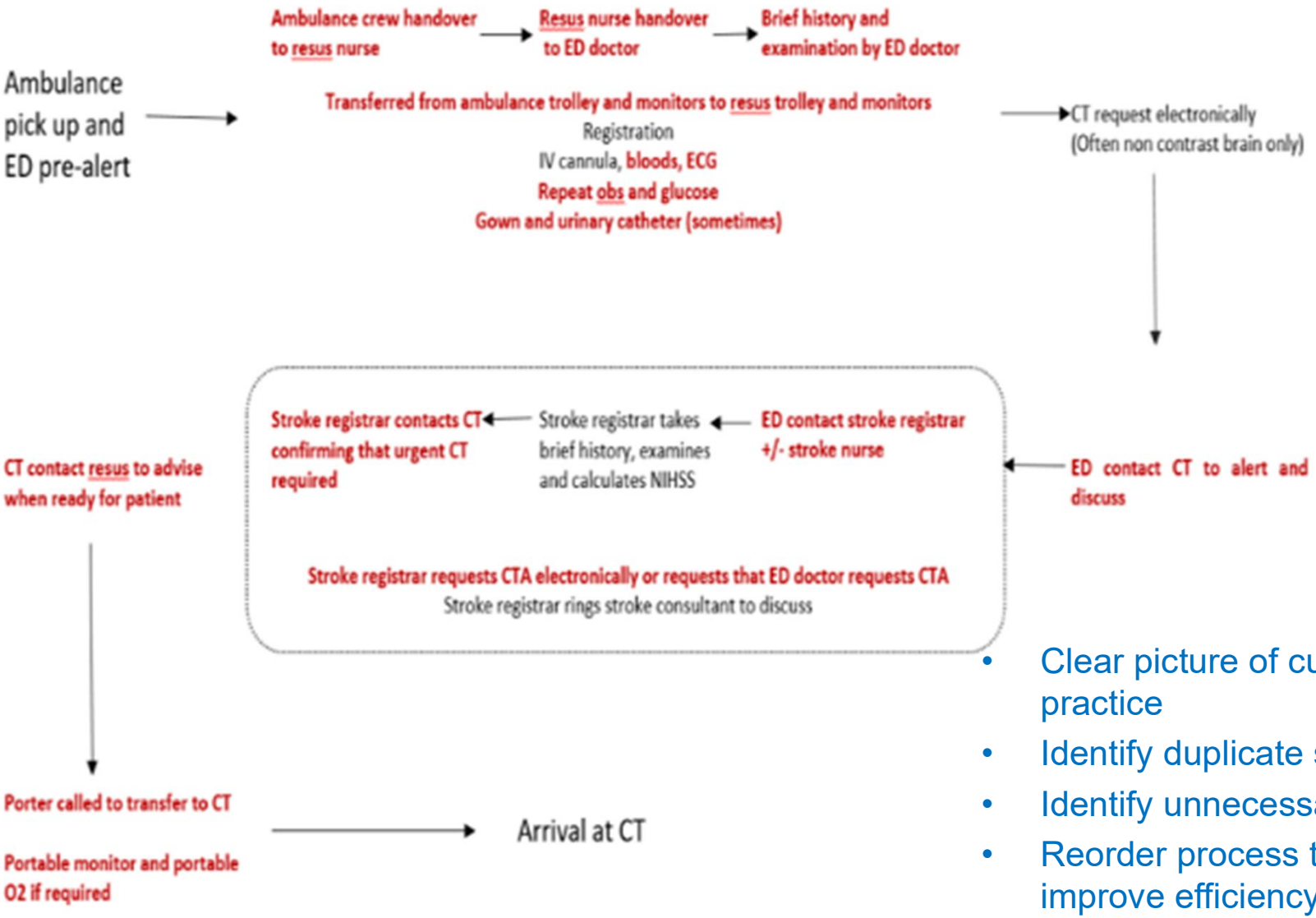
Method:

1. 360 degree process mapping

2. Issues log

3. Benchmarking

360 Degree Process Mapping



- Clear picture of current practice
- Identify duplicate steps
- Identify unnecessary steps
- Reorder process to improve efficiency

Issue Log

1. Stroke team not aware of stroke until after ED assessment
2. Duplicate handovers and assessments
3. Difficulty with communication between Resus and CT
4. Multiple phone calls required to assemble full team
5. Complex CT request process
    a) Full history and NIHSS usually required prior to request
    b) Multiple contacts required to transfer to CT
6. Team approach needed refinement

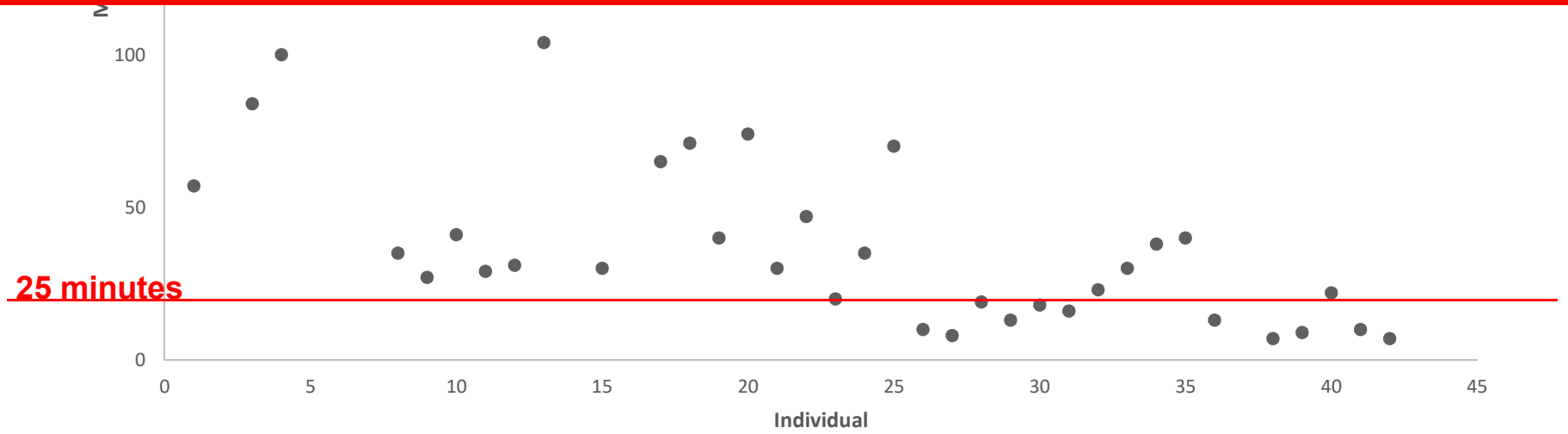
Benchmarking

- Target: Stroke ^{SM} campaign
- QuICR campaign Ontario
- Mater Hospital

Action Taken

Change	Result
Early stroke team involvement - Patient en-route = pre alert - Front door assessment	Multiple handovers eradicated Duplicate assessments eradicated
Communication - Direct phone line CT and Stroke	No delay in contact
Single alert nurse - One alert to Stroke Reg, Nurse, Porter and CT	4 less calls made per patient CT on alert and ready for patient
CT request process - Streamline & simplify	5 steps reduced to 2
Improve teamwork - One morning briefing together - Assignment of roles	Teams working in parallel rather than in series
Awareness & education - Pathway posters - Display of charts to track progress	Improved awareness by all teams

RECORD TIME = 6 MINUTES!



October 6	November 6	December 7	January 16	February 5
120 minutes	35 minutes	71 minutes	21.5 minutes	11 minutes

DOOR TO DECISION IN UNDER 30!!

A National Quality Improvement Project for the care of Patients with
Acute Ischaemic Stroke (AIS)

Despite the fact that IV Thrombolysis and Thrombectomy are now standard of care, we have not managed to achieve optimal rates of door to needle times & door to decision times throughout Ireland.

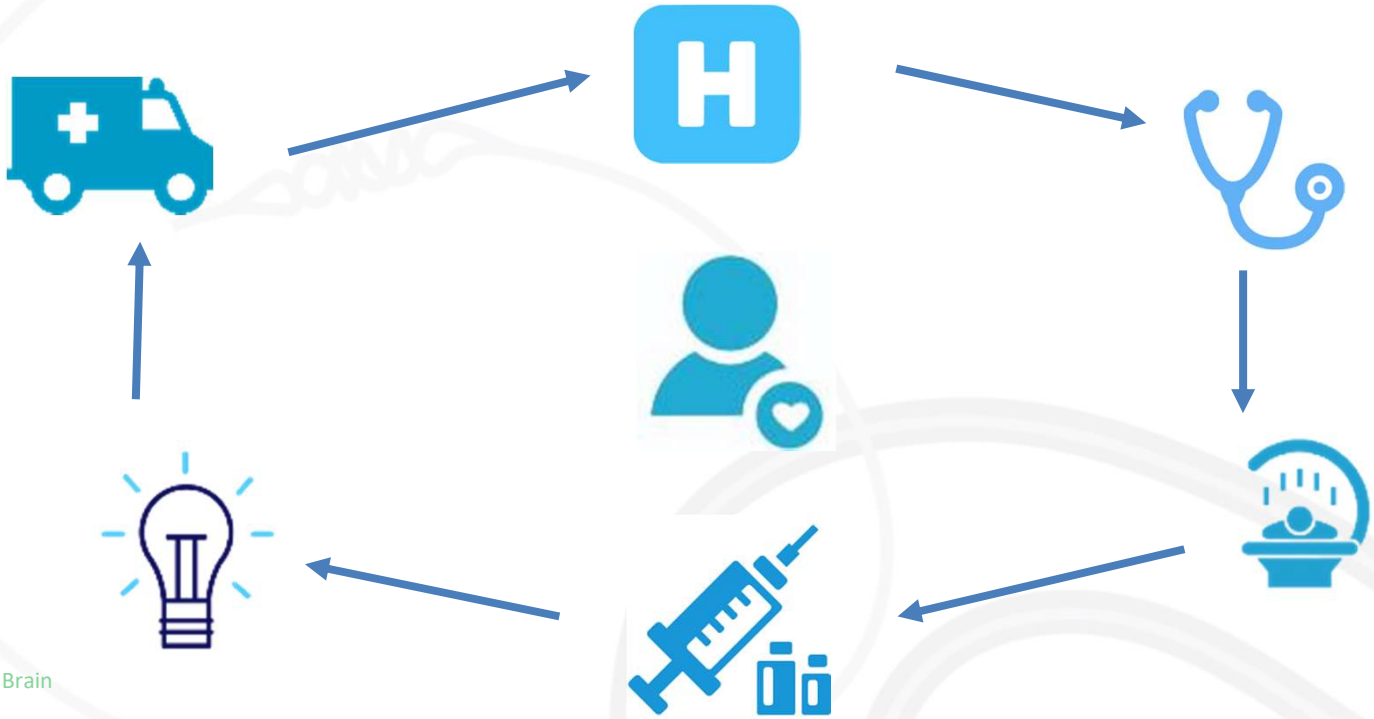
There is a gap between what we know and what we do.

Treatment within a shorter timeframe, improves patient outcomes!!

Act FAST | Time is Brain

NATIONAL THROMBECTOMY SERVICE

GOAL: To provide maximum availability and efficiency in achieving recanalization, in as rapid a timeframe as possible ,in all patients presenting with AIS throughout the country.

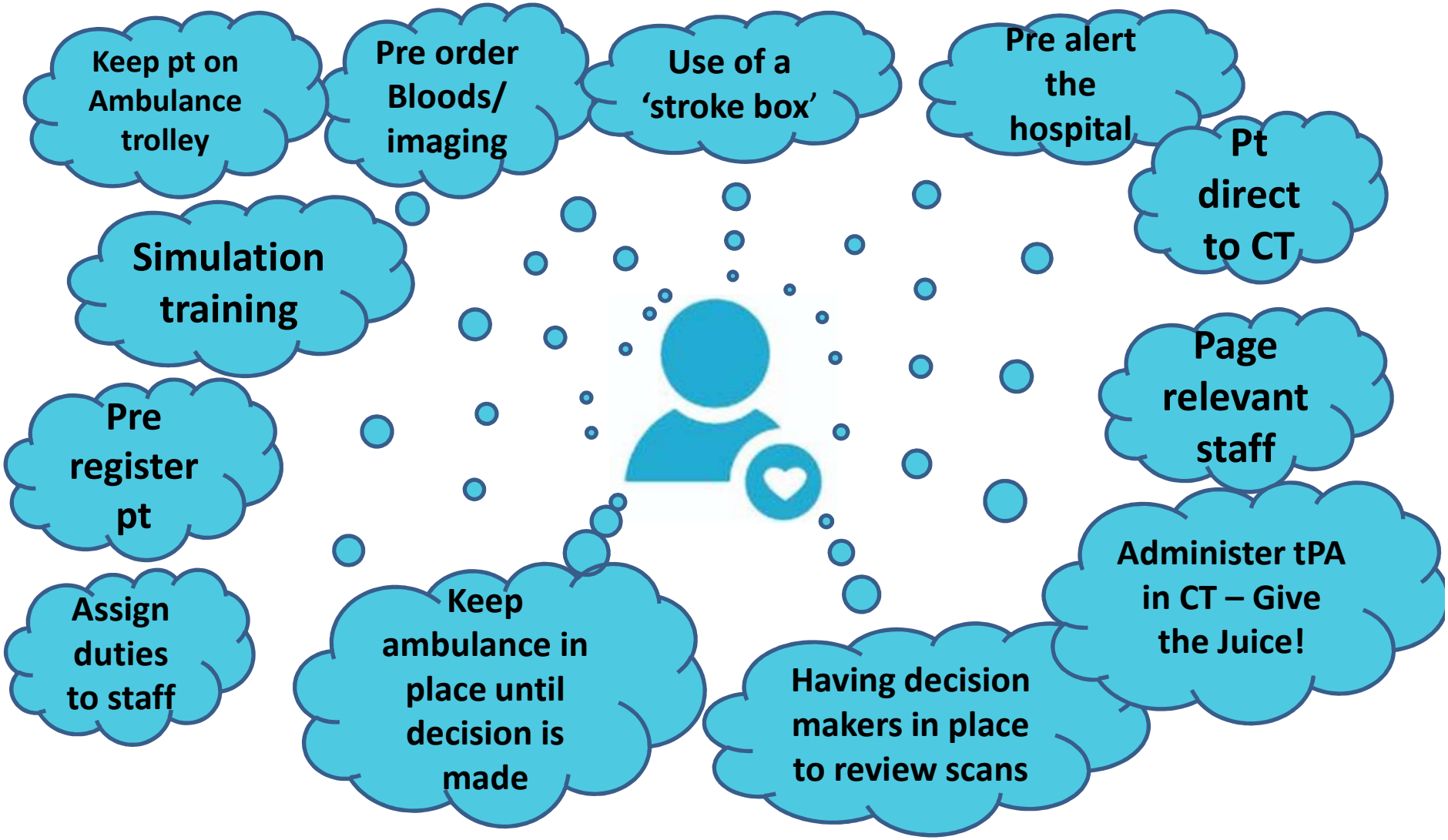


DOOR TO DECISION IN UNDER 30!

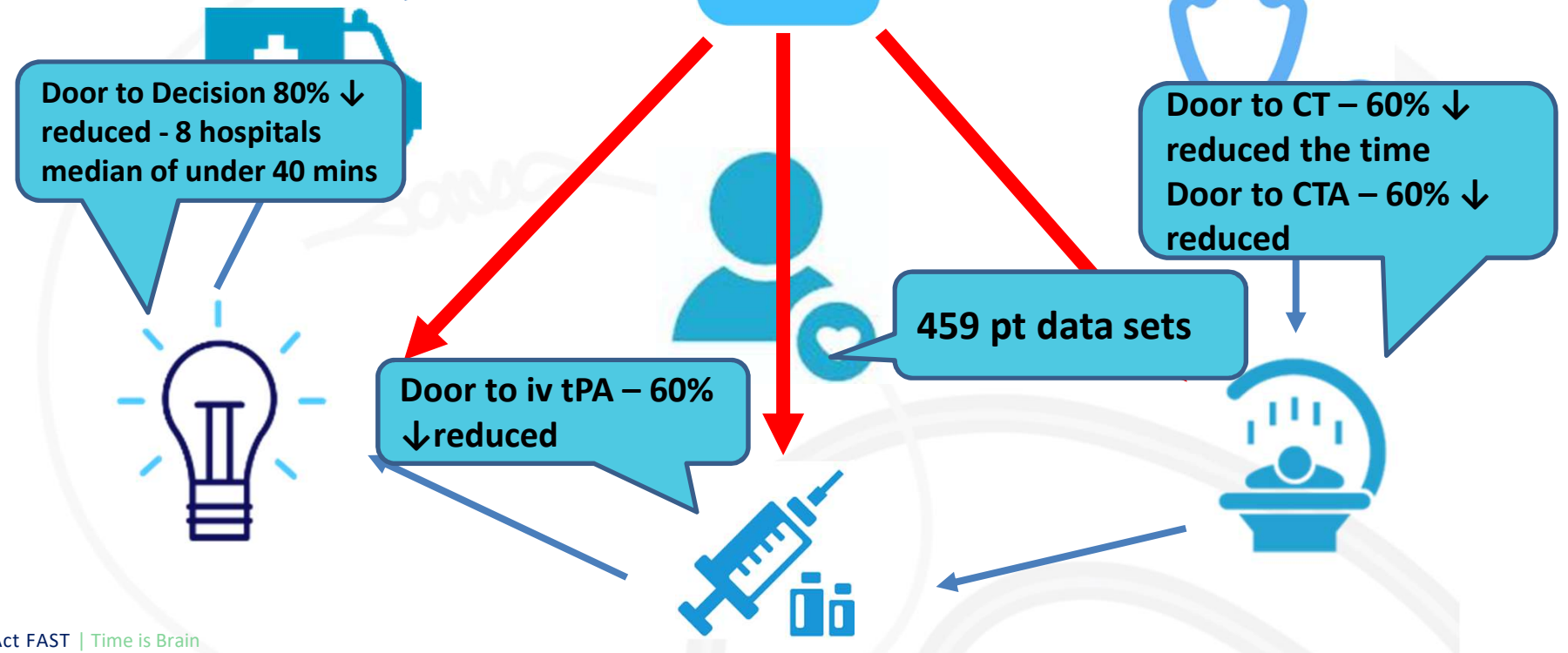
The first round of this collaborative training programme ran from Jan to Oct 2018, with 10 hospitals from across Ireland (QI1).

Round two ran from Oct – June 2019, with another 12 hospitals (QI2).

Each hospital sends a 3-4 member team ,to attend the learning sessions in Dublin, supported by a local steering group.


Keep pt on Ambulance trolley
Pre order Bloods/ imaging
Use of a 'stroke box'
Pre alert the hospital
Pt direct to CT
Simulation training
Pre register pt
Page relevant staff
Assign duties to staff
Keep ambulance in place until decision is made
Having decision makers in place to review scans
Administer tPA in CT – Give the Juice!

FAST + DATA QI2 teams…



Conclusion

- Endovascular thrombectomy is a safe, highly effective and cost-effective procedure that saves lives and dramatically reduces disability WHEN:
  - Patients are carefully selected by imaging to identify proximal occlusions, and exclude large core and exclude patients with absent collaterals
  - Treatment is extremely fast with target first slice
    - imaging → to groin puncture < 60 min and
    - imaging → to reperfusion < 90 min
  - Safe effective technology (retrievable stents) is used

N Engl J Med 2015;372:1019-1030