



STATEMENT ON INTRAVENOUS THROMBOLYSIS FOR ISCHAEMIC STROKE

1. PURPOSE

This Statement documents the views of the Australasian College for Emergency Medicine (ACEM) with respect to intravenous thrombolysis therapy for acute ischaemic stroke.

2. BACKGROUND

In recognition of conflicting evidence and controversy regarding the administration of intravenous thrombolysis as an intervention for acute ischaemic stroke [1,2], ACEM commissioned an independent systematic review of the relevant scientific literature. This review found that, on current evidence, intravenous thrombolysis as an intervention for acute stroke, administered to selected patients within three hours of symptom onset, may increase the odds of a better functional outcome, while at the same time increasing the risk of intracranial haemorrhage and conferring no mortality benefit. [3] It is noted that the review raised concerns about the quality of many of the studies.

3. SCOPE

This statement applies to all Emergency Departments (EDs) with the potential to receive patients suffering from an acute stroke.

4. ACEM POSITION

On current evidence, intravenous thrombolysis as an intervention for acute stroke, administered to selected patients within three hours of symptom onset, may increase the odds of a better functional outcome. This is despite thrombolysis in stroke increasing the risk of intracranial haemorrhage and conferring no mortality benefit. [3]

ACEM considers that discussion with patient and family/carers by the treating clinicians and informed consent is vital to any decision about use of thrombolytic therapy in stroke.

5. RECOMMENDATIONS

ACEM considers the minimum infrastructure required for stroke thrombolysis to be an appropriately skilled and adequately resourced ED in conjunction with a stroke care service as defined in Section 6.

Consent information should be structured to enable layperson understanding of the key clinical issues and risks associated with the therapy. Key issues to be discussed with patient, tailored to their clinical situation, may include:

- Thrombolysis provides no mortality benefit.
- Numbers needed to treat (NNT) to achieve functional independence, as measured by modified Rankin Scale (mRS) outcome of 0-1, is 10 (i.e. 10 patients needed treatment for one additional good functional

outcome, 95%CI 19 to 6). However, NNT to achieve functional independence, as measured by mRS outcome of 0-2, is 13 (95%CI 29 to 8).

- Treatment has a risk of causing a symptomatic intracranial haemorrhage (sICH), with numbers needed to harm (NNTH) being 42 (i.e. 42 patients needed treatment for one to experience sICH), and 122 for risk of death from sICH. It should be acknowledged that there is wide variation in the literature regarding the NNTH with the confidence intervals ranging from 119 to 13 for sICH and 830 to 30 for death.
- There is disagreement about the strength of the evidence.

ACEM notes that the independent review on stroke thrombolysis raised concerns about the quality of many of the studies, and strongly supports replication research into stroke thrombolysis; i.e. further placebo controlled clinical trials to reduce the current uncertainty.

6. CONTEXT FOR THE PROVISION OF THROMBOLYSIS

Thrombolysis should only be undertaken in a hospital stroke service setting with appropriate infrastructure, facilities and network support, and must include [4]:

- Access to a multidisciplinary acute care team with expert knowledge of stroke management who are trained in delivery and monitoring of patients receiving thrombolytic therapy;
- Pathways and protocols available to guide medical, nursing and allied health acute phase management, in particular acute blood pressure management; and
- Immediate access to imaging facilities and specialist services with specific expertise in interpreting neuroimaging.

7. REFERENCES

1. Brown MD, Burton JH, Nazarian DJ, Promes SB. Clinical Policy: Use of Intravenous Tissue Plasminogen Activator for the Management of Acute Ischemic Stroke in the Emergency Department. *Annals of Emergency Medicine*. 2015; 66, no.3: 322-333.
2. Donaldson D, Fitzgerald E, Flower O, Delaney A. Review article: Why is there still debate regarding the safety and efficacy of intravenous thrombolysis in the management of presumed acute ischaemic stroke? A systematic review and meta-analysis. *Emergency Medicine Australasia*. 2016; 28, no.5: 496-510.
3. Upton D, Upton P, Busby-Grant J, Norton M. (2016) Systematic Review of Intravenous Thrombolysis in Acute Ischemic Stroke. University of Canberra, Health Research Institute.
4. National Stroke Foundation. Clinical Guidelines for Stroke Management 2017. Melbourne, Australia.

8. DOCUMENT REVIEW

Timeframe for review: every five (5) years, or earlier if required.

8.1 Responsibilities

Document authorisation: Council of Advocacy Practice and Partnerships
 Document implementation: Scientific Committee
 Document maintenance: Policy and Research Department

8.2 Revision History

Version	Date of Version	Pages revised / Brief Explanation of Revision
V1	Jul-12	Approved by Council
V2	Mar-14	Approved by Council
V3	Nov-16	Approved by CAPP Template updated. 'Background' expanded to include reference to the <i>Systematic Review</i> . 'Recommendations' expanded to include further information regarding mortality benefit, NNT and risk of sICH. Dot point three under 'Definitions' edited to incorporate specialist services with expertise relating to neuroimaging.
V4	Aug-17	Approved by CAPP Statement updated due to publication of Stroke Foundation Guidelines 2017.

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