

Mechanical clot retrieval for treating acute ischaemic stroke

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NICE interventional procedure guidance 458

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1 Guidance

The current evidence on mechanical clot retrieval for treating acute ischaemic stroke shows that efficacy is unproven. With regard to safety, there are risks of serious complications. The following recommendations balance these considerations against the poor prognosis of many patients with stroke. Suitability for thrombolysis can be guided by criteria used in the [Pragmatic Ischaemic Stroke Thrombectomy Evaluation \(PISTE\) trial](#).

1.1 Patients with acute ischaemic stroke for whom thrombolysis is

unsuitable or has failed: The procedure should only be used with special arrangements for clinical governance, consent and audit or research.

Clinicians wishing to use mechanical clot retrieval for treating acute ischaemic stroke in these patients should take the following actions:

- Inform the clinical governance leads in their Trusts.
- Ensure that patients (and when appropriate their relatives or carers) understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's [information for the public](#) is recommended.
- Submit details of all patients to the [Safe Implementation of Treatments in Stroke Thrombectomy \(SITS-TBY\) register](#).
- NICE encourages prospective studies of mechanical clot retrieval in these patients, including comparison of outcomes against those of patients who do not have the procedure. These studies should report details of patient selection, timing of the intervention after onset of symptoms, the devices and techniques used, and functional outcomes.

1.2 Patients with acute ischaemic stroke for whom thrombolysis is suitable:

The procedure should only be used in the context of research:

- Research should include randomised studies comparing mechanical clot retrieval against thrombolysis or other current methods of management and should report details of patient selection, timing of the intervention after onset of symptoms, the devices and techniques used, complications and functional outcomes.

- NICE encourages clinicians to enter patients into randomised trials such as the PISTE trial. In addition, details of all patients should be entered into the [SITS-TBY register](#).

1.3 Selection of patients for mechanical clot removal should be done by clinicians experienced in the use of thrombolysis for stroke. The procedure should be carried out in specialist centres by experienced interventional neuroradiologists with appropriate facilities and support.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Acute ischaemic stroke refers to stroke caused by arterial thrombosis or embolism. This results in loss of neurological function, leading to symptoms such as numbness or weakness of the face, arm or leg on one side of the body, and often problems with speech and swallowing.
- 2.1.2 Rapid assessment and early intervention, typically by thrombolysis, can limit ischaemic damage to brain cells. Mechanical clot retrieval is used for treating occlusions of large vessels.

2.2 Outline of the procedure

- 2.2.1 Mechanical clot retrieval for treating acute ischaemic stroke is carried out with the patient under sedation with local anaesthesia or general anaesthesia. Patients first undergo conventional cerebral angiography to demonstrate the presence and location of arterial occlusion. A delivery catheter is inserted, usually through the femoral artery at the groin, and advanced using X-ray guidance to the occluded artery. A clot retrieval device attached to a guidewire is introduced through the delivery catheter to the site of the occlusion. Several types of device and different techniques have been used for clot retrieval, including looped or corkscrew-like devices, snares or micro-forceps, and suction devices. In current practice, stent retrievers are the most commonly used type of device.

- 2.2.2 The aim is to perform the procedure as soon as possible, within a few hours after the onset of stroke symptoms.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

2.3 Efficacy

The efficacy outcomes described below include death occurring more than 30 days after the procedure. Deaths occurring within 30 days or as a result of intracranial haemorrhage are reported as safety outcomes.

- 2.3.1 A meta-analysis of 1113 patients reported complete recanalisation in 41% of the 580 patients for whom data were available (absolute number not reported). A meta-analysis of 147 patients reported successful flow restoration in 71% (104/147) of patients. A systematic review of 262 patients reported successful recanalisation in 90% (235/262) of patients.
- 2.3.2 A randomised controlled trial (RCT) of 113 patients reported successful recanalisation without symptomatic intracranial haemorrhage in 61% (34/56) of patients treated by a stent retriever and 24% (13/54) of patients treated by a coil retrieval device. A case series of 141 patients (74 received intravenous recombinant tissue plasminogen activator [rtPA] plus mechanical thrombectomy) reported successful revascularisation (defined as modified thrombolysis in cerebral infarction [mTICI] scores 2b or 3) in 85% (120/142) of arterial occlusions.
- 2.3.3 The meta-analyses of observational or interventional studies of 1113 and 147 patients reported a favourable outcome (90-day modified Rankin scale (mRS) score of 2 or under) in 40% of patients for whom data were available (961 patients; absolute number not reported) and 33% (49/146) of patients respectively. The systematic review of 262 patients reported an mRS of 2 or under in 51% (133/262) of patients (1 to 3 months after the procedure), with improvements of at least 10 points in the National Institutes of Health Stroke

scale (NIHSS) in 52% (102/196) of patients (reported as 'immediate to 3 months' after the procedure).

- 2.3.4 In an RCT of 656 patients comparing endovascular therapy (n=434) against intravenous tissue plasminogen activator (tPA) alone (n=222), there was no significant difference in the number of patients with an mRS of 2 or under (indicating functional independence) at 90 days (41% for endovascular therapy compared with 39% for intravenous tPA). A case series of 223 patients reported that endovascular therapy (n=123, including mechanical thrombectomy [25% of patients], intra-arterial thrombolysis with rtPA [35% of patients] or both [40% of patients]) was significantly associated with a favourable outcome (defined as an mRS of 2 or under) at 90 days, compared with intravenous thrombolysis (odds ratio 4 [95% confidence interval 1.8 to 9; p=0.0004]).
- 2.3.5 The meta-analysis of 1113 patients reported a pooled mortality rate of 28% in patients for whom data were available (n=952; absolute number not reported; p<0.0001; I²=60%; follow-up not reported). The meta-analysis of 147 patients reported an overall 90-day mortality rate of 31% (45/147; level of significance not stated) with rates of 29% (37/126) for patients with clots accessible by a mechanical retrieval device, compared with 38% (8/21) for patients with inaccessible clots. The case series of 141 patients reported death within 90 days in 24% (16/67) of patients who were treated by mechanical clot retrieval alone and in 18% (13/74) of patients who were treated by mechanical clot retrieval and intravenous rtPA. Causes included stroke, cardiac events, pulmonary disease and renal failure.
- 2.3.6 The Specialist Advisers listed key efficacy outcomes as successful device deployment, clot retrieval, angiographic recanalisation of the occluded vessel (for example assessed by TIMI/TICI [thrombolysis in myocardial infarction/ thrombolysis in cerebral ischaemia] score), time to recanalisation, clinical recovery, NIHSS before and after the procedure, mRS score at follow-up, and reduction in death rates and long-term dependency. One of the specialist advisers stated that efficacy should be related to clinical outcome and not technical success of the procedure.

2.4 Safety

- 2.4.1 Death within 7 days was reported in 12% (52/434) of patients treated by endovascular therapy and in 11% (24/222) of patients treated by intravenous tPA in the RCT of 656 patients; this difference was not significant.
- 2.4.2 Death (within 7 days) as a result of intracranial haemorrhage was reported in 2% (4/181) of patients treated by endovascular treatment and less than 1% (1/181) of patients treated by intravenous tPA in an RCT of 362 patients.
- 2.4.3 Distal emboli in a new territory was reported in 2% (1/58) of patients treated by a stent retriever and 6% (3/55) of patients treated by a coil retrieval device in the RCT of 113 patients. Embolisation to a previously uninvolved territory was reported in 7% (6/88) of patients treated by a stent retriever and 4% (4/90) of patients treated by a coil retrieval device in an RCT of 178 patients. Re-occlusion of the target vessel during the procedure was reported in 2% (3/125) of patients in a case series of 125 patients. Re-occlusions or distal occlusions were described in 5 patients included in the US Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database, 1 of whom died as a result.
- 2.4.4 Air embolism was reported in 1 patient in each of the stent retriever and coil retrieval device treatment groups in the RCT of 113 patients (timing not reported).
- 2.4.5 Symptomatic intracranial haemorrhage was reported in 8% of patients for whom data were available (n=983; absolute number and follow-up not reported) in the meta-analysis of 1113 patients. Symptomatic haemorrhagic complications were reported in 7% (16/236) of patients in the systematic review of 262 patients (timing not reported). There were 5 procedure-induced subarachnoid haemorrhages in the systematic review of 262 patients.
- 2.4.6 Symptomatic intracranial haemorrhage (as defined in the European Cooperative Acute Stroke Study [ECASS] III), was reported in 7% (6/88) of patients treated by a stent retriever and 9% (8/90) of patients treated by a coil retrieval device in the RCT of 178 patients. Symptomatic intracerebral

haemorrhage (within 30 hours) was reported in 6% (27/434) of patients treated by endovascular therapy compared with 6% (13/222) of patients treated by intravenous rtPA in the RCT of 656 patients. Asymptomatic haemorrhage (within 30 hours) was reported in 27% (119/434) of patients treated by endovascular therapy compared with 19% (42/222) of patients treated by intravenous rtPA ($p=0.01$) in this RCT. Symptomatic intracranial haemorrhage (within 24 hours of the procedure; defined as parenchymal haematoma type 2 with neurological worsening on NIHSS or leading to death) was reported in 3% (2/66) of patients treated by mechanical clot retrieval with intravenous rtPA and 5% (3/58) of patients treated by mechanical clot retrieval alone in the case series of 141 patients.

- 2.4.7 Access site complications needing surgical repair or blood transfusion were reported in 2% (2/88) of patients treated by a stent retriever and 1% (1/90) of patients treated by a coil retrieval device in the RCT of 178 patients.
- 2.4.8 Non-specific haemorrhage and subarachnoid haemorrhage were each reported in 5 patients included in the MAUDE database. There was 1 death after non-specific haemorrhage and 3 deaths after subarachnoid haemorrhage.
- 2.4.9 Clinically significant groin haemorrhages that needed surgical repair were reported in 2% (3/141) of patients in a case series of 151 patients.
- 2.4.10 Intramural arterial dissection was reported in 1% (1/90) of patients treated by a coil retrieval device in the RCT of 178 patients. Vessel dissection was reported in 3% (2/58) of patients treated by a stent retriever and in 2% (1/55) of patients treated by a coil retrieval device in the RCT of 113 patients. Vessel dissection was reported in 1% (2/141) of patients in the case series of 141 patients treated by mechanical clot retrieval (alone or with rtPA). Dissections occurred in 3 patients included in the MAUDE database.
- 2.4.11 Vessel perforation was reported in 1% (1/88) and 2% (1/58) of patients treated by a stent retriever, and in 10% (9/90) and 6% (3/55) of patients treated by a coil retrieval device in the RCTs of 178 patients and 113 patients, respectively.

- 2.4.12 There were 2 incidences of self-detachments of the stent retriever, 1 entanglement of the stent retriever and 1 in-stent thrombosis reported in the systematic review of 262 patients. Device separation was reported in 2% (1/58) of patients treated by a stent retriever in the RCT of 113 patients. Device fractures occurred in 3% (11/341) of clot retrieval devices used in the case series of 151 patients. In 2 of these patients device fracture was reported as likely to have contributed to the patient's death.
- 2.4.13 In addition to the above, the Specialist Advisers listed myocardial infarction, anaphylaxis, exsanguination, contrast reactions, anaesthetic complications and reperfusion cerebral oedema as theoretical adverse events.

2.5 Other comments

- 2.5.1 The Committee noted that the prognosis for patients with large vessel occlusion(s) for whom thrombolysis is considered unsuitable or has failed is very poor and this underpinned the [recommendation in 1.1](#).
- 2.5.2 The Committee noted the substantial amount of reported data on the technical success of mechanical clot retrieval for acute ischaemic stroke in contrast to the small volume of data relating to clinical outcomes in the context of the natural history of stroke.
- 2.5.3 The Committee noted that a range of devices and techniques can be used for this procedure, that the technology is evolving, and that there is evidence of significantly different associated outcomes. This made interpretation of the evidence difficult.

3 Further information

- 3.1 For related NICE guidance see [the NICE website](#).

Information for patients

NICE has produced information on this procedure for patients and carers ([Information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Changes after publication

April 2014: Minor maintenance

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced a [summary of this guidance for patients and carers](#).

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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