

MECHANICAL THROMBECTOMY For acute ischaemic Stroke: Challenges and Opportunities

Gary Ford, **Martin James**, and **Phil White** outline the key considerations when implementing a mechanical thrombectomy service

echanical thrombectomy (MT) is a breakthrough in the treatment of acute ischaemic stroke (AIS) caused by a large artery occlusion (LAO), and has been shown to be much more effective than intravenous thrombolysis (IVT) for this subgroup of stroke. Even with IVT, only a quarter of this group of patients with acute stroke survive without major disability. The evidence base for MT for anterior-circulation LAO stroke is clear, with eight randomised controlled trials demonstrating substantial benefits over best medical therapy in patients presenting early after stroke,1 and high-quality evidence for benefit emerging in carefully selected, patients presenting after 6 hours.^{2,3}

National and international stroke guidelines, including those published by NICE,⁴ recognise MT as standard treatment, and progress has been made in terms of a national commissioning policy for MT from NHS England, which supports the routine commissioning of MT for LAO AIS.⁵ The NHS Long Term Plan agrees with the efficacy of MT.⁶ MT for LAO AIS may also be associated with cost savings: on average, each patient treated with MT would save the NHS and social services more than £35,000 over 5 years.⁷

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However, there are still significant challenges in rolling out this service across the UK. Approximately 1100 MT procedures were performed in England in 2018–19, representing only 1.4% of all cases of AIS;⁸ Northern Ireland currently provides MT to around 3% of stroke admissions, few procedures are performed in Wales, and Scotland currently has no MT services. The NHS Long Term Plan aims for an increase in this figure to around 8000 MT procedures in England by 2022, recognising that 1600 more people every year would be independent after their stroke as a result;⁶ however, given that some parts of the UK are still virtually devoid of an MT service, a concerted effort to deliver this treatment from all agencies and disciplines involved in stroke care will be needed. This article outlines the key considerations when introducing an MT service, focusing on the most significant changes—reconfiguration of hyperacute stroke, ambulance, and imaging services—and offering practical recommendations for stroke service reorganisation and development of a business case. Lessons learned from the earlier implementation of IVT, primary percutaneous coronary intervention (PPCI) for ST elevation myocardial infarction, and centralisation of acute stroke services are also considered.

RECONFIGURING HYPERACUTE STROKE SERVICES

Hyperacute stroke services are conventionally divided between comprehensive stroke centres (CSCs), which are both IVT- and MT-capable, and primary stroke centres (PSCs), which deliver IVT but depend on secondary transfer to a CSC for MT treatment. Hyperacute stroke care may be delivered through two models. In the 'mothership' model, all patients with suspected stroke are taken directly to a CSC, possibly bypassing a nearer PSC, which results in greater onset-to-treatment times for IVT for some patients but removes the need for secondary transfer by road ambulance or helicopter. In the 'drip-and-ship' model, local IVT may be delivered at PSCs before patients with AIS eligible for MT are transferred to the CSC. The choice of approach depends on geography and travel times, availability of appropriately skilled staff, urban/rural split, and other factors, including the maximum practical size of a CSC under a mothership configuration and the minimum recommended size of a PSC in a drip-and-ship model.

To maintain the recommended minimum 600 admissions to any hyperacute stroke unit, the number of acute admitting centres in the UK will need to be reduced—for example, the modelled maximum number of PSCs and CSCs combined in England would need to be about 80, whereas the maximum number of MT-capable CSCs treating a minimum of 150 patients would be 40.9 Time to MT is reduced if patients directly attend a CSC, even if that involves travelling further than the nearest PSC; however, such decisions applied universally jeopardise the sustainability of networks by overloading CSCs and reducing admissions to many PSCs to unsustainably low levels.9 Modelling has shown that planning at a regional or national level is needed when significant reconfiguration of services for both IVT and MT is required if the benefits are to be optimised, because planning at sustainability and transformation partnership level is likely to lead to suboptimal service organisation for patients.10

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Ambulance services

Approximately half of patients with suspected stroke who present to ambulance services have a final diagnosis of a stroke mimic, meaning that fewer than one in 10 are likely to meet the clinical and radiological characteristics appropriate for MT. Ideally, these patients should be identified early and rapidly transported to a CSC to reduce time to treatment. Although centralisation of stroke care already requires ambulance services to provide pathways promoting rapid access to specialist care in line with national clinical guidelines,11 the main immediate impact of MT provision

for ambulance services will be further centralisation of specialist care for a small proportion of patients with major stroke.

Stroke pathways within ambulance services in the UK vary considerably, and regions expanding MT provision will need to consider whether differences may impact on efficient direct transfers for treatment. Ambulance services and commissioners must be involved early in the planning of acute stroke pathways, including repatriation pathways. Services must plan to deal with the resource implications of an increasing number of MT secondary drip-and-ship transfers. A coordinated network approach will be needed.

Radiology

Emergency vascular imaging of LAO stroke is critical for the selection of appropriate patients for onward referral to MT. Computed tomography (CT) is the basis of most emergency neuroimaging for suspected stroke in the UK, and is preferred to the alternative magnetic resonance imaging for reasons such as speed and ease of access. For the selection of patients suitable for MT, a combination of non-contrast computed tomography-a well-established standard imaging modality for stroke prior to IVT-and computed tomography angiography (CTA) is most appropriate. The relatively low levels of MT currently being performed in the UK are, in part, due to lack of routine use of CTA in local stroke imaging protocols. Universal implementation of CTA in all hospitals receiving patients with suspected acute stroke therefore represents the first phase in forming effective acute stroke MT networks across the UK. Because most initial stroke imaging will be performed in non-neuroscience centres, this is where the largest expansion in the provision of acute stroke imaging will be needed, requiring new equipment, new software, and training of radiologists and stroke physicians to interpret CTA or use appropriately validated artificial

intelligence (AI) software for immediate CTA decision support. Because MT provision extends to 24-7 coverage, around-the-clock imaging interpretation/ support will be needed to facilitate clinical decision making, and it may be necessary to use outsourced emergency radiology reporting and validated AI software where local radiology services are not available out of hours.

THE LESSONS OF PAST Experience

Thrombectomy is not the first high-value treatment to require major service reconfigurations, and it is helpful to reflect on the implementation of other disruptive innovations to learn what does and does not work. Boxes 1–3^{12–17} review the service reconfigurations required for PPCI for myocardial infarction, IVT, and centralisation of acute stroke services, respectively, highlighting the key lessons learned.

Three 24-7 MT services are already running successfully in England, and their experiences are helpful to illustrate the challenges, pitfalls, and drivers needed to adapt existing stroke services to deliver MT to eligible patients. For example, the first commissioned 24-7 MT service was established in the University Hospitals of North Midlands NHS Trust (then North Staffordshire NHS Trust) in January 2010, and has since treated more than 500 patients.¹² This required redesign of acute stroke treatment pathways within the trust and across the region. Communication was key throughout, and the service could not have worked without the cooperation of many specialties. The current challenges for successful implementation of an MT service are related to workforce limitations and the adoption of a functioning network approach to the service by CSCs and their referring PSCs. NHS England's initiative in establishing integrated stroke delivery networks (ISDNs) is

Box 1: Key lessons from the implementation of PPCI for STEMI

Much like MT, PPCI for STEMI was a ground-breaking treatment that required massive changes to infrastructure and service provision. Strong support from the DH and professional societies was required for the implementation of PPCI as the new standard of care for STEMI to gain traction, with national leads tasked with facilitating implementation. Despite the challenges and barriers, an increase from 39% of eligible patients treated with PPCI to 90% was achieved within just 3 years between 2008 and 2011,¹² and PPCI is now the default treatment for STEMI.

Key lessons from this experience were:

- co-ordinated regional networks were critical to the implementation of reconfigured services
- all centres offering a new emergency interventional treatment should have a plan that ensures that patients will be able to access this treatment on a 24-7 basis, 365 days a year, within a finite time period (e.g. 2 years)
- regular communications and meetings allow newer centres to quickly move up the learning curve and adopt best practice
- continuous data monitoring of the process and outcome measures is essential to demonstrate that treatment is benefitting patients and providing cost-effective care.

MT=mechanical thrombectomy; PPCI=primary percutaneous coronary intervention; STEMI=ST elevation myocardial infarction

Box 2: Key lessons from the implementation of IVT

Although some UK sites participated in previous trials of IVT for AIS in the 1990s, NHS services and the DH had no plan or strategy for the implementation of an acute stroke therapy once alteplase was licenced in 2003. Thrombolysis was a disruptive innovation that was challenging to incorporate into existing care pathways for stroke, and there was resistance to the shift to a 24-7 service capable of delivering IVT that meant progress was slow until the National Stroke Strategy prioritised implementation from 2007 onwards. It was not until 17 years after the publication of the pivotal alteplase study that all hospitals in England that receive acute stroke patients were delivering IVT and around 12% of all ischaemic stroke admissions were receiving alteplase.¹²

Key lessons from the experience with IVT were:

- regional clinical networks provided clinical leadership and managerial support and were key to the development of local implementation plans and sharing best practice to deliver IVT
- working with ambulance services and emergency department teams was critical to improving recognition of stroke and expediting the emergency response
- protocol-driven access to urgent brain CT was critical to reducing door-to-needle time for IVT
- development of teams to deliver around-the-clock IVT services required multiple specialties to support on-call rotas
- in some large metropolitan areas, rates of IVT did not improve until services were centralised.

AIS=acute ischaemic stroke; CT=computed tomography; IVT=intravenous thrombolysis

critical to the success of delivering equitable care. Developing a robust business case for provider trusts is also essential. Box 4 summarises the key learnings from the development of the North Midlands service.

Box 3: Key lessons from the centralisation of acute stroke services

Centralisation of London and Greater Manchester's stroke services in 2010 was driven by a combination of compelling evidence and policy ambition as a result of substantial variations in care¹³ and a lack of 24-7 delivery of care, which meant that only people presenting to certain hospitals within certain hours were receiving the right care at the right time. There was a particular need to improve access to IVT.¹⁴

In 2010, London and Greater Manchester implemented 'hub-and-spoke' models, with a small number of HASUs providing acute stroke care over the first hours following stroke, then transferring stable patients to units providing ongoing acute rehabilitation care.¹⁵ In London, eight 24-7 HASUs offered rapid access to imaging, specialist assessments, and treatment with IVT if appropriate. All patients with suspected stroke were eligible for treatment in a HASU within 48 hours of onset, with all patients in London within a 30-minute 'blue-light' ambulance journey of a HASU. The London centralisation resulted in significant reductions in patient mortality and length of hospital stay compared with the rest of England,¹⁶ and a significantly higher likelihood of delivering evidence-based clinical interventions than elsewhere,¹³ with cost-effectiveness achieved through the impact on outcomes.¹⁷

In Greater Manchester, 'partial' centralisation was implemented initially, within two out of three HASUs: two operating 'in hours', and a third operating 24-7 and accepting 'out-of-hours' patients from the other two HASUs. However, further centralisation was required, as the original partial centralisation had not delivered the anticipated benefits.

Key lessons from the experience of centralising stroke services were:

- service models should ensure that all patients with stroke have access to timely evidence-based care
- local change leaders should have sufficient authority to ensure that all stakeholders engage throughout the planning process
- meaningful clinical standards linked to financial incentives, including capital investment and additional transition funding, can help to ensure that services have sufficient capacity to deliver care
- sufficient operational capacity, e.g. from networks, can facilitate timely implementation of change
- a clear evaluation plan can help to determine whether the planned objectives are achieved.

HASU=hyperacute stroke unit; IVT=intravenous thrombolysis

SUMMARY

MT for AIS represents a once-in-a-generation opportunity to alter the miserable prognosis for the most devastating form of stroke, with substantial benefits for individuals and for wider health and social care. Such a step change in treatment for many people with major disabling stroke requires considerable infrastructure to deliver, and will involve further centralisation of services for hyperacute stroke. The NHS Long Term Plan's objective of a 10% increase in MT in England by

2022⁶ is commendable, but previous centralisations in the UK have been limited to a small number of mainly metropolitan areas, with others proving very slow to progress. National implementation of MT for stroke requires the resources and leadership that were necessary to implement similar innovations in the recent past, working within new collaborative ISDNs. The opportunity to make thrombectomy a routine option for the treatment of eligible patients with stroke across the UK requires visionary and concerted input from all agencies and disciplines involved in stroke care, but the

game-changing outcomes for patients eligible for this treatment will certainly be worth that effort.

Mechanical thrombectomy for acute ischaemic stroke: an implementation guide for the UK can be freely downloaded from: www.oxfordahsn.org/our-work/ adopting-innovation/mt-guide/

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Box 4: Key lessons from existing MT service reconfigurations

- Setting up a 24-7 service requires a change of institutional mindset
- Many issues with establishing the service can be overcome through collaborative working within a regional network
- Necessary infrastructure must be planned, including access to biplane neuroangiography equipment and sufficient HASU capacity at the CSC to manage patients transferred from other hospitals
- A clear idea of total costs and how many thrombectomies are required to deliver a financially sustainable service is crucial
- Coordination with ambulance services is essential
- Staff across the care pathway, including those who interpret CTA and assess patient suitability in referring PSCs, must be trained with the new skills to identify and select appropriate patients
- High-quality, post-MT procedure care is essential to achieve successful patient outcomes
- Appropriate system governance is required to review outcomes and feedback results and timings to referrers to ensure the pathway is safe and efficient.

CSC=comprehensive stroke centre; CTA=computed tomography angiography; HASU=hyperacute stroke unit; MT=mechanical thrombectomy; PSC=primary stroke centre

Key points

- MT for AIS represents a once-in-a-generation opportunity to alter the miserable prognosis for the most devastating form of stroke, with substantial benefits for individuals and for wider health and social care
- Such a step change in treatment for many people with major disabling stroke requires considerable infrastructure to deliver, and will involve further centralisation of services for hyperacute stroke
- The most significant changes will be reconfiguration of hyperacute stroke services, ambulance services, and neuroimaging
- National implementation of MT for stroke as a routine option for the treatment of eligible patients with stroke across the UK requires visionary and concerted input from all agencies and disciplines involved in stroke care.

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