Standards for providing safe acute ischaemic stroke thrombectomy services

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These groups are recognised Special Interest Groups of their respective Royal Colleges and the short life working party was operating under the oversight of the Intercollegiate Stroke Working Party

Providing a Safe cerebral thrombectomy service

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Introduction

Stroke is the third leading cause of death and the leading cause of disability in Europe. The management of acute ischaemic stroke is a major healthcare challenge but improving outcomes for acute stroke patients offers major benefits to patients, healthcare systems and society as a whole.

The immediate aim of treatment of acute ischaemic stroke is to recanalise an occluded vessel as quickly, safely and effectively as possible so as to restore reperfusion to the ischaemic brain region. Currently the standard treatment for acute ischaemic stroke for patients presenting up to 4.5 hours after onset is intravenous thrombolysis using tissue plasminogen activator (IVT) (1). This treatment is effective in only 50% of patients with distal vessel occlusions. However, recanalisation rates of large proximal artery occlusion (LAO) are disappointing at 24 hours after IVT treatment, with rates of 10% for internal carotid arteries and 35% for middle cerebral arteries being reported (2).

The prognosis for patients with clinically severe stroke secondary to proximal occlusion is poor with the NINDS trial demonstrating that only 10% of patients with an NIHSS score of 20 or more achieved independence at three months (2). Endovascular approaches to the treatment of acute ischaemic stroke caused by large vessel occlusive stroke are promising but as yet unproven. In many locations outside UK, these procedures have been incorporated into usual clinical practice.[3] The rationale to deploy the use of endovascular therapies for ischaemic stroke is to potentially improve outcomes by facilitating early recanalisation of an occluded large artery as quickly as possible.

The only randomised trial to date on early IA therapy as an **adjunct** to IVT was IMS 3, which was neutral. [4] However, this trial did not utilise CTA/MRA to document LAO prior to randomisation, it utilised lower dose IVT in intervention arm and did not test modern endovascular therapeutic thrombectomy approaches, which have been shown to be superior to the obsolete devices used in IMS 3 (5, 6). In fact a thrombectomy was actually undertaken in only 44% of patients in the endovascular arm of IMS 3 {192/434}).

Despite higher recanalisation rates in the endovascular group of IMS 3, this did not translate into improved outcomes reinforcing that at present IVT should continue to be the first line treatment for patients with acute ischaemic stroke presenting within 4.5 hours after major vessel occlusion. Time window for treatment is a crucial factor and subgroup analysis from IMS 3 suggested that improved outcomes (although not statistically significant) were observed in patients who received endovascular therapy within 90 minutes of IVT if thrombolysis treatment was commenced within 2 hours of stroke onset (4). More data however are required to identify which patients may potentially benefit from endovascular therapy or be harmed from it. Newer devices coupled with shorter therapeutic windows need to be rigorously evaluated.

Despite the lack of supportive evidence from RCTs for endovascular treatment, these therapies are being used at least occasionally in 21 hospitals in the United Kingdom (7) with 295 cases recorded by SSNAP April 2013 to March 2014 inclusive. The European Stroke Organisation (ESO) Consensus statement in 2010 recommended that endovascular therapy should not be used in routine clinical practice but could be considered in cases such as patients with contraindications to IVT (8). This statement was supported by the NHS Improvement Stroke Working Party document in 2012 (9). In line with subsequent NICE guidance, the group recommended that Intra-arterial intervention in acute stroke should only be undertaken within the context of a trial or

national/international registry and at specialist stroke centres that fulfil agreed standards of care. The Working Party recommended further work be undertaken by relevant professional bodies in conjunction with the intercollegiate stroke working party to agree and describe the required standards of care for both staff and processes at such centres. This document arises from that recommendation.

In July 2013, NICE guidance on mechanical clot retrieval for treating acute ischemic stroke was published (10). The following recommendations were made: The procedure should only be used with special arrangements for clinical governance, consent, audit and research. Patients who are suitable for thrombolysis and satisfy the criteria for a research study (e.g. Pragmatic Ischaemic Stroke Thrombectomy Evaluation-PISTE) (11) should be considered for enrolment into a randomised controlled trial and finally patients for whom thrombolysis has failed or is unsuitable due to contraindications can be considered for thrombectomy if not eligible for a trial, but each case must be entered into an established registry (e.g. SITS TBY) documenting outcomes, performance and safety.

As this is a new procedure without evidence yet from RCTs for effective pathways to guide practice, it is important to produce a consensus on the minimum standards of care required to support such a service in terms of specialist staffing/skill mix and organisation of services. Until trials complete it is recommended that such interventions should only be undertaken within specialist stroke centres that fulfil agreed standards of care for both staff and process and meet any additional requirements of a RCT or Registry.

Every trust where such procedures are undertaken has a duty to ensure that safe arrangements are in place.[10] This document is designed to aid that by describing what is an appropriate service for endovascular acute ischaemic stroke therapy. Until the technique is proven (by level 1 evidence) it is not appropriate to pronounce on the hours of service provision but it is appropriate to describe the minimum service support requirements and basic performance standards that should be met.

Recommendations for Endovascular Therapy for Acute Ischaemic Stroke

Organisation of Care

Sites

If endovascular therapy is being considered for the treatment of acute ischaemic stroke either within the context of a randomised controlled trial or part of a multicentre registry (e.g. the SITS thrombectomy registry), this should be confined to neuroscience centres incorporating hyperacute stroke units (HASU) embedded within a high quality comprehensive stroke service with access to neurosurgical, neurocritical care and specialist in and out-patient stroke services.

The key features of what a HASU should incorporate include:

- 24 hour availability of an experienced consultant stroke physician (12)
- Immediate access to brain imaging including CTA/P & MRI as required (13)
- Direct admission to HASU from A&E < one hour
- Continuous physiological monitoring (ECG, oximetry, blood pressure)
- Specialist stroke physician ward rounds 7 days per week
- Acute stroke protocols/guidelines
- Nurses trained in swallowing screening, stroke neurological assessment (including the NIHSS assessment), eligibility assessment for thrombolysis and administering thrombolysis treatment

Endovascular therapy should only be carried in the context of high quality hyperacute stroke services with the appropriate experience in delivering such interventions. Evidence suggest that hospitals with an annual thrombolysis volume ≥ 50 cases per annum achieve significantly better onset to needle, door to needle and door to imaging time than thrombolysis volumes < 50 cases (14) and this may enhance endovascular delivery times.

Skill Mix

The decision to undertake endovascular therapy should be made jointly by a multidisciplinary team compromising a consultant stroke physician, neurointerventionist (with the necessary experience and skills) and an anaesthetist (preferably experienced in neurological care).

The stroke physician undertaking the decision to consider endovascular therapy must satisfy the BASP criteria for stroke specialist including:

- Completion of specialist training or recognised expertise (existing specialists)
- Ongoing active involvement in stroke management (at least 5PA of which 3 PA is direct clinical care)
- Annual attendance of at least one specific training event
- Evidence of continued professional development in the field of stroke medicine
- Participation in national stroke related audit
- Basic research skills (participation or facilitation of stroke research)

The stroke physician should be trained in delivering thrombolysis and in the monitoring of any complications associated with thrombolysis and endovascular therapy.

This must be underpinned by regular quality and audit meetings within a quality improvement group incorporating stroke physicians, neuro-interventionists, neuroradiologists, intensivists ± emergency medicine physicians (3,15).

There should be provision of 24/7 consultant cover provided by at least 6 BASP thrombolysis trained consultants on a rota able to make thrombolysis and hyper acute treatment decisions (1). BASP have recommended that for a hyperacute service admitting 600 new admissions annually, 13 direct clinical care PA dedicated to management of patients on the acute stroke ward would be required to support such a service. (16)

Pre-Hospital:

Emergency Medical Services (EMS) play a vital role in hyper-acute stroke care and local protocols and algorithms should be in place for dispatch, assessment, pre-notification and transport strategies.

All potential eligible patients for intravenous thrombolysis initially should be transferred immediately to a centre with hyper-acute stroke services with early notification of the specialist stroke team. There is currently no existing literature on training EMS in identifying potential patients eligible for endovascular therapy. There is no evidence that EMS should directly transfer patients outside the intravenous thrombolysis window directly to centres with endovascular capability.

Inter Hospital Transfer:

Transfer from a primary hospital to a centre providing endovascular therapy can potentially result in considerable delays in administrating treatment. This needs to be considered in the decision whether to transfer or not. As there is currently no level 1 evidence to support interventional stroke treatments such pathways will include the decision not to transfer any patients or to transfer only for potential access to neuroscience care (including research studies) in some parts of the country. It is important that provision of intravenous thrombolysis is not delayed under any circumstances.

'Hub and Spoke' models have been used regionally to deliver IVT successfully however, regional strategies with a Network approach for endovascular therapy cannot be currently supported in the absence of level 1 evidence for this procedure.

If algorithms are to be developed for secondary transfer of patients eligible for endovascular therapy as part of a randomised controlled trial or where there are contraindications to IVT, then local protocols for transferring and accepting patients need to be clearly outlined.

Process of Care

Endovascular Therapy Recommendations and Quality Benchmarks:

Eligibility for mechanical thrombectomy should not delay the initiation of IVT where this is indicated.

Consider endovascular therapy in the following patients:

Proximal large vessel occlusion in a symptomatic territory leading to a disabling neurological deficit (NIHSS ≥6) of known onset and IAT treatment initiation within 6h of onset* and one of the following:

- Randomisation into clinical trial appropriate
- In carefully selected patients (e.g. contraindications to intravenous thrombolysis, recent surgery, warfarin treated with therapeutic INR)
- Failure to respond to intravenous thrombolysis *(However the time window defining failed IV tPA has not been established and thus further trials may be required to define the criteria for failed IVT)*

**Initiation time is from stroke onset to groin puncture for IAT in confirmed LAO stroke. If the major vessel occlusion is in posterior circulation, time window may be up to 12-24h depending on clinical status of patient*

The metric of 'arrival to start of treatment' should be within 2 hours wherever possible, unless the indication for intervention only developed after arrival (e.g. deterioration after thrombolysis or in a patient not eligible for thrombolysis).

Door to Imaging:
All patients with an acute stroke being evaluated for endovascular therapy should be imaged immediately (ideally the next imaging slot).

Use of CT angiography or MR imaging/angiography should not delay therapy with intravenous thrombolysis or delay door to arterial puncture. *In practice hospitals that undertake CTA routinely in acute stroke achieve this by review of plain CT occurring whilst CTA is performed and then not waiting for CTA report before instituting IVT (where indicated).*

General Anaesthesia:
If general anaesthesia is used due to clear indications and patient safety concerns during the procedure, then ongoing physiological monitoring including airway management should be undertaken in the appropriate setting until stable. This should occur either within high dependency or intensive care settings, where necessary with specialist stroke support.

The following outcomes should be measured from the SITS TBY data collection set:

- Revascularisation achieved [with a TICI grade 2b or 3 achieved in >60% of patients]
- Rankin 0-2 at 3 months [should be achieved in ≥30% of cases]
- Symptomatic Intracranial Haemorrhage using SITS definition (parenchymal haemorrhage type 2 combined with deterioration of NIHSS score ≥ 4 points at 22-36 hours - no more than 12% rate of SICH should be expected)
- Early deaths (within 72 hours)

Recommendations for individual trusts

Neuroradiology departments

1. Recognition that existing interventional neuroradiology (INR) services should be able to provide stroke endovascular therapy to underpin gaining evidence on its effectiveness and efficacy within the NHS, as the potential benefits to patients could be substantial.

- Whether this is confined to normal working hours or extended hours will depend upon local circumstances
- Planning for future delivery of extended hours services should be undertaken

2. There should be clarity within the trust and among referring clinicians and service commissioners about what endovascular stroke services are available, when they are available and what happens when the service is not available

- Local patient pathways should exist, be clear and widely available
- Local protocols and SOPs for each step of the pathway should be accessible
- The local use of IA treatment should be reviewed through the trust's local clinical governance mechanisms before offering the procedure, and the results of audit regularly reviewed, at least annually. Referring clinicians need to be aware of the situation
- Delivery of intra-arterial interventions in acute stroke should only be in the context of established, high quality stroke services, where all patients have timely access to specialist stroke units
- Consideration for intra-arterial interventions in acute stroke should not compromise the timely delivery of intravenous thrombolysis in eligible patients

3. Service provision must be subject to a formal rota

- It is not safe or sustainable to rely on ad hoc arrangements [17]
- Nor is it acceptable to assume another centre will be willing or able to provide the service without official and agreed service level agreements (this will be essential if level 1 evidence on clinical efficacy is forthcoming)
- A mechanism should be in place for informing clinical teams about when service is available

4. There should be recognition of the resource implication on INR consultants of supporting even a limited hours stroke endovascular service and also of the knock on impact on diagnostic neuroimaging services

- Appropriate diagnostic neuroimaging support and protocols should be in place
- A whole support team of staff is required to deliver endovascular stroke therapy and this needs to be IMMEDIATELY available
- Anaesthetic staff with appropriate training/experience in neurocritical care plus ODP support
- Angio suite staffing – nursing and radiographic
- After care is a critical requirement – neurocritical care facility should be immediately available post procedure

5. Services should have regular clinic-radiological MDT where endovascular stroke patients can be reviewed/discussed. As well as enrolment into RCT/Registry (if not in RCT), appropriate local audit processes should be in place. All cases should also be entered into SSNAP

- Quality improvement processes for IAT should be in place
    - quality improvement group could include a combination of interventionists, neurologists, stroke physicians, intensivists & diagnostic neuroradiologists. Additional members might include representative(s) from quality assurance/improvement or risk management teams

6. IA intervention should be delivered in specialist stroke centres that fulfil the following attributes

- demonstrable research capability and activity
- adherence to defined standards (as section above)
- consultant-led & delivered services with adequate volumes of activity
- formal INR commissioning arrangements in place

Recommendations for individual endovascular operators

1. All doctors are bound to adhere to GMC guidance and comply with principles and values set out in Good Medical Practice

2. Operators should not normally carry out procedures with which they are unfamiliar (in the UK at present this, to all intents and purposes, essentially limits provision of endovascular stroke therapy to consultant interventional neuroradiologists)

- If a procedure is required on a reasonably regular basis then individual operators must maintain the necessary skills
- There will inevitably be a risk benefit assessment to be made in any individual case and patients and presentations do vary considerably. The risk of any patient transfer, presence or absence of alternative therapies and INR experience will all need to be taken into account.
- This risk benefit analysis should be reflected in the consent/assent obtained and documented.

3. Operators should recognise that ad-hoc rotas are not in the best interest of patients [17]

- This form of service provision may conceal lack of safe, reliable service provision
- There must be a safe environment for performing the procedure and close liaison with the appropriate clinical team(s)

4. Operators should participate in multidisciplinary case review

5. It is the duty of the operator to report any risk management concerns to the trust's clinical governance committee.

Implementation of standards and quality benchmarks

Departmental leads should ensure the following:

- Local agreement is reached amongst INRs about what service is provided
- Process for maintenance of skills is in place (this may include updating practical skills by spending time in other Departments)
- Mechanism for information to be available to clinicians on regular basis about when service is available
- Formal contracts exist with referring trusts
- Agreed local protocols should be evidenced based (within limits of evidence)
- National guidelines are adhered to
- Appropriate case review and quality improvement processes are in place

Quality Benchmarks for Endovascular stroke therapy

1. Local protocol specifies reasonable indications for the procedure to be undertaken:

- Proximal large artery occlusion in symptomatic territory plus symptom onset known and <5.5h ago, and one of :
    - Randomisation into RCT undertaken
    - IV tPA contraindicated & ineligible for trial in that unit
    - Fails to respond to IV tPA by end of infusion & ineligible for trial in that unit
        - *Time window greater if vertebrobasilar occlusion*

- If time of onset unknown, IAT should only be undertaken within context of a RCT
- Account is taken in indication protocol of NIHSS and patient factors – co-morbidity and possibly age
- As guidance to inform local audit:
    - *At least 95% of patients treated with IA therapy should meet the institutional selection criteria. 100% of patients have the required process and outcomes data entered into SSNAP*

2. Timings

Median door to groin puncture time (DTG), puncture time to start of revascularisation and puncture time to end of revascularisation should be the subject of ongoing audit

As guidance to inform local audit:

- Median time of <90 minutes should be achieved
    - "Door " is defined as time of arrival in the ED or the time first discovered to have a stroke for an inpatient.
    - When patients are transferred, ''door'' refers to the arrival time at the receiving facility and in such cases a median DTG of <60 minutes should be the aim
- Puncture time to start of revascularisation: <45 minutes in at least 65%
- Puncture time to end of revascularisation: median ≤60 minutes

3. Clinical outcomes: should be the subject of ongoing audit and entered into SSNAP

As guidance to inform local audit– see page 6:

Anaesthetic management of endovascular treatment of acute ischaemic stroke

1. Recommendations for provision of care

- The anaesthetic care of these patients should be supervised by Neuroanaesthetists with skilled assistance. It should be consultant led.
- If a patient is sedated the responsible anaesthetist must be present in the procedure suite.

2. Recommendations for pre assessment

- These patients present as time critical emergencies, akin to evacuation of an extradural haematoma or category 1 caesarian section. Delays have detrimental effects on patient outcome. Pre assessment of the patient must be done as quickly as possible to avoid delay.

3. Recommendations for anaesthetic management

- The choice of anaesthetic should be tailored to the individual patient based on neurological status, airway control and treatment plan in close communication with the INR.
- Local anaesthesia should be aimed for, if feasible, in patients who are cooperative and can protect their airway.
- General anaesthesia is recommended in patients with a reduced level of consciousness, uncooperative or agitated patients, those who cannot protect their airway or those already intubated.
- Patients receiving local anaesthesia with sedation should be monitored and provision made to enable rapid conversion to a general anaesthetic if necessary.

4. Recommendations for airway management

- Tracheal intubation is recommended for those patients with reduced level of consciousness, signs of brain stem dysfunction, those unable to protect their airway, with active nausea and vomiting before intervention and patients who become hypoxic or develop airway obstruction under sedation.
- Supplemental oxygen administration is recommended during sedation.
- All patients should be monitored with pulse oximetry and capnography.
- FiO_2 should be titrated to maintain SpO_2 94-98% (18). Ventilation should be adjusted to maintain normocapnia under anaesthesia. Hypercapnia should be avoided in patients undergoing sedation.

5. Recommendations for haemodynamic management

- Haemodynamic monitoring should include ECG and continuous blood pressure or, if non-invasively, measured at least once every 3 minutes.
- Continuous invasive arterial monitoring is recommended for all interventional procedures as long as arterial cannulation will not delay intervention. The femoral artery cannulated by the neurointerventionist may sometimes be used to provide continuous arterial monitoring if necessary.
- In patients having general anaesthesia systolic blood pressure should be maintained within 10% baseline with fluids and / or vasopressors. Suggested targets are >140mmHg but < 220mmHg (< 180mmHg in patients who have received IV tPA).
- These blood pressure targets may need adjustment in communication with stroke physician/INR.

6. Recommendations for Postoperative Care

- Critical care should be contacted to establish the availability of level 2/3 facilities for postoperative care. However this should not delay the start of intervention. If necessary, alternative facilities can be sought whilst the procedure is performed.
- Patients who have received GA should be managed on NICU or High dependency care / stroke unit postoperatively to continue invasive monitoring and neurological monitoring.

7. Protocols

Irrespective of anaesthetic technique the two most important anaesthetic goals are minimising any time delay and haemodynamic control. Institutional protocols can assist in the safe and timely delivery of care. These protocols should address:

- Choice of anaesthetic agents
- Timeliness of induction
- Blood pressure parameters
- Postoperative care

7. Audit

Institutions should audit their practice including type of anaesthetic, monitoring, timing, anaesthetic agents used and complications.

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Abbreviations

CS = Conscious sedation
ED = Emergency Department
GA = General anaesthesia
GMC = General Medical Council
IA = Intra-arterial
IAT = Intra-arterial thrombectomy (clot extraction)
IMS 3 = Third interventional management of stroke trial
INR = Interventional Neuroradiologist
IV = Intravenous
IVT = Intravenous thrombolysis
mRS = modified Rankin score
NICE = National Institute for Health & Clinical Excellence
NIHSS = National Institutes for Health stroke scale
NSU = Neurosciences Unit
RCT= randomised controlled trial
SICH = symptomatic intracerebral haemorrhage
SITS-TBY = Safe Implementation of Thrombolysis in Stroke - Thrombectomy
tPA = tissue plasminogen activator

Appendix 1

North East IAT Pathway – Neuroscience hospital A&E/direct HASU admissions

Operational hours: *e.g. Monday-Friday 8-6 for referrals (8-8 for procedures)*

1. A/E/HASU notify on call stroke team that an acute stroke patient expected (arrived)
2. Stroke team review stat in A&E/HASU or at CT suite
3. CT/CTA obtained asap (**next scan slot**)
    - If LAO stroke is suspected clinically, stroke reg/consultant contact duty INR consultant before CT/A
    - If LAO not suspected, urgent review of CT/A by duty neuroradiologist. Stroke team to phone duty INR if LAO identified
        - *If duty INR scrubbed/not contactable, try any other INR available*

4. Duty INR Consultant to review CT/CTA stat & initiate team cascade if suitable for Thrombectomy (IAT)
    - INR phones Neuro X-Ray nurse who alerts other theatre staff including anaes/ODP if no ongoing GA case & starts preparation of trolleys etc.
    - INR phones agreed Anaesthetic "crash number" if INR GA case currently ongoing
    - Anaesthetist alerts ODP/Recovery/HDU
    - If duty INR scrubbed s/he will suggest the alternative person to contact

5. Patient taken direct to neuroangio from CT (or A&E/HASU) by stroke team (no porter unless one can be waiting)
6. IA Thrombectomy procedure performed as per local protocol
7. Return post IAT to recovery for 4h then if well enough back to HASU (Neuro Critical Care if not)

Audit key process components of pathway

- Time from stroke to arrival at Neurosciences Unit (NSU) Hospital
- Time from arrival (door) to CT/CTA
- Time door to arrival at Neuroangio
- Door to groin puncture time
- Time groin puncture to final recanalisation
- Time puncture to end of procedure
- TICI results
- SICH rate
- Other complications
- NIHSS at 24h and 90 day Rankin

Other hours: Sat/Sun 8-6
Discussion of cases suitable for research trial on an individual basis (no standard OOH service until resourced) - Stroke Consultant to INR consultant on call

Adapted from North East IAT Pathway –referrals to Neuroscience unit from external hospital

Operational hours: *e.g. Monday-Friday 8-6 for referrals (8-8 for procedures)*

1. On call NSU hospital stroke consultant contacted by stroke consultant at referring centre

(NB referrals will be routinely accepted from hospitals with an ASU within 45 mins by road ambulance of the NSU)

Accepts patient for transfer if the following criteria met:

- Adult with acute disabling stroke clinically
    - Known stroke onset **within 4h** of telephone referral *[8h for suspected V-Bas occlusion]*
    - NIHSS ≥6
    - Pre stroke Rankin estimated at ≤2
    - CT/CTA (or equivalent) performed & LAO occlusion **suspected** on this imaging

2. Referring hospital immediately arranges Category A ambulance transfer to NSU HASU
3. NSU stroke consultant contacts duty INR Consultant to review CT/CTA & INR initiates team cascade if felt suitable for IAT

- INR phones Neuro X-Ray nurse who alerts other theatre staff including anaes/ODP if no ongoing GA case & starts preparation of trolleys etc.
- INR phones agreed Anaesthetic "crash number" if INR GA case currently ongoing
- Anaesthetist alerts ODP/Recovery/HDU
- If duty INR scrubbed s/he will suggest the alternative person to contact

4. NSU duty Stroke consultant/SpR alerts HASU that patient coming & confirmed (or not) for IAT.
5. IAT candidates triaged very briefly (<3mins) immediately on arrival HASU to confirm NIHSS remains ≥6
6. Patient taken by HASU staff direct to neuroangio (no porter unless one can be waiting on ward)
7. IA Thrombectomy procedure performed as per local protocol
8. Return post IAT to recovery for 4h then if well enough back to HASU (Neuro Critical Care if not)
9. Repatriate asap to referring hospital after 24h check CT (within 48h if possible)

Audit key process components of pathway

- Time from stroke onset to referral call to NSU
- Time from referral call to leaving outside hospital
- Time from referral call to arrival at NSU hospital
- Time arrival NSU hospital to arrival at Neuroangio
- Time arrival at NSU to groin puncture
- Time puncture to final recanalisation
- Time puncture to end of procedure
- TICI results
- SICH rate
- Other complications
- NIHSS at 24h and 90 day Rankin *(referrers to supply mRS as going forward it will be recorded for SSNAP)*

Other hours: Sat/Sun 8-6. Discussion of cases suitable for research trial on an individual basis (no standard OOH service until resourced) - Stroke Consultant to INR consultant on call

Appendix 2

NHS Improvement
Stroke

Intra-Arterial Interventions in Acute Stroke

Consensus Statements

Summary

1. The group considered that the widespread adoption of the use of intra-arterial interventions in acute stroke could not be recommended at the present time, on the grounds that the available randomised controlled trial evidence was insufficient.

2. The group acknowledged that a number of trials are in progress that may help clarify the appropriate role of such therapies and devices and strongly recommended that further research was conducted

3. The group recommended that Intra-arterial intervention in acute stroke should only be undertaken within the context of a trial or national/international registry and at specialist stroke centres that fulfil agreed standards of care.

4. The group recommended that further work should be undertaken to agree and describe the required standards of care for both staff and processes at such centres: standards that would include demonstrable research capability and activity in trials of interventional treatments.

Background

In October 2011, NHS Improvement-Stroke hosted a meeting of representatives of the range of professional bodies involved in the delivery of the various intra-arterial interventions in acute stroke. The remit of the group was to consider the current evidence and practice base and to attempt to reach consensus on the following areas:

1. Agreement on whether sufficient evidence already exists, or not, to recommend wider adoption of each of the interventions of: intra-arterial thrombolysis, intra-arterial angioplasty and intra-arterial thrombectomy

2. Agreement on the necessary pathways and referral protocols required to increase access to those interventions where the group considers adequate evidence exists, to include implications for imaging requirements

3. Agreement on service models required to deliver such agreed interventions, including consideration of service redesign, imaging consequences, commissioning arrangements and of the skills, competences and experiences of staff necessary to safely and effectively deliver the interventions.

The remainder of this document summarises the outputs from the consensus group meeting.

Interventions

4. Whilst the group recognised that large artery occlusion in acute ischaemic stroke is associated with a high morbidity and mortality if left untreated, and that the odds for favourable outcome in general are significantly increased with early vessel recanalization, the group considered that the widespread adoption of the use of intra-arterial interventions in acute stroke could not be recommended at the present time, on the grounds that the available randomised controlled trial evidence was insufficient.

   The group strongly recommended that further research was conducted and acknowledged that a number of trials are in progress that may help clarify the appropriate role of such therapies and devices.

5. The group considered separately the use of (a) intra-arterial thrombolysis and the use of (b) intra-arterial clot retrieval, disruption and aspiration devices:

   a. **Intra-arterial thrombolysis**. It was noted by the group that 3 randomised controlled trials (RCTs) have been published in the use of intra-arterial thrombolysis in acute stroke – PROACT I and II studies and MELT - and whilst they were considered to provide proof of principle, they were considered to provide insufficient evidence for widespread adoption at the present time. It was noted that both the European Stroke Organisation (ESO) and the American Heart Association (AHA) guidance contained recommendations that Intra-arterial thrombolysis is an option for treatment of acute MCA occlusion within a 6-hour time; in patients who have contraindications to use of intravenous thrombolysis, (such as recent surgery), and for acute basilar occlusion in selected patients.

      The group considered that such patients should be entered into a trial, or if treated in specialist and experienced centres (in selected cases, for example where intravenous thrombolysis was contraindicated or failed), entered onto a registry to record clinical outcomes.

   b. **Intra-arterial clot retrieval, disruption and aspiration devices**. The group noted that no RCTs have been performed with any of the thrombectomy devices. The group noted the 2010 ESO Consensus statement that, due to the lack of evidence of randomized control trials for clinical efficacy, mechanical thrombectomy should not be used in clinical routine, but that, in selected patients (e.g. with indication for iv-treatment but also contraindication), endovascular approaches may be considered as part of a institutional protocol.

      The group agreed with this recommendation and in addition, that these devices should ideally be used as part of a clinical trial with any patient treated using such a device be entered onto a registry to record clinical outcomes.

Organisation of Care

6. The group noted that, whilst there was presently insufficient evidence for widespread adoption of intra-arterial interventions in acute stroke, such practice is undertaken in a sporadic way across the country. The group strongly considered that documented evidence of formal arrangements for the delivery of intra-arterial interventions in acute stroke should exist between provider organisations, commissioners and ambulance trusts across relevant networks and regions. It was felt stroke networks were well positioned to lead local discussion and agree appropriate protocols and pathways.

7. The group emphasised that the delivery of intra-arterial interventions in acute stroke should only be in the context of established, high quality stroke services, where all patients have timely access to specialist stroke units.

8. Consideration for intra-arterial interventions in acute stroke should not compromise the timely delivery of intravenous thrombolysis in eligible patients, for up to 4.5 hours after onset of stroke.

Standards of Care

9. The group recommended that if intra-arterial interventions in acute stroke are undertaken, it should be within the context of a trial or national registry and that such activity should be confined to specialist stroke centres that fulfil the standards of care criteria below, including participation in trials of interventional treatments.

   All patients who match the inclusion criteria for ongoing randomized controlled trials of intra-arterial interventions should be offered the opportunity to participate in relevant NIHR-adopted stroke trials. For patients who either are excluded from these trials or do not consent to be involved and undergo interventional treatment, then the procedure and outcomes should be recorded in a national registry. These interventions should be delivered in specialist stroke centres with the following attributes:

   a. Demonstrable research capability and activity

   b. Adherence to defined standards for staff and processes (see below)

   c. Ongoing audit of activity, including the entry of treated patients onto a registry

   d. Consultant-led and Consultant-delivered service

   e. Minimal volumes of activity (to be advised, see below)

   f. Formal links between neuro-interventionalists, stroke physicians and neurologists

   g. Formal commissioning arrangements with ambulance trusts for transfer and bypass arrangements for appropriate patients

10. Imaging standards for identification of people for intra-arterial interventions in acute stroke should be clearly specified and agreed within local protocols It was considered that these would include, as a minimum, the requirement for demonstration of vessel occlusion (e.g. by CTA, MRA) prior to DSA, in addition to non-contrast CT brain scanning. It is therefore recommended that this should be referred for comment by the ICSWP within their next National Clinical Guideline

11. The group considered that further work should be undertaken to create an assurance process for the quality of both staff and sites undertaking intra-arterial interventions in acute stroke:

    a. **Staff**. The group acknowledged that, because the evidence base is evolving, it is presently difficult to predict what the scale of uptake of intra-arterial interventions in acute stroke in the future may be. However, the group considered that ground work should commence to identify the skills, competences and experience needed by staff involved in the delivery of such interventions. An agreement was reached that the following organisations would be formally approached following publication of the consensus statements to collaborate in undertaking to this work forward: Royal College of Radiologists (RCR), British Society of Neuro Radiologists (BSNR), British Association of Stroke Physicians (BASP), UK Neurointerventionalist Group (UKNG) and the Stroke Speciality Advisory Committee (SSAC). The National Stroke Nursing Forum (NSF) will also be consulted to agree with neurology/interventional nurses the skills and competencies required to provide the care for patients during and having received IA interventions.

    b. **Sites**. The group considered that processes for accreditation of sites should be developed in the future once the evidence, outcomes and cost-effectiveness of these interventions are available to inform their development. Such standards for sites should include: specification of minimal levels of activity, staffing levels, specify requirements for access to appropriate levels of neuroimaging and critical care (and links to neurosurgery should it be required). Ongoing audit of activity and the entry of treated patients onto a registry should occur. Specification of standards for processes and outcomes of care should be agreed within the commissioning arrangements, and outcomes subject to regular review.

    The group recommended that the Intercollegiate Stroke Working Party (ICSWP) should be approached to describe the standards for such sites and that the Royal College of Physicians (RCP) Peer Review process may be used as part of the accreditation process.

With recognition for the expert advice from the participants at the Intra Arterial Intervention Consensus Meeting held on 5th October 2011:

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