

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 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:

Dr Andy Beale
Consultant Radiologist
National Clinical Lead Stroke Imaging
NHS Improvement: Diagnostics

Dr James Kennedy
Consultant Geratologist & Stroke Physician
John Radcliffe Hospital Oxford

Andrea Dayson
Assistant Director of Commissioning
NHS Stockport
Greater Manchester and Cheshire
Cardiac and Stroke Network

Dr David Kessel
Consultant Vascular Radiologist
President British Society Interventional
Radiology (BSIR)

Dr Anil Gholkar
Consultant Neuroradiologist
President British Society Neuroradiologists
(BSNR)

Jackie King
Interim Director
Essex Cardiac and Stroke Network

Dawn Good
Clinical Stroke Specialist
National Stroke Nursing Forum
Clinical Associate
NHS Improvement: Stroke

Dr Jim McLenahan
Consultant Interventional Cardiologist
National Clinical Lead
NHS Improvement: Heart

Dr Iris Grunwald
Consultant Neuroradiologist
Oxford University Hospitals NHS Trust

Dr John Millar
Consultant Interventional Neuroradiologist
Chairman UK NeuroInterventional Group
(UKNG)

Dr Paul Guyler
Consultant Stroke Physician
Clinical Associate
NHS Improvement: Stroke

Dr Christine Roffe
Consultant Stroke Physician
British Association of Stroke Physicians
(BASP)
Clinical Standards Committee

Sue Hall
National Improvement Lead
NHS Improvement: Stroke

Professor Tony Rudd
Consultant Stroke Physician
Royal College of Physicians (RCP)
Associate Director
Chair. Intercollegiate Stroke Network

Dr Damian Jenkinson
Chair
Consultant Stroke Physician
National Clinical Lead
NHS Improvement: Stroke

Adrian South
Deputy Clinical Director
South West Ambulance NHS Trust
Clinical Associate
NHS Improvement: Stroke

Dr Jozef Jarosz
Consultant Radiologist
Kings College London

Dr Phil White
Consultant Radiologist Edinburgh
British Society Neuroradiologists