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Standardising mechanical thrombectomy complication reporting: A Delphi consensus study to support guidance for national audit

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Abstract

Background: Complications following mechanical thrombectomy (MT) are common and impact on clinical outcome. However, unless complication reporting is standardised, there is scope for significant variation in results across multiple centres, potentially undermining both inter and intra unit comparisons and multicentre national quality improvement audit programmes. We therefore sought to achieve consensus amongst interventional neuroradiologists (INRs) in England and Wales for reporting of MT complications as part of national audit.

Methods: We conducted a two-round electronic Delphi survey with initial invitation to forty INR panellists representing each neurointerventional centre in England and Wales with questions covering timing, staffing and mode of data entry, specific MT complications (vessel perforation, intracerebral and subarachnoid haemorrhage, vessel dissection, vasospasm and distal or new territory embolisation) and topics for future content inclusion.

Results: There were 22 and 21 respondents in round one and two, respectively. Consensus was achieved in methods of data entry and in reporting of specific complications (strongly supportive of symptomatic haemorrhagic complication reporting rather than non-clinically relevant changes with clear definitions of when to report distal, new territory embolic or vasospastic complications or arterial dissection). There was also agreement to include tandem lesion, access site and procedural-related physiological complications in future.

Conclusion: In this exercise, we have achieved accordance and developed guidance with an emphasis on reporting of clinically relevant/outcome impacting post-MT complications, which will allow for a better standardised and more meaningful national audit process going forward.

Keywords

Stroke, thrombectomy, audit, complications

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Introduction

Mechanical thrombectomy (MT) is the standard of care for patients with large vessel occlusive stroke but it is an invasive procedure undertaken in specialist centres and complications are not infrequent.[1,2] Monitoring of the complication rate is of importance as this has the capacity to significantly impact on clinical outcome, length of stay and mortality.[3] National audit has a role in maintaining standards and highlighting areas in need of improvement, with the benefits of establishing average complication rates and other outcome measures across multiple centres.[4] For ischaemic stroke in England, Wales and Northern Ireland, this role is currently fulfilled by the Stroke Sentinel National Audit Programme (SSNAP),[5] which collects self-reported data on all stroke admissions including those patients treated with MT. With regard to the latter, a two-page data sheet covering all pre-procedural imaging, timings, technique, angiographic outcome and complications is completed. Complications are recorded using a binary tick-box method for 'distal clot migration', 'embolisation to a new territory', 'intracerebral

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Table 1. Example question.

Who should input complication data regarding MT?	1 Very Strongly Disagree	2 Strongly Disagree	3 Disagree	4 Neutral	5 Agree	6 Strongly Agree	7 Very Strongly Agree
• Neurointerventionist performing case (consultant responsible)							
• Any consultant Neurointerventionist							
• Any Neurointerventionist at centre (including trainees)							
• Stroke physician							
• Stroke nurse							
• Radiographer							
• Radiographer with Neurointerventional oversight							

haemorrhage', 'subarachnoid or intraventricular haemorrhage', 'arterial dissection or perforation' or 'other'.

When multiple MT centres' results for complication incidence were compared in 2022 using this data as part of a national communities of practice exercise (a collaboration between the NHS Getting It Right First Time Programme, the National Stroke Programme, SSNAP and Newcastle University),[6] it was clear that there was significant heterogeneity of complication rates between units. Subsequent audit in 2023–24 has demonstrated similar variation.[7] For example, rates of recorded intracerebral haemorrhage (ICH) raged from 0 to 18% and emboli to a new territory (ENT) from 0 to 36%. This could, in part, be due to technical factors around data entry; for example, if a data sheet is not fully complete and negative answers are left unchecked, this data does not contribute to the common denominator for calculation of complication rate. Alternatively, and/or additionally the discrepancy could relate to timing of data entry, the expertise or experience of the individual entering the data and their familiarity with the specific patient's case information and differing thresholds for complication reporting between operators and units.

The aim of this exercise was to use an electronic Delphi survey to develop a national consensus amongst interventional neuroradiologists (INRs) (who undertake >95% of MT cases in the UK)[7] to produce guidance around a) what constitutes definition of individual complications and need for inclusion in national audit and b) the timing and staffing of data entry in order that more comparable data can be obtained going forward. We also aimed to get consensus on any additional content necessary for a future or evolving national MT audit program.

Methods

This study was approved by the UK Neurointerventional Group's executive committee as part of the work performed by the Standards and Guidelines subcommittee of the organisation. The data collection period was May 2024 to March 2025. Based on the Delphi process literature,[8,9] we aimed to recruit between 15 and 25 panellists who could provide a representative view on MT complication diagnosis and reporting. Initially 40 invitations to participate were emailed to consultant INRs registered with the UK Neurointerventional Group representing at least one consultant in every neurointerventional unit across England and Wales. Invitations were made with an explanation for the purposes of the study that came after two presentations at bi-annual national professional meetings to the INR community. To place this in context, in the UK currently, all MT procedures occur within Regional Neuroscience Centres (RNSCs) and there were 105 INR consultants in post in 25 RNSCs in England and Wales in May 2024. The initial recruitment of these INRs for the Delphi exercise comprised a purposive sampling strategy predicated on the grounds that they possess the critical clinical and radiological knowledge and skills required for the recognition of MT complications. As procedural complications often involve angiographic or post-procedural imaging interpretation, we deliberately sought the opinion of neurointerventionalists rather than non-operators.

A period of 2 months was allocated for panellists to respond to each round. We intended to perform no more than two Delphi rounds in order to ensure the process did not become too repetitive and time-consuming to maintain an adequate response rate.

With reference to the current literature, national standards and discussions within the research team,[1,2] a Jotform.com electronic survey was constructed. The research team was blinded to the identity of respondents, whose participation was anonymous, with correspondence occurring through the Jotform website after email invitation. Piloting of the questionnaire was undertaken with members of the research team. In the first Delphi round, each panellist was asked to assign ratings using a 7-point Likert scale (1 = very strongly disagree to 7 = very strongly agree) to each of 16 stem questions governing the current audit process and future inclusions (example Table 1; stem and sub questions in each round available in Appendix 1) with the opportunity to provide free-text comments at each stage of the questionnaire. A second Delphi round was used to, where necessary, narrow or clarify consensus on points gaining a first-round positive but close response and additionally to gain agreement on supplementary points that had been raised by panellists in

the first Delphi round (these were reviewed by the research team and agreement for subsequent inclusion was achieved by consensus). If clear consensus was reached on specific points in the first round this was not included in the second. Consensus for 'approval' was defined as ≥70% of the panellists' ratings for each option falling within three categories (agree, strongly agree or very strongly agree) on the 7-point Likert scale.

Results

Twenty-two panellists from the UK Neurointerventional Group completed the first Delphi round and 21 completed the second (at top end of required range of respondents).

Mode and timing of complication data collection

Results for timing, mode and staffing of data recording are displayed in Figure 1. The results suggest that the preferred mode of data collection is by the Consultant Neurointerventionist responsible for the case (consensus in 90%), with follow-up imaging performed at 24 h (± 6hrs) (consensus in 81%) with data entry immediately after the MT procedure (consensus in 81%) and at 24hrs (consensus in 80%) when follow-up imaging is available and time has passed for complications to become apparent. Ideally in future, the preferred method of data entry would be electronic via a website or application (consensus in 76%).

Individual complications

Results for haemorrhagic complications are displayed in Figure 2. Haemorrhagic complications including ICH, subarachnoid haemorrhage (SAH) and vessel perforation are currently included in the SSNAP (though the latter is, potentially misleadingly, combined with record of vessel dissection).

- There was consensus that ICH should be included if symptomatic (whether adjudged by the local stroke team (consensus in 85%) or using formal criteria of NIHSS score increase ≥4 (or ≥2 in a subcategory of NIHSS) (consensus in 95%).
- There was consensus in 76% that SAH be included if associated with an NIHSS score increase of ≥4 and that any vessel perforation, involving a target (consensus in 100%) or conduit artery (consensus in 81%) and should be recorded if evident either angiographically or via diagnosis using post-procedural imaging even if clinical impact was mild (consensus in 100%).

A question was also included regarding contrast staining. There was consensus in 96% that post-procedural contrast staining be defined as obvious parenchymal high density in the target affected/ischaemic territory. There was also consensus in 90% that this should not be included as a procedural complication.

Potentially ischaemic complications currently included in SSNAP are vasospasm, vessel dissection, distal embolisation (DE) within the affected territory and ENT. Results are displayed in Figure 3.

- There was consensus in 100% that vasospasm be recorded as a complication if requiring pharmacological or interventional treatment. A purely radiological definition of >50% calibre reduction for >10 min did not acquire consensus support (agreement in 60% only).
- There was consensus in 71% that DE be recorded as a complication if at least one medium vessel occlusion (MeVO) occurred after MT. There was insufficient support (agreement in 57% only) to suggest that if successfully treated, this does not require record.
- There was consensus in 90% that ENTs be included only if that territory was perfused prior to the MT procedure, that this should include ACA or PCA embolisation if treatment of a terminal ICA thrombus was complicated by embolisation (consensus in 90%) and that it should be recorded if the angiographic result is less than TICI 2C in the newly affected territory (consensus in 70%).
- There was consensus in 90% for the option to respond as to whether the ENT had been (successfully) treated. There was strong support that iatrogenic target or conduit artery dissection be included rather than just the target artery (but that intra or extracranial/conduit dissections be recorded separately). There was consensus to report flow-limiting dissections (72%) but not to confine reporting to those that required medical or interventional therapy.

Additional complications

Results are displayed in Figure 4. There was consensus for inclusion of multiple acute access site complications (level of consensus in parentheses):

- arterial perforation (90%)
- dissection (95%)
- occlusion (95%)
- pseudoaneurysm (95%)
- failed closure device (85%)
- haematoma delaying discharge (90%) or requiring surgical or interventional management (90%)
- radial catheter/sheath entrapment (80%).

Any contrast allergy also had consensus for inclusion in 87%. The following procedure-related complications with physiological impact had consensus support for inclusion:

- aspiration (91%)
- prolonged hypoxia (95%)
- prolonged hypotension (91%)
- prolonged hypertension (86%)
- cardiac arrest (95%).

Another group of complications that also had consensus for inclusion were those involving tandem lesions. Symptomatic (consensus in 70%) but not asymptomatic tandem lesion re-occlusion had support for inclusion. Additionally, record of antithrombotic strategy after tandem lesion treatment had consensus support for inclusion in 100%.

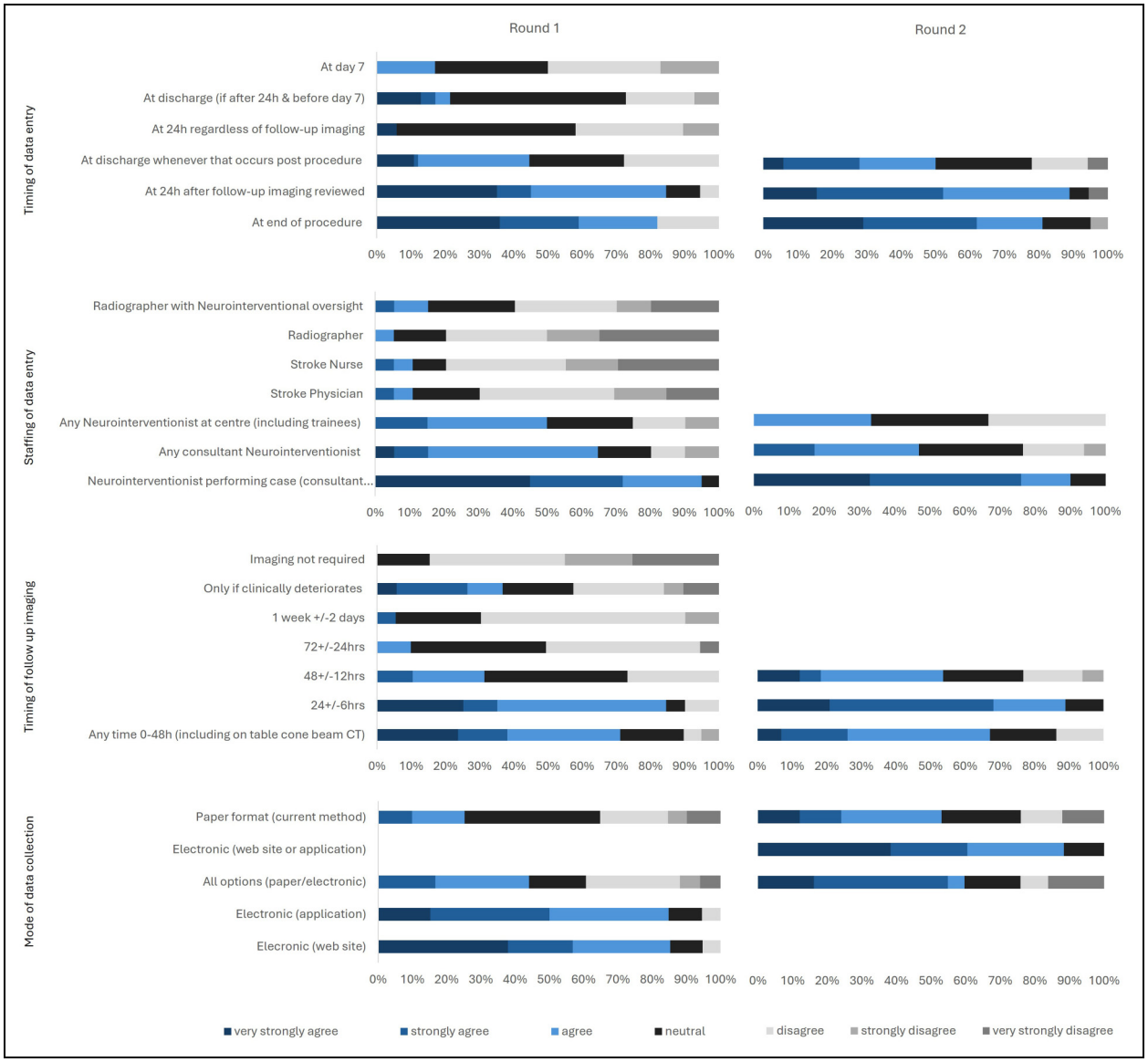

Figure 1. Relative agreement in each round for timing, mode and staffing of thrombectomy complication data collection.

Discussion

MT complications are common: in analyses of national registries based in France[3] and Italy,[10] each of over 4000 patients, procedural complications occurred in 8% and 20% of cases respectively. Similarly, a systematic review and meta-analysis of the initial MT randomised trials, reported a complication rate of 15%.[11] ENTs and vessel perforations were amongst the most numerous with significant impact on outcome in the ETIS registry.[3] In the Italian Registry,[10] SAH and arterial perforation and symptomatic ICH worsened both functional independence and mortality and DE was associated with neurological deterioration.

National audit has a role in maintaining standards through recognition of rising complication rates or declining functional outcomes to identify a need to improve patient care.[4] However, standardised definitions and processes for complication reporting are vital to ensure consistency and comparability across institutions, enabling meaningful evaluation of procedural outcomes. Without appropriate standardisation of definitions and data acquisition/entry, comparisons between centres are at best meaningless and at worst may be counter-productive (e.g. by encouraging gaming or engendering complacency). The latest SSNAP report[7] demonstrated dramatic differences in rates of complications reported between different centres: rates of ICH ranged from 0 to 18%, DE ranged from 0 to 36%, ENT ranged from 0 to 12%, SAH/IVH ranged from 0 to 17%, arterial dissection or perforation ranged from 0 to 5% and vasospasm ranged from 0 to 13%. This enormous variation between centres highlights the need for standardisation of complication reporting.

Clinical implications

Based on the results of this two-round Delphi process employing the opinion of over 20 consultant INRs working in England and Wales (>15% of the total workforce), we recommend the following for completion of national audit for MT:

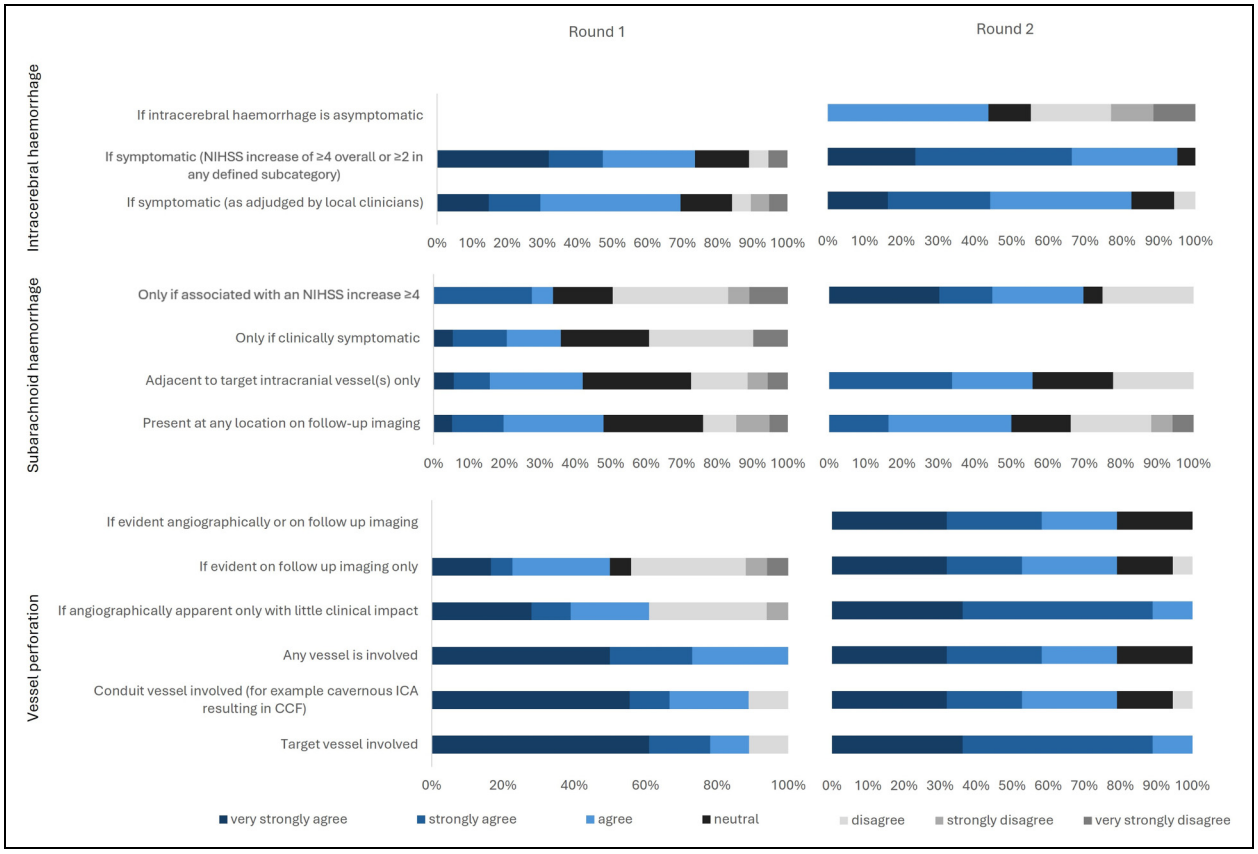

Figure 2. Relative agreement in each round for inclusion and classification of haemorrhagic complications (NIHSS: National Institutes of Health Stroke Scale; ICA: internal carotid artery; CCF: carotid-cavernous fistula).

- Follow-up brain imaging is mandatory and should be performed at approximately 24 h post-MT, if it is not needed earlier for clinical deterioration/suspicion of intra-procedural event.
- Data should be inputted immediately post procedure and after follow-up imaging at 24hrs, ideally by the consultant neurointerventionist responsible for treating the patient.
- A suitable electronic option for data input should be developed.

Regarding specific complications:

- **ICH** should be recorded if deemed symptomatic by the local stroke team or if formal criteria for clinical deterioration (NIHSS score increase ≥4 or ≥2 in a subcategory of NIHSS) are met.
- **SAH** should be recorded if present and there is an NIHSS score increase ≥4.
- **Vessel perforation** (involving a target or conduit artery) should be recorded if evident either angiographically or by diagnosis using post-procedural imaging, even if clinical impact is mild.
- **Vasospasm** should be recorded only if requiring pharmacological or interventional treatment.
- **DE** should be recorded if at least one MeVO occurs after MT.
- **ENT** should be recorded only if that territory was perfused prior to the MT procedure. This could include ACA or PCA embolisation if treatment of a terminal ICA thrombus was complicated by embolisation. It should be recorded if the ultimate angiographic result is less than TICI 2C (<90% perfused) in the newly affected territory.
- Either target or conduit artery **iatrogenic dissection** should be recorded and differentiated as to whether flow limiting.
- There should be an option to record whether DE or ENT have been treated and whether iatrogenic injuries involve intra- or extracranial or target or conduit arteries.

Regarding future audit development, the following complications should be recorded:

- All allergic contrast reactions.
- Acute access site arterial complications (dissection/occlusion/pseudoaneurysm/closure device failure), and clinically relevant haematoma formation.
- Symptomatic re-occlusion of tandem lesions (whether stenting or angioplasty performed).
- Complications relating to the procedure that could have a physiological clinical impact including aspiration, prolonged hypoxia, marked hypo- or hypertension (necessitating active management) and cardiac arrest.

Importantly for the first time, we have developed guidance on approaching contrast staining post-MT, an extremely common phenomenon,[12] whereby we had very strong

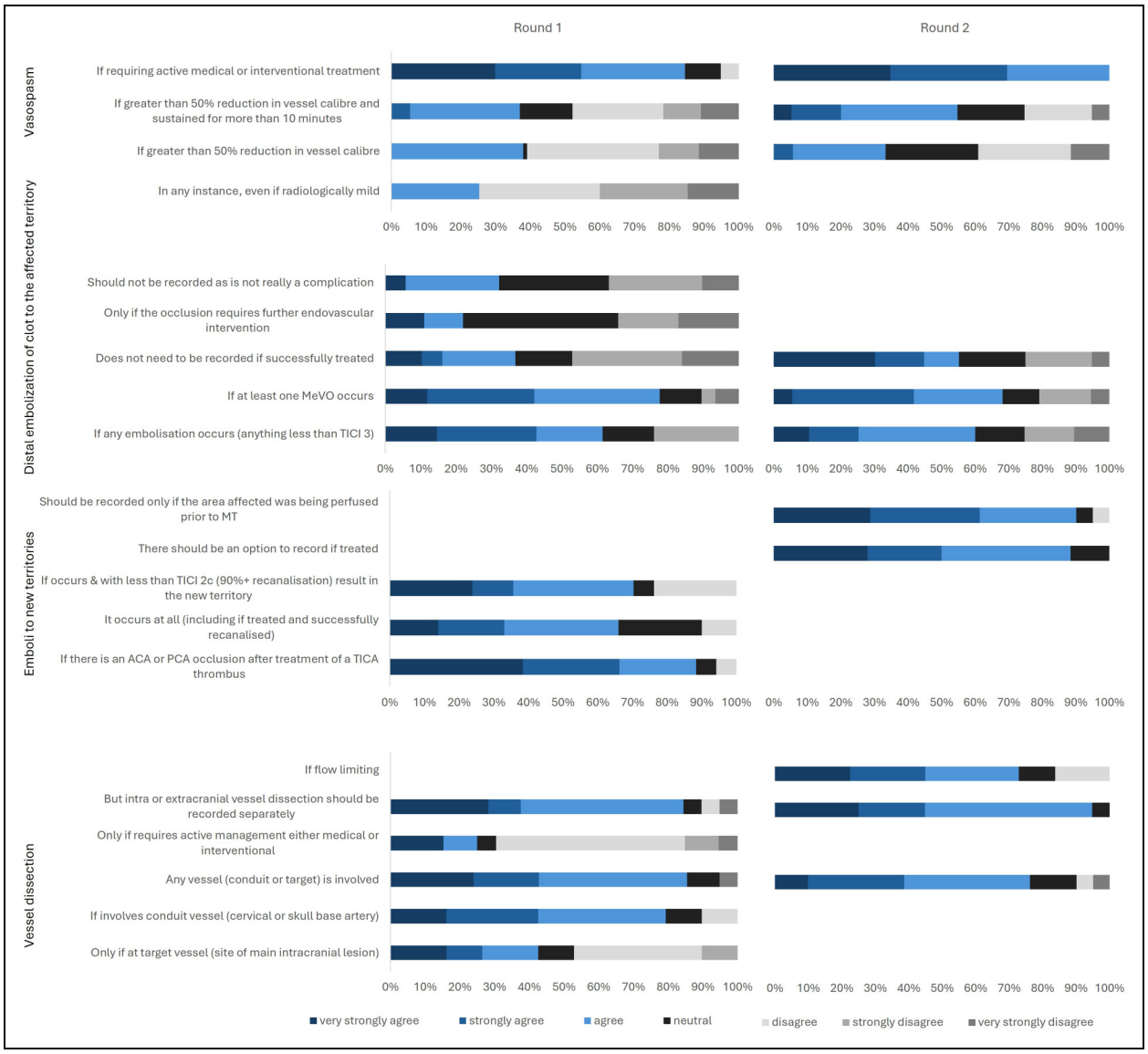

Figure 3. Relative agreement in each round for inclusion and classification of ischaemic complications (MeVO: medium vessel occlusion; TICI: Thrombolysis in Cerebral Infarction; MT: mechanical thrombectomy; ACA: anterior cerebral artery; PCA: posterior cerebral artery; TICA: terminal internal carotid artery).

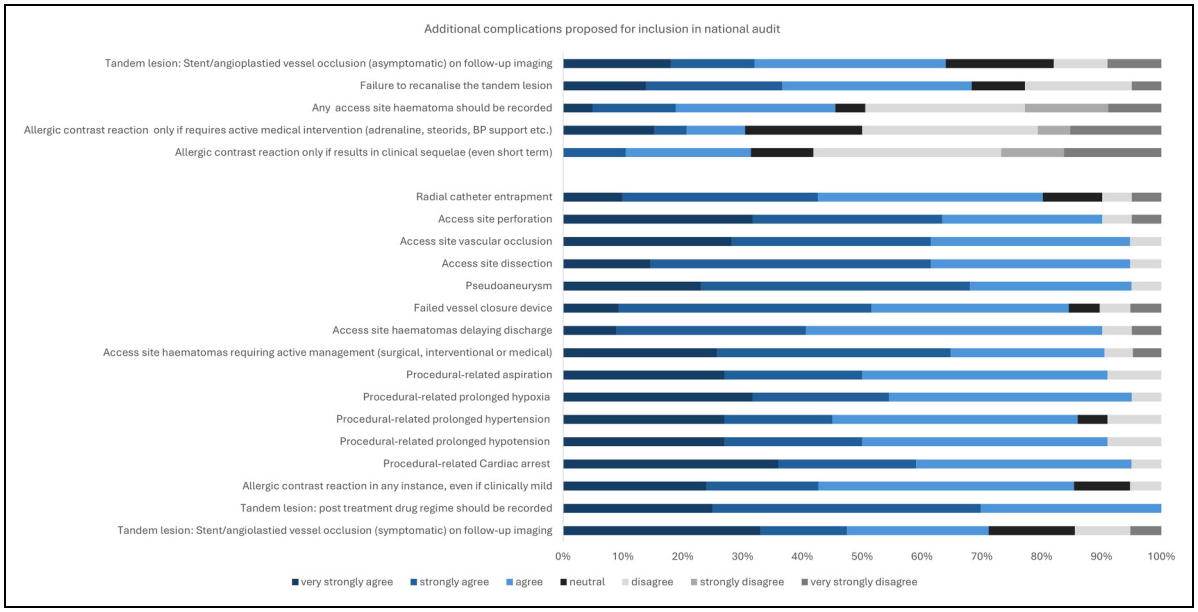

Figure 4. Relative agreement for inclusion of additional content in national audit (BP: blood pressure).

consensus on both its definition and reporting (not a complication). The literature appears divided on the consequences of contrast staining[13] but it is likely difficult to resolve its impact from that of an associated infarct with blood–brain barrier disruption.

One of the most impactful complications for patients of MT is ENT[3] and here we achieved strong consensus on both the definition and recording of outcome, which will be critical to focussing quality improvement initiatives on the most impactful (i.e. clinically relevant and important) complications. The consensus achieved in this exercise favoured record of symptomatic complications but not over-recording of more benign non-clinically relevant complications such as SAH or ICH that are asymptomatic or without appreciable NIHSS score increase. Any ICH is common, occurring in around 30% of cases but symptomatic ICH is much less common at ~4% and there is debate as to the clinical significance of asymptomatic ICH or SAH.[14–17] However, reporting of ICH varies on definition used, when/who records and whether routine imaging follow-up of MT is performed (and how/when done). As a result, it is extremely likely that the wide post-MT variation in ICH rate recorded in SSNAP (0–18% with modal rate of 0%) is due to variable identification/recording/reporting of ICH.[7] Inconsequential DE (3–4%), vasospasm (4–23%) and SAH (1–5%) accounted for at least a third of the overall 15% complication rate identified in a meta-analysis of the initial HERMES MT trials.[11]

Currently in the SSNAP audit, there is a lack of clarity or standardisation of any of these issues. Our recommendations on who should report complication data (and when) plus consensus achieved to refrain from reporting of incidental ICH, incidental vasospasm or incidental/minimally symptomatic SAH or minor non-flow-limiting arterial dissections[18] would help improve accuracy and streamline the audit process. Adoption of the definitions and reporting guidelines could facilitate meaningful comparisons within and between units. Importantly, standardisation could impact on the overall complication rate, bringing it closer to the 8% reported in the ETIS Registry[3] rather than the 20% reported in SSNAP data,[7] which is not only more realistic but may reassure referrers, patients and the wider public about MT in the UK.

Strengths and limitations

This study offers auditors and clinicians valuable data that previous research on MT complications has not captured, using a well-established methodology that has been employed since the 1950s.[19,20] The initial round of the Delphi process presented a broad array of options, whilst the subsequent round allowed for a more focused exercise aimed at reaching consensus and addressing points raised in the first round. Like any Delphi study, the findings may be influenced by how the study team formulated specific propositions. Variations in wording could have led to different nuances in the results.[19] This limitation is heightened by the closed, pre-defined nature in which the options were presented to participants. Nevertheless, the first round included a comprehensive range of options for each stem question. These were informed by existing literature on thrombectomy complications and refined through detailed discussions within the research team. Whilst acknowledging that some options had weaker evidential support or limited feasibility in practice, all were included intentionally. The goal of this Delphi process was also to reach expert consensus on which options were less effective or practical, rather than to restrict the scope from the outset. Additionally, a free-text comment box was provided, and participants' input was reviewed and integrated into the second round where appropriate.

Conclusion

Through a Delphi study, we have gathered widely representative expert opinions on audit of MT complications in the UK and developed proposed recommendations to improve and enhance the process. Two Delphi rounds achieved strong consensus across most options presented. By implementing these recommendations, audit can more accurately reflect procedural performance and better support clinical improvement.

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Supplemental material

Supplemental material for this article is available online.

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