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Research Article

Development of a New Thrombectomy Technical Difficulty Index (TTDI)

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Abstract

Aim: Multiple recent trials have proven the efficacy of thrombectomy in large vessel occlusive stroke and earlier reperfusion correlates with improved outcomes. We developed a thrombectomy technical difficulty index (TTDI) to predict the expected procedural difficulty as an aid to operator decision making for the achievement of a fast and successful recanalization.

Materials and Methods: Key thrombectomy factors were used to grade predicted difficulty of thrombectomy on a 3-point scale, from minimal, mild to moderate to severe. Thirty patients that underwent thrombectomy had their computed tomography angiograms scans analysed by seven neurointerventionists using the TTDI to predict level of difficulty to establish its reliability (intra-class correlation, ICC) and validity.

Results: An almost perfect level of agreement on TTDI scores between the 7 neurointerventionists was reported (ICC = 0.89, 95% CI = 0.81 to 0.94), and an expert INR opinion of case difficulty using the TTDI (ICC = 0.861, 95% CI = 0.77 to 0.93). Validity analysis showed that that length of procedure was shorter for minimal compared to mild to moderate difficultly cases as assessed with TTDI.

Conclusion: The TTDI is a promising tool to assess predicted thrombectomy case difficulty, allowing operator to consider potential problems and inform decisions about whether a modification to technique, including access, equipment and anaesthesia, should be considered. Larger prospective studies evaluating the TTDI are warranted.

INTRODUCTION

Over the past twenty years, the development of revascularisation treatment with intravenous thrombolysis (IVT) has led to improvements in stroke outcomes [1,2]. Recently, multiple trials have demonstrated improved outcomes with mechanical thrombectomy, paving the way for major changes in the acute management of patients with ischaemic stroke [3-11].

Thrombectomy can be performed in patients with contraindications to IVT and in those presenting later than the 4.5 hours' time frame for which IVT is licensed [12]. Even if a patient presents within 4.5 hours and has no contraindications to IVT, recanalization rates with IVT are poorer in patients with more proximal and longer occlusions; 8-40% depending on location [13].

From recent thrombectomy trials, a good reperfusion rate, as assessed by a modified treatment in cerebral ischaemia (mTICI) 2b/3 score, varied between 58-88% [3-11]. However, thrombectomy can be technically very challenging especially in elderly patients with tortuous atherosclerotic vasculature. In this study, we present a new technical scoring index that allows neurointerventionists to rapidly and reliably predict the difficulty of a thrombectomy procedure. This could usefully inform: (a) decisions on the techniques to be used (route of arterial access, equipment, general anaesthetic versus sedation, first pass thrombectomy technique: eg. aspiration, stent retriever or a combination) and (b) structure information provided to patients/relatives during assent conversations. However, due to the time critical nature of thrombectomy any such assessment tool needs to be evidence-based, intuitive and capable of being rapidly completed and interpreted.

MATERIAL AND METHODS

Development of the Thrombectomy Technical Difficulty Index (TTDI)

Five domains were included in the TTDI based on relevant literature review of factors affecting the difficulty when performing a mechanical thrombectomy: aortic arch anatomy; vascular tortuosity; stenotic disease; clot burden score; and any other extra anatomical or pathological problems (Appendix 1). The TTDI was designed to be used in conjunction with CTA examinations prior to performing a thrombectomy procedure.

The TTDI underwent clinical face and content validity assessment by 5 consultant neurointerventionists who suggested minimal refinements to the proposed assessment tool.

The total TTDI score represents a technical difficulty index (scores of ≤ 4 representing minimal difficulty, 5-7 representing mild to moderate difficulty, and ≥ 8 representing severe difficulty) by summing the scores assigned to each of the five domains (Appendix 2).

A) A TTDI scoring proforma was developed, which included key images as an aide memoire (Appendix 3). A laminated proforma was placed next to workstations used for stroke CTA assessment by neurointerventionists.

Aortic arch elongation

Examples of the three-standard different aortic arch elongation grades were presented on the proforma (Figure 1a).

B) Head & neck target artery tortuosity

We utilised a three-point qualitative scale to assess tortuosity of the target artery; this refers to the artery that needs to be accessed with endovascular tools. The descriptions with illustrative examples of the scale used are shown in Figure 1b.

C) Target artery stenosis

Any target artery stenosis was classified as follows: <50%, 50 – 69%, 70 – 95% and acute occlusion / critical stenosis and these were assigned scores of 0, 1, 2 and 3 respectively (Appendix 2).

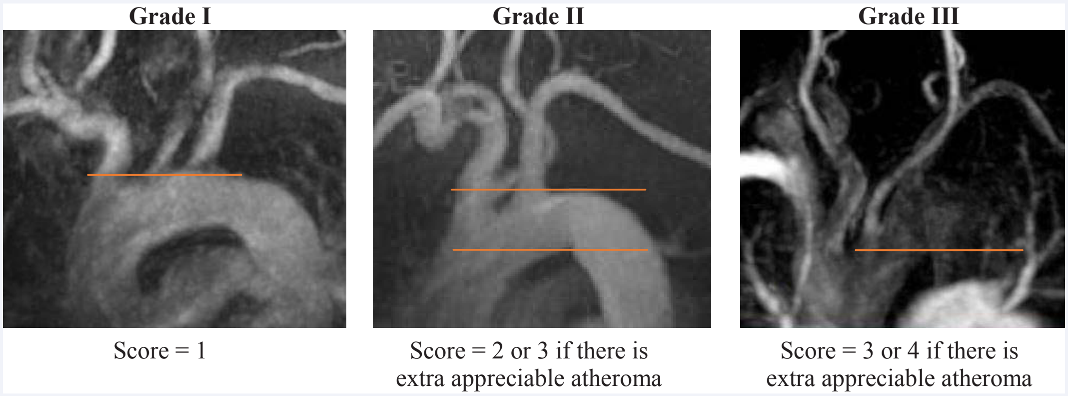

Figure 1a Aortic Arch Elongation Classification.

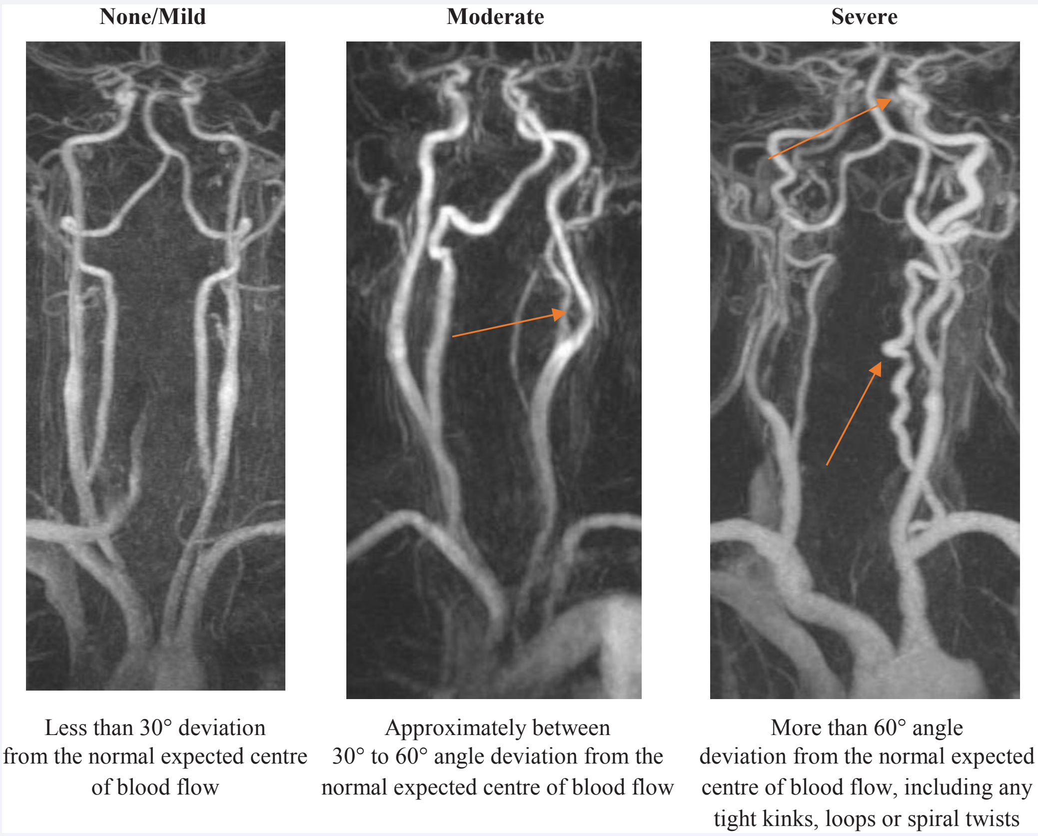

Figure 1b Cervical Arterial Tortuosity Qualitative Scoring.

D) Clot burden score

For this domain, we used a previously described clot burden score [12-14] for patients with anterior circulation strokes (Figure 2). A score of 10 is normal and points are subtracted depending on the thrombus location. A CBS of 8 or greater was classed as mild and scored 0; a CBS of 6-7 was classed as moderate and scored 1; a CBS of ≤ 5 was classed as severe and scored 2.

For posterior circulations strokes there is no accepted clot burden scoring. Therefore, a simple thrombus scoring tool was utilised:

- Minimal to mild thrombus: PCA or another single branch beyond basilar tip, or isolated basilar clot (<1/3 occluded) – score 0
- Moderate thrombus: <2/3 Basilar trunk + another vessel with clot occlusion, or >2/3 but not entire basilar trunk occluded but not entire basilar trunk occluded – score 1
- Severe thrombus: Vertebral + >1/3 basilar vessel clot, or 3/3 basilar affected, or >2/3 basilar + another major vessel (PCA/SCA/PICA) – score 2

E) Additional problems (e.g. variant anatomy)

A further single point can be added to the TTDI score (at the discretion of the neurointerventionist) if any other problem that could potentially lead to procedural difficulty is identified. These could include any of tandem occlusion, aortic coarctation, common brachiocephalic trunk (bovine arch) if left carotid territory clot, variant origin of the vertebral artery, right aortic arch, double aortic arch and any other relevant variant anatomy. In addition, any other pathology that could potentially lead to procedural difficulty could also attract an extra point to the TTDI score- including known severe peripheral vascular disease (PVD), International Normalized Ratio/Prothrombin Time significantly prolonged or other arterial access problem. A maximum of 1 point for "additional problems" can be added irrespective of the number of issues.

Patient Selection and Data Collection

A consecutive sample of data on 30 patients who underwent mechanical thrombectomy at our institution with a comprehensive CT angiogram (CTA) as part of their initial assessment were collected retrospectively from routine audit information and used to assess the reliability and validity of the TTDI.

CTA studies were imported from our local PACS (Picture Archiving and Communication System) and fully anonymised. One senior consultant INR (PW) with more than 15 years' experience reviewed each case and assigned an expected procedural thrombectomy difficulty rating for each case: minimal, mild to moderate or severe difficulty. These ratings were used as the reference standard for assessing the extent of agreement (intra-class correlation, ICC) between the TTDI scores assigned to each patient by the 7 INRs. The ICC was also used to assess the extent of agreement of the 7 INRs with the expert opinion.

Landis and Koch provided guidelines for interpreting ICC values and, specifically, values between 0.61 to 0.80 indicate substantial agreement, with values of 0.81 to 1.0 indicating almost perfect to perfect agreement (15).

A total of 7 INRs (1 senior consultant >10y experience, 3 senior- consultants of >2y experience, 3 junior – senior trainee or consultant of <2y experience) used the TTDI to assess each case. No clinical details were provided, except what was present on the scans and whether the thrombus was on the right/left side or in the anterior/posterior circulation. The total time that each INR took to assess all cases with the TTDI was recorded.

The TTDI category for each case scored by the 7 INRs was subsequently analysed with reference to data on actual

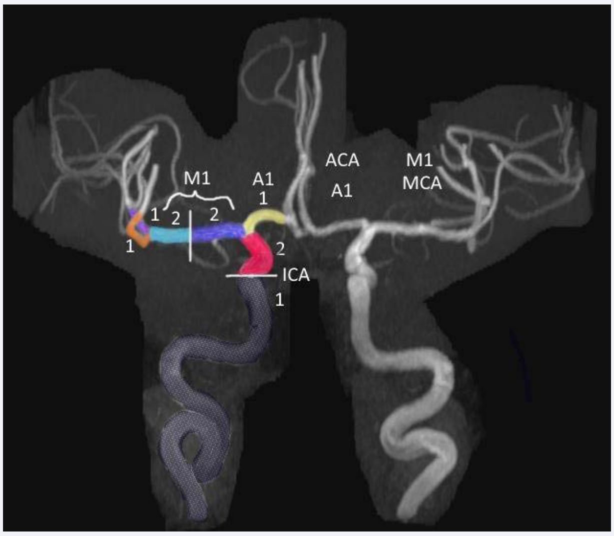

Figure 2 Clot burden score in the anterior circulation. There is a total of 10 points and the score is calculated by subtracting points according to clot location: 2 points are subtracted for thrombus in the supraclinoid ICA and each of the proximal and distal halves of the MCA trunk. 1 point is subtracted for thrombus in the infraclinoid ICA, in the A1 segment and for each affected M2 branch. For example a carotid T occlusion with thrombus in the distal ICA, the proximal A1 ACA and the proximal M1 MCA would have a clot burden score of 10–(2 +1+2)=5.

procedure duration, number of devices used, recanalization using the mTICI (modified Treatment in Cerebral Infarction) grading of angiographic reperfusion and the 90 day mRS (obtained from ongoing stroke and thrombectomy audits). For this analysis, each case was attributed a consensus thrombectomy difficulty score by using the average TTDI score as determined by the 4 senior INRs. Appropriate tests of differences (independent t tests and Mann-Whitney U tests) were used to establish whether actual data on procedures differed as a function of TTDI categories (due to the small number of severe cases, analyses were conducted using cases assigned as minimal and mild to moderate difficulty).

RESULTS

Data from thirty patients, 19 male and 11 female, of median age 72 (range 33 – 87) was assessed. They had a median NIHSS (National Institutes of Health Stroke Scale) of 18.5 (IQR = 13.5 – 22.5). Occlusion location was present in the M1 MCA in 18/30 (60%), ICA in 5/30 (17%), M2 MCA in 3/30 (10%), basilar artery in 3/30 (10%) and vertebral artery in 1/30 (3%). Treatment with IVT was administered in 16/30 (53%) of patients. Symptom onset to groin puncture was achieved in a median of 216 min (IQR 188 – 285). Symptom onset to reperfusion was achieved in a median time of 276 min (IQR 228 – 333).

Neurointerventionists recorded the total time to look at all cases and this resulted in a range of between 2 to 4 minutes to assess a case with the TTDI.

Reliability analysis

Intra-class correlation coefficient (ICC) between ratings from the 7 INRs was 0.89 (95% CI = 0.81 to 0.94), indicating almost perfect agreement; Once the TTDI score was categorized into a difficulty grading (minimal, mild to moderate, severe), the ICC was 0.85 (95% CI = 0.75 to 0.92).

The ICC for the TTDI scores between the reference expert opinion and the other 7 INRs was 0.86 (95% CI = 0.77 to 0.93).

Validity analyses

Out of the 30 patients, 15 patients (50%) were assigned a minimal level of difficulty (TTDI ≤ 4), 13 patients (43%) were assigned as [mild to moderate] difficult (TTDI 5-7) and only 2 patients (7%) as severe difficulty (TTDI ≥8).

Mean procedure duration was 46 (SD=20), 73 (SD=36) and 59 minutes for the patients in the minimal, mild to moderate and severe categories respectively. Further analysis showed that there was a trend towards increase in fluoroscopy times from the minimal to the [mild to moderate] category. The mean difference for procedure duration between minimal difficulty cases compared with the TTDI mild to moderate group was -27.61 mins, 95% CI = -50.02 to -5.19 mins; this was statistically significant t = -2.437 [df=26], p = 0.025.

The mean number of thrombectomy devices used was 1.1, 1.3. and 2 for the patients in the minimal, mild to moderate and severe categories respectively. The mean number of devices used between cases assigned as minimal and [mild to moderate] difficulty was not statistically significant (p = 0.132).

Good recanalization rates (2B/3) were achieved in the majority of patients within the minimal and [mild to moderate] category, and in half of the patients within the severe category, see Table 1. mTICI between cases assigned as minimal and mild to moderate difficulty was not statistically significant (p > 0.05).

The mRS at 90 days post thrombectomy as a function of TTDI category is shown in Figure 3. 53% (8/15) of the patients assigned a minimal difficulty category TTDI (score ≤ 4), had a good outcome (mRS 0-2). For patients within the mild to moderate category, only 8% (1/13) had a good outcome, with approximately half with mRS = 3. For patients in the severe difficulty category, neither of the 2 patients had good functional outcome; despite good recanalization being achieved in one of these patients. However, the 90 day mRS outcome between cases assigned using TTDI as minimal and [mild to moderate] difficulty was not statistically significant (p > 0.05). In terms of procedural complications, 2/30 (7%) patients had intracranial subarachnoid hemorrhage, one symptomatic and one asymptomatic; and another 2/30 (7%) patients had groin hematomas, none of which were life threating.

DISCUSSION

Previous studies based on carotid artery stenting analysed multiple factors associated with a higher procedural complexity including: femoral arterial access, the arch anatomy, carotid artery tortuosity, stenotic grade and calcification [15]. Similarly, for thrombectomies different anatomical and pathological factors, including thrombus location and length have the potential to impact significantly on the procedure and its final outcome.

We developed a simple, rapid (for practising neurointerventionists) clinical tool to assess technical difficulty of undertaking thrombectomy for acute stroke. The TTDI demonstrated excellent inter-rater agreement between the raters, including difficulty ratings assessed at baseline by expert opinion. This demonstrates the TTDI is reliable for use in clinical practice.

The fluoroscopy time was not longer for the patients in the severe category, presumably because only 2 patients were in this sub-group and one of the cases was abandoned fairly rapidly as ICA access was simply not possible. A trend towards using more devices with increasing difficulty grade was demonstrated. Good recanalization with a mTICI score of 2B/3 was achieved in ~75% of patients within the minimal and mild to moderate categories and within 50% of the severe category, again showing a trend towards better procedural success for patients with lower TTDI scores.

Most importantly, there was a statistically significant difference in the length of procedure between minimal and [mild to moderate] difficulty categories, with shorter times for patients with minimal technical index scores on the TTDI, which provides evidence of the predictive validity of the TTDI.

To our knowledge there is no other technical difficulty assessment tool currently being advocated for pre op evaluation of thrombectomy procedures. A previous small study of carotid stenting has shown that anatomical vascular assessment using contrast enhanced MR angiography prior to surgery, altered the operative technique in 38% of patients and the procedure was aborted in 5% due to unfavourable anatomy [16].

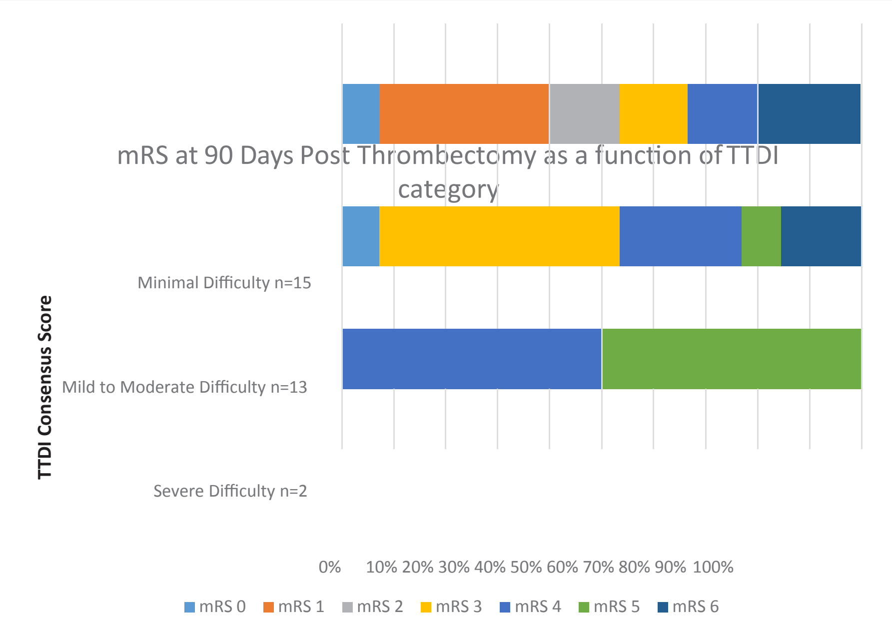

Figure 3 mRS outcomes at 3 months post thrombectomy as a function of TTDI category.

Table 1: mTICI recanalization and predicted difficulty on TTDI; % rounded to nearest whole number.

mTICI	Minimal Difficulty N = 15	Mild to Moderate Difficulty N= 13	Severe Difficulty N = 2
0	3 (20%)	1 (8%)	1 (50%)
1	1 (7%)	2 (16%)	0
2A	0	0	0
2B	4 (27%)	3 (23%)	1 (50%)
3	7 (47%)	7 (54%)	0

There are however several limitations. This is a small retrospective study of only 30 consecutive patients in a single centre with outcomes derived from routine audit data (and thus they are not independently assessed). There were also difficulties with assessing very long clots as the vessel of interest could not readily be adequately visualised. In these instances, the contralateral circulation was assessed for an approximation, although this in turn does have its limitations; for example, in extensive ICA clots, there may be a very tight stenosis that is not fully appreciated. Another limitation is that there were patients at the start of the retrospective data collection period who had thrombectomy before all current modern thrombectomy techniques were available (large bore distal aspiration catheters). However, this is a minor limitation as RCT data on MT are predominantly stent-retriever based and in such a fast moving field, new device iterations are so common that any study accruing data over more than a few months would be exposed to this problem (i.e. we recognise it as a limitation but couldn't realistically have prevented it).

The newly developed TTDI is a promising tool that can be used before performing a thrombectomy. It allows the neurointerventionists to take a few focused minutes to fully consider all the factors which may influence the procedure. It can help with decisions regarding anaesthesia (local sedation versus a general anaesthetic), whether there are any possible access issues (possibility of needing a prepared ultrasound machine nearby or whether a different access site should be considered), if for example the aortic arch is of higher grade and/or the great vessels are tortuous, it may prompt the interventionist to start the procedure directly with a different catheter better suited for those situations.

Depending on the clot burden, it may also help with deciding how to perform the initial pass: stent retriever, direct aspiration or a combination of both. The TTDI score together with the clinical picture may also be used for consenting purposes, possibly predicting the chances of success and relating this information to the patient and/or relatives. This may be very useful in the older patient population (≥ 80) where outcomes are poorer overall and it is useful to look at all the available tools for decision making.

Our study may affect thrombectomy planning and delivery, however further work is needed to assess the TTDI using prospective cases, in different centres and in a larger number of patients, to better evaluate its usefulness for decision making prior to thrombectomy and consent purposes.

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COMPETING INTERESTS

G A Ford has received personal remuneration for lectures or advisory Board work from Bayer, Daiichi Sankyo, Medtronic, Stryker, and Pfizer. His employing organisation has received unrestricted educational grants relating to stroke management from Medtronic and Pfizer.

P M White reports personal fees from MicroVention-Terumo and institutional grants from Stroke Association, Stryker, Penumbra, Medtronic and NIHR EME and RfPB outside the submitted work

STUDY APPROVAL

This study was done retrospectively using clinical audit data therefore not requiring ethics approval in the UK.

FUNDING

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