Correlation between imaging markers and clinical and radiological outcome in hyperacute stroke patients undergoing thrombectomy

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Nicholas O Wroe, Robert P Palin, Tufail Patankar, Alastair Bailey, Mark Igra, Tony Goddard

**Abstract**

**INTRODUCTION:** To determine whether imaging biomarkers or clinical characteristics could be used to predict recanalisation and 90-day outcomes in stroke patients undergoing mechanical thrombectomy.

**METHODS:** Forty-three patients undergoing mechanical thrombectomy between 2009 and 2015 were included for analysis. Non-contrast CT (NCCT) determined clot density in Hounsfield Units (HU) and volume, along with Alberta Stroke Program Early CT Score (ASPECTS) on admission and at 24 h. CT angiography (CTA) yielded clot length, clot burden score (CBS) and collateral score (CS). Intraoperative fluoroscopy was used to determine thrombolysis in cerebral infarction (TICI) scores pre- and post-treatment. The principle outcome measure was the modified Rankin Scale (mRS) at 90 days. **RESULTS:** The only biomarker in the acute phase that predicted 90-day mRS was admission ASPECTS (p=0.0186). Non-significant trends towards positive outcome were seen with low clot volume (p=0.45), shorter clot length (p=0.33) and favourable collateral score (2 or 3, p=0.319). There was no association between outcome and clot density (p=0.67) or CBS (p=0.792). None of the biomarkers significantly predicted successful recanalisation. **CONCLUSIONS:** ASPECTS can be used to predict 90-day-mRS and thus outcomes in hyperacute stroke patients.

**Keywords:** thrombectomy, volumetry, ASPECTS, mRS, biomarkers

**Abbreviations**

<table>
<thead>
<tr>
<th>ACA</th>
<th>Anterior cerebral artery</th>
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<tbody>
<tr>
<td>ASPECTS</td>
<td>Alberta Stroke Program Early CT Score</td>
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<tr>
<td>CBS</td>
<td>Clot burden score</td>
</tr>
<tr>
<td>CS</td>
<td>Collateral score</td>
</tr>
<tr>
<td>CT</td>
<td>Computed tomography</td>
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<td>CTA</td>
<td>CT angiography</td>
</tr>
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<td>HU</td>
<td>Hounsfield units</td>
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<td>Internal carotid artery</td>
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<td>mRS</td>
<td>modified Rankin Score</td>
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<td>NCCT</td>
<td>Non-contrast CT</td>
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<td>NICE</td>
<td>National Institute for Care Excellence</td>
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<td>NIH</td>
<td>National Institute for Health</td>
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<td>NIHSS</td>
<td>National Institute for Health Stroke Score</td>
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<tr>
<td>MCA</td>
<td>Middle cerebral artery</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
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<tr>
<td>PISTE</td>
<td>Pragmatic Ischaemic Stroke</td>
</tr>
<tr>
<td>ROI</td>
<td>Region of interest</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>TICI</td>
<td>Thrombolysis in cerebral infarction score</td>
</tr>
</tbody>
</table>

Correlation between imaging markers and clinical and radiological outcome in hyperacute stroke patients undergoing thrombectomy

Nicholas O Wroe* (Corresponding Author) — University of Leeds Medical School, Leeds, UK

Correspondence: 27 Whitton Close Swavesey, Cambridge, CB24 4RT, UK

Email: um11nop@leeds.ac.uk | Mobile: +44 (0) 7547759920

Robert P Palin* — University of Leeds Medical School, Leeds, UK

Tufail Patankar — Department of Interventional Neuroradiology, Leeds Teaching Hospitals Trust, Leeds, UK

Alastair Bailey — Brain Attack Team, Leeds Teaching Hospitals Trust, Leeds, UK

Mark Igra — Department of Radiology, Leeds Teaching Hospitals Trust, Leeds UK

Tony Goddard — Department of Interventional Neuroradiology, Leeds Teaching Hospitals Trust, Leeds, UK

* NW and RP contributed equally to this study and are joint first authors

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Introduction

As the fourth leading cause of death and a major cause of adult disability in the United Kingdom (UK), stroke presents a major health burden both for the National Health Service (NHS) and informal carers, with an economic cost of around £9 billion [1]. The current treatment paradigm of thrombolysis within 4.5 h of symptom onset [2,3] carries a risk of haemorrhage [3] and is only given in 2-10 % of acute ischaemic strokes [4]. Intravenous treatment is effective in fewer than 30 % of large vessel occlusions [5].

Endovascular treatments using stent retriever devices offer emergent reperfusion with higher recanalisation rates [6] and the potential for treatment outside the 4.5 h window [6]. Recent major trials have been published which confirm thrombectomy as the future of large vessel anterior circulation stroke treatment [7-11]. The Dutch trial MR CLEAN (n=500) showed thrombectomy to be “effective and safe” in large vessel occlusion within 6 h of symptom onset, reporting an absolute increase of 13.5 % in patients with good functional outcome with intra-arterial over intravenous treatment [9]. SWIFT PRIME (n=196) showed an even greater improvement in good functional outcome of 25 % when thrombectomy was combined with intravenous therapy and was thus stopped early [10].

EXTEND-IA (n=70), ESCAPE (n=316) and REVASCAT (n=206) were also stopped early due to efficacy [7,8,11]. The key to the positive results of these trials appears to be patient selection. EXTEND-IA used perfusion CT to identify treatable infarcts [7], whereas ESCAPE excluded patients with particularly large infarct cores or poor collateral circulation [8]. Collateral circulation to maintain some perfusion to the ischaemic area has previously been associated with favourable outcomes [12]. The implementation of endovascular stroke reperfusion in the UK likely rests on the on-going Pragmatic Ischaemic Stroke Thrombectomy Evaluation (PISTE), which is recruiting patients from across the country and is scheduled to finish in 2018 [13].

For thrombectomy to be implemented nationally, a good understanding of prognostic factors is key: this paper aims to see if clinical and radiological biomarkers, such as clot morphology and collateral circulation, can be used to predict clinical outcomes and hence which patients will benefit from thrombectomy.

Methods

Data were collected from 79 consecutive patients who received mechanical thrombectomy for acute ischaemic stroke between 2009 and 2015. Posterior circulation strokes were excluded (n=32) as these have worse clinical outcomes [14]. Of the remaining anterior circulation strokes (n=47), three were excluded for missing data. A single case of anterior cerebral artery (ACA) occlusion was also excluded, leaving 43 patients for analysis.

Non-contrast CT (NCCT) imaging, CT angiography (CTA) (where available) and intraoperative fluoroscopy images were collated for each patient. Demographic data were extracted from clinical notes or BlueSpier records, as was the time of symptom onset. The time at which reperfusion was achieved - and hence the interval between symptom onset and reperfusion - was recorded from the earliest “post procedure” fluoroscopy acquisition available.
Image Analysis

Clot volumetry was assessed on NCCT using manual segmentation of image regions of interest (ROIs) by two observers - RP and NW - to determine interobserver agreement. Image analysis was conducted using OsiriX; clot volume was obtained either through volume rendering or integration of ROI areas across slice thicknesses. Clot density was defined as the mean pixel intensity in Hounsfield units (HU) across all thrombus-containing ROIs. Clot length was estimated from maximum intensity projections on CTA. NCCT was also used to determine the Alberta Stroke Program Early CT Score (ASPECTS), which has well validated interobserver agreement [15]. Starting from 10 points, one point is deducted for ischaemic changes such as hypodensity or loss of grey-white matter differentiation in each of the following areas [16]: caudate, putamen, internal capsule, insular cortex and the cortical territories of M1-M6 [16]. A second ASPECTS was taken from NCCT at 24 h, as described by Liebeskind DS et al. [17], which has been shown to better predict outcome than baseline ASPECTS.

CTAs were assessed to determine both clot burden score (CBS) and collateral score (CS) as described by Tan et al. [12]. CBS is also a subtraction system from 10: two points are subtracted for thrombus in the proximal or distal half of the middle cerebral artery (MCA) or the supraclinoid internal carotid artery (ICA). One point is subtracted for thrombus visible in each M2 branch, the anterior cerebral artery or the infratentorial ICA [12].

CSs were calculated from CTA on a scale of 0-3 as follows [12]:

- **CS = 0**: no collateral filling to the ischaemic territory
- **CS = 1**: collateral vessels filling ≤50 % of the ischaemic territory
- **CS = 2**: collateral vessels fill >50 % but ≤100 % of the ischaemic territory
- **CS = 3**: collateral vessels fill 100 % of the ischaemic territory

Clinical data was derived from BlueSpier records where available or from clinical notes. The NIHSS from 0-42 was taken on admission to describe clinical stroke severity in the sample. Full details of the National Institute for Health Stroke Score (NIHSS) criteria can be found on the National Institute for Health (NIH) website [18].

CS, thrombolysis in cerebral infarction score (TICI) and ASPECTS were calculated by Consultant Radiologist TP. Medical students RP and NW conducted volumetry, and clot lengths were measured by NW and checked by TP.

Outcome Measures

The primary outcome measure was modified Rankin Score (mRS) at 90 days. Details of the scale from 0 (no symptoms) to 6 (dead) can be found on The Stroke Centre website [19]. The mRS is well validated as a reliable measure of functional outcome in stroke [20].

Radiological outcome, e.g. technical success of the procedure, was determined on fluoroscopy using the TICI score [21] as a measure of recanalisation of the occluded vessel and hence reperfusion. Study definitions of TICI categories vary [22]. This study uses the TICI score as originally defined by Higashida et al. [21]:

- Grade 0: no perfusion
• Grade 1: penetration beyond the obstruction but minimal perfusion
• Grade 2a: partial perfusion of less than half of the occluded territory
• Grade 2b: complete filling of territory, slower than normal
• Grade 3: total perfusion of territory

Statistical tests
Testing was conducted using STATA. Functional outcome at 90 days was dichotomised into “good” (mRS ≤ 2) or “bad” (mRS > 2). Similarly, the TICI score was divided into “successful” (TICI 2b or 3) or “unsuccessful” (TICI 0, 1 or 2a) recanalisation of the vessel. CS was divided into “good” (CS 2 or 3) and “poor” (CS 0 or 1). Means were reported as ± standard error. The time from symptom onset to reperfusion and clot density showed normal distribution: these were analysed by a two-sample t-test. Non-parametric analysis was used in all other cases: chi squared test was applied to binary exposures and the Wilcoxon Signed Rank (Mann-Whitney U test) to non-binary exposures. Bland-Altman plots and Pearson’s Correlation Coefficients assessed inter-rater and intra-observer variability for clot volumetry.

Results
Of the 44 patients, there were 17 missing data points, meaning the dataset was 98.5 % complete. Thirteen patients did not survive to 90 days, giving a mortality rate of 29.5 %. Recanalisation was achieved in 60.5 % of patients, as shown in Table 1. There were more males than females in the sample, reflecting the natural epidemiology of ischaemic stroke [1]. Clinical stroke severity defined by admission NIHSS was comparable between genders, as was the time from symptoms to reperfusion and frequency of intravenous thrombolysis, at around 61 %.

The vast majority (84 %) of clots involved the M1 segment, with ICA involvement being the second most prevalent. Clots involving the distal branches of the MCA were uncommon.

A range of thrombectomy devices were used, the most common being the Solitaire stent retriever, used in 23 cases (71.9 %). A mixed approach was used in 35 % of cases. The Acandis system was used in one case, as was a combination of the Solitaire and TREVO devices.

Imaging Biomarkers
Clot Volume
Clot volumes were skewed towards lower values in patients with good functional outcome at 90 days, as shown in Figure 1 below, but this change was not significant (median 0.15 cm3 versus 0.18 cm3, Mann Whitney U test p=0.45). Clot volume was not a significant predictor of recanalisation (p=0.21).

Clot Density
Functional outcome at 90 days was independent of clot density (mean values 38 ± 6.1 versus 37 ± 5.6 HU, two-sample t-test p=0.67, shown in Figure 2). Clot density was not predictive of recanalisation (37 ± 6.6 compared to 38 ±4.6, two sample t-test p=0.21).
Clot Length
Median clot length was higher but not significantly for patients with poor functional outcome, shown in Figure 3 (14.9 versus 10 mm, Mann Whitney U test p=0.33), and similar regardless of recanalisation (10.99 versus 12.22 mm, p=0.75). Dichotomised clot lengths of greater or less than 8 mm failed to predict recanalisation or functional outcome (Chi-Squared test p=0.43 and p=0.72 respectively).

ASPECTS
There was a significant association between ASPECTS derived from admission NCCT and functional outcome at 90 days (median scores 9 for mRS≤2 versus 8 for mRS>2, Mann Whitney U test p 0.0186, shown in Figure 4 below). Patients with mRS>2 spanned a greater range of ASPECTS values (IQR 4.8 - 8.3), whereas patients with mRS≤2 occupied a smaller range of higher scores (IQR 8-9). There was no association between admission ASPECTS and recanalisation (p=0.288).

ASPECTS measured at 24 h repeat NCCT (see Methods [17] ) was also significantly lower in patients with poor functional outcome at 90 days, as shown in Figure 4 (ASPECTS 3 versus 8, Mann Whitney U test p=0.0079). Repeat ASPECTS was not associated with successful recanalisation (p=0.601).

Collateral Score
The presence of good collateral circulation (defined by a CS 2 or 3) showed a non-significant tendency towards favourable outcome: 65.2 % of patients with mRS2 at 90 days had good CSs, compared to 52.9 % of patients with mRS>2 (Chi-Squared test p=0.319). A CS of 2 or 3 carried an odds ratio (OR) of 2.0 for favourable outcome. Good CS did not predict successful recanalisation (p=0.582).

Clot Burden Score
The CBS was comparable between patients with high and low mRS at 90 days (median scores 7, shown in Figure 7), and did not predict favourable mRS (p=0.792) or recanalisation (p=0.580).

Measures of Agreement
Intra-observer variability (NW) in clot density was low (Pearson’s correlation coefficient r=0.91), but was inconsistent for clot volume (r=0.62). This trend was more pronounced between observers (NW and RP), with coefficients r=0.87 for density and r=0.37 for volume. There was no significant bias between raters for either volume (one sample t-test of mean difference against zero, t=0.52 p=0.69) or density (t=-1.19, p=0.12) on Bland Altman analysis.

Clot length measurement showed poor agreement between NCCT and CTA based methods (Pearson’s correlation coefficient r=0.36). NCCT significantly overestimated clot length (one-sample t-test of mean difference against zero, t=-5.6 p<0.0001).
Bland-Altman plots for each measure of agreement can be found in Appendix 1.

Discussion
This paper aimed to determine whether radiological biomarkers could be used to predict positive outcome in mechanical thrombectomy. The most significant predictor was pre-treatment ASPECTS (p=0.02). Decreased clot volume and decreased clot length were generally skewed towards better outcomes, as was a high collateral score, but both failed to reach significance on analysis. Clot density and CBS showed no association with outcomes.
Literature on pre-treatment ASPECTS demonstrates poor outcomes with lower scores [26,27]. Specifically, patients with ASPECTS 0-4 fare markedly worse than others [23]. This study shows a significantly greater lower range of ASPECTS in the poor outcome group compared with the good outcome group, suggesting that ASPECTS can be used to predict outcome. The literature shows reperfusion to be sensitive to ASPECTS [24]; this finding is not reproduced in our data.

A higher repeat ASPECTS was also associated with good clinical outcomes (p=0.01), which would be expected in light of the pre-treatment association. However, this imaging marker is not as useful for guiding treatment. Its utility lies only in predicting long-term post-treatment prognostic information. For this reason, this result has much less utility in aiding hyperacute stroke care.

This paper found no association between clot volume and successful recanalisation (p=0.21), corroborating the literature [29] [30]. There was, however, a small non-significant association seen between large clot volume and poor functional outcome at 90 days. To the authors’ knowledge, this has yet to be shown in the literature but fits with the conjecture that voluminous clots occlude more perforating branches from the MCA (for example), resulting in more ischaemic damage and worse outcomes.

Clot density was not shown to be associated with outcome, contradicting previous research that claimed that the composition of low density clots rendered them resistant to removal [29,30]. However, the lack of significant association found in our data supports other research [27]. There has been speculation that the Solitaire device showed sensitivity to clot density, but the Penumbra device did not [26]. This study refutes this: patients in this study received predominantly Solitaire treatment and yet no significant change was observed. Clot density was similar regardless of outcome (p=0.21) as once ischaemic damage has occurred, infarction will proceed regardless of the clot composition.

Clot lengths of longer than 8 mm are associated with resistance to thrombolysis [28]. These data show clot length to be equivalent whether recanalisation was achieved or not (12.2 mm and 11.0 mm, p=0.75), and dichotomy at 8 mm failed to show significance (p=0.43). This analysis suggests that thrombectomy is advantageous where thrombolysis is ineffective, as it is not dependent on penetration of the drug along the length of the clot. This effect, regardless of clot length, has been replicated previously [26]. It does, however, conflict with recent findings in the literature suggesting the combination of thrombolysis followed by thrombectomy yields the best recanalisation rates, and in these circumstances clot length is a predictor of recanalisation [29]. This paper observed longer clot lengths (p=0.33) in patients with worse outcomes, potentially via a similar mechanism to clot volume.

In their original paper, Tan et al. [12] reported significant differences in 90-day mRS with the CBS, which our study was been unable to reproduce (p=0.79). Moreover, data from both our study (p=0.58) and the literature fail to associate CBS with recanalisation [26], reiterating the relative unimportance of clot volume and length in thrombectomy - compared with thrombolysis as used by Tan et al. [12] - and casting doubt on the prognostic value of the CBS. Attempts to replicate the original association in thrombectomy are indicated.

Behme et al. recently scrutinised the classification of whether an occlusion was sited in the distal or proximal segment of M1 and reported that it was significantly associated with outcome [30]. Classification was based on whether the lenticulostriate perforators were occluded, a more precise method than the traditional anatomical split of half the vessel length. The CBS is heavily weighted with the M1 segments [12], meaning that incorrect classification can reduce the sensitivity of the CBS. Further
investigation combining the CBS and the suggested improved classification is required to clarify whether the CBS is sensitive to outcome.

Tan et al. also found an association between the CS and 90-day outcomes. While our data support this trend, it was not significant (p=0.32). The evidence base corroborates the value of collateral supply for successful reperfusion [31]. Leptomeningeal supply has an established role in bolstering perfusion to the ischaemic penumbra, sustaining viable brain tissue until reperfusion can be achieved [32,33]. This is evidenced by the observation that re-perfused patients with poor collaterals fail to improve [31] and that collateral supply reduces the dependence on time to reperfusion [32].

**Study Limitations**

Volumetric methodology involved manual segmentation with limited experience, resulting in high inter-observer variation, especially with clot volume values. Most NCCT images were downloaded with slice thickness of 5 mm, resulting in low axial resolution for assessment of clot length and volume and distorting the results obtained. Unlike other studies, there was no correction of thrombus HU for variations in haematocrit using the contralateral side [26].

Sample size is arguably the greatest weakness of the study, limiting both statistical analysis and inference that can be extrapolated from any significant associations. This was further impacted by the study’s retrospective nature, which resulted in some missing data. In addition, due to retrospective data collection, there was no assessment of complication rates - although complete data for more recent patients was available - or equal assessment of local sedation compared to general anaesthesia, a factor which emerged as predictive of outcomes from the MR CLEAN data [33].

The clinical information adjusted for in this paper also neglects hypertension and previous history of stroke. There were a minority of patients in this study who demonstrated previous infarct on NCCT, which will have influenced 90-day mRS. Equally, one patient was included twice in the dataset for two separate thrombectomies. Assessment of premorbid mRS may have allowed the study to adjust for this.

**Conclusions**

Pre-treatment ASPECTS was the only sensitive imaging marker for good functional outcome at 90 days (p=0.02).

These data supports existing evidence that clot density is not sensitive enough to predict outcome at 90 days post stroke. Clot volume and length showed association with better outcomes but was not significant on analysis.

Of the other imaging markers evaluated, only a high CS showed some associations with good outcome, but was not significant on analysis. CBS showed no association.

**Acknowledgements**

We thank TP for overall supervision and image analysis, and AB for assistance obtaining clinical information. We thank MI for image analysis, and TG for assistance with previous data collection.
Ethical standards and consent

We declare that our study adheres to the ethical principles outlined in the 1964 Declaration of Helsinki and later amendments. We declare that ethical approval was waived due to the fact this study uses routinely collected clinical data from patients under the care of TP and TG. We declare that all patients or their representatives gave informed consent prior to enrolment.

Conflict of interest

TP proctors for Sequent Medical, Stryker and Codman. TG undertakes paid consultancy work for Codman, Stryker and Sequent. Stryker and Codman assist with study leave expenses.
References

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14. Merwick Á, Werring D; Posterior circulation ischaemic stroke; BMJ. 2014;348(May):g3175. doi:10.1136/bmj.g3175.


Figures

Figure 1 - Clot volume is lower, but not significantly, in patients with mRS ≤ 2 at 90 days (p=0.45)

Figure 2 - Clot density does not predict successful recanalisation (p = 0.21)

Figure 3 - Clot length is not significantly lower in patients with good functional outcome at 90 days (p=0.33)
Figure 4 - Admission ASPECTS occupies a broader range, and has a lower median value in patients with poor outcome at 90 days. This observation is significant (p=0.0186)

![Comparison of admission ASPECTS by functional outcome](chart.jpg)

Figure 5 - Higher scores on repeat ASPECTS at 24 h also show a significant association with functional outcome (p=0.0079)

![Comparison of repeat ASPECTS by functional outcome](chart.jpg)

Figure 6 - There is a higher proportion of patients with good CSs in the patients with good functional outcome at 90 days, although this trend was not significant. (p=0.319)

![Chart comparing collateral scores by functional outcome](chart.jpg)
Figure 7 - CBS shows no sensitivity towards outcome at 90 days (p=0.792)
Tables

Table 1 - Demographic data

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<tr>
<th></th>
<th>Male</th>
<th>Female</th>
<th>Combined</th>
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<tbody>
<tr>
<td>Frequency</td>
<td>27</td>
<td>16</td>
<td>43</td>
</tr>
<tr>
<td>Median age in years (IQR)</td>
<td>63</td>
<td>62</td>
<td>62</td>
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<tr>
<td>Frequency thrombolysed (%)</td>
<td>17</td>
<td>10</td>
<td>27</td>
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<tr>
<td>Mean time from symptom onset to reperfusion (min)</td>
<td>306</td>
<td>312</td>
<td>308</td>
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<tr>
<td>Recanalisation achieved (TICI 2b/3) (%)</td>
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<td>7</td>
<td>26</td>
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<tr>
<td>Atrial fibrillation</td>
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<td>Diabetes</td>
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<td>Median NIHSS on admission (IQR)</td>
<td>18</td>
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Table 2 - Breakdown of clot location.

<table>
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<tr>
<th>Clot Location</th>
<th>Frequency (%)</th>
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<tbody>
<tr>
<td>M1 only</td>
<td>2 (4.5 %)</td>
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<tr>
<td>M1 and M2</td>
<td>29 (65.9 %)</td>
</tr>
<tr>
<td>M2 only</td>
<td>3 (6.8 %)</td>
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<td>M3 only</td>
<td>1 (2.2 %)</td>
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<tr>
<td>ICA only</td>
<td>2 (4.5 %)</td>
</tr>
<tr>
<td>ICA, M1 and M2</td>
<td>6 (13.6 %)</td>
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<tr>
<td>ACA only (excluded from analysis)</td>
<td>1 (2.2 %)</td>
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Table 3 - Breakdown of devices used.

<table>
<thead>
<tr>
<th>Devices</th>
<th>Frequency (%)</th>
<th>Recanalized (%)</th>
<th>mRS≤2 at 90 days (%)</th>
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<tr>
<td>Solitaire</td>
<td>13 (32.5 %)</td>
<td>7 (58 %)</td>
<td>7 (58 %)</td>
</tr>
<tr>
<td>Penumbra</td>
<td>4 (10 %)</td>
<td>4 (100 %)</td>
<td>2 (50 %)</td>
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<tr>
<td>Solitaire and Penumbra</td>
<td>5 (12.5 %)</td>
<td>4 (80 %)</td>
<td>4 (80 %)</td>
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<tr>
<td>Revive</td>
<td>7 (17.5 %)</td>
<td>3 (43 %)</td>
<td>4 (57 %)</td>
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<td>Revive and Solitaire</td>
<td>6 (15 %)</td>
<td>3 (50 %)</td>
<td>5 (83.3 %)</td>
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<tr>
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<td>3 (7.5 %)</td>
<td>0 (0 %)</td>
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<td>Other</td>
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Appendix 1
Bland-Altman Plots for Measures of Agreement

Figure 8 - Poor Intraobserver agreement is shown between Clot length measurements on NCCT versus CTA, with NCCT consistently reporting greater clot lengths than CTA. This effect is greater for extensive clots.

Figure 9 - Clot density shows good interobserver agreement (Pearson's r = 0.87)

Figure 10 - Interobserver agreement is poor for measurements of Clot Volume, especially for larger clots (Pearson's r = 0.37)