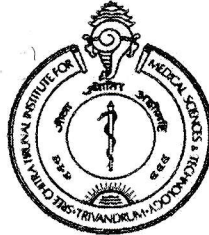


SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY

THIRUVANANTHAPURAM, KERALA



DOES THROMBUS IMAGING CHARACTERISTICS PREDICT THE DEGREE OF RECANALISATION AFTER ENDOVASCULAR THROMBECTOMY IN ACUTE ISCHAEMIC STROKE?

Dissertation submitted in partial fulfilment of the rules and regulations for

PDF Degree Examination of

Sree Chitra Tirunal Institute for Medical Sciences and Technology

By

Dr. Harikrishnan R

Postdoctoral fellow, Stroke

Month and Year of Submission: December 2021

Department of Neurology

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Thiruvananthapuram

01/01/2021 to 31/12/2021

DECLARATION

I, Dr.Harikrishnan R, hereby declare that this project was undertaken by me under the supervision of the faculty, Comprehensive Stroke Care Centre, Department of Neurology, Sree Chitra Tirunal Institute for Medical Sciences and Technology.

Thiruvananthapuram
Date: 14-12-2021


Dr.Harikrishnan R

Forwarded:

The candidate, Dr.Harikrishnan R, has completed the project under my guidance.

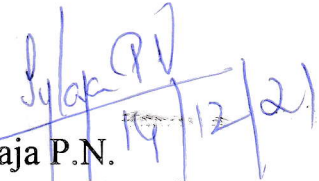
Thiruvananthapuram
Date: 15-12-2021


Dr. Sylaja P N 14/12/21
Professor and HOD
In charge, Comprehensive Stroke Care Centre
Department of Neurology
SCTIMST

Forwarded:

This candidate, Dr. Harikrishnan R, has carried out the minimum required project for post-doctoral fellowship.

Thiruvananthapuram
Date: 15-12-2021


Dr. Sylaja P.N.
Professor and Head
Department of Neurology
SCTIMST

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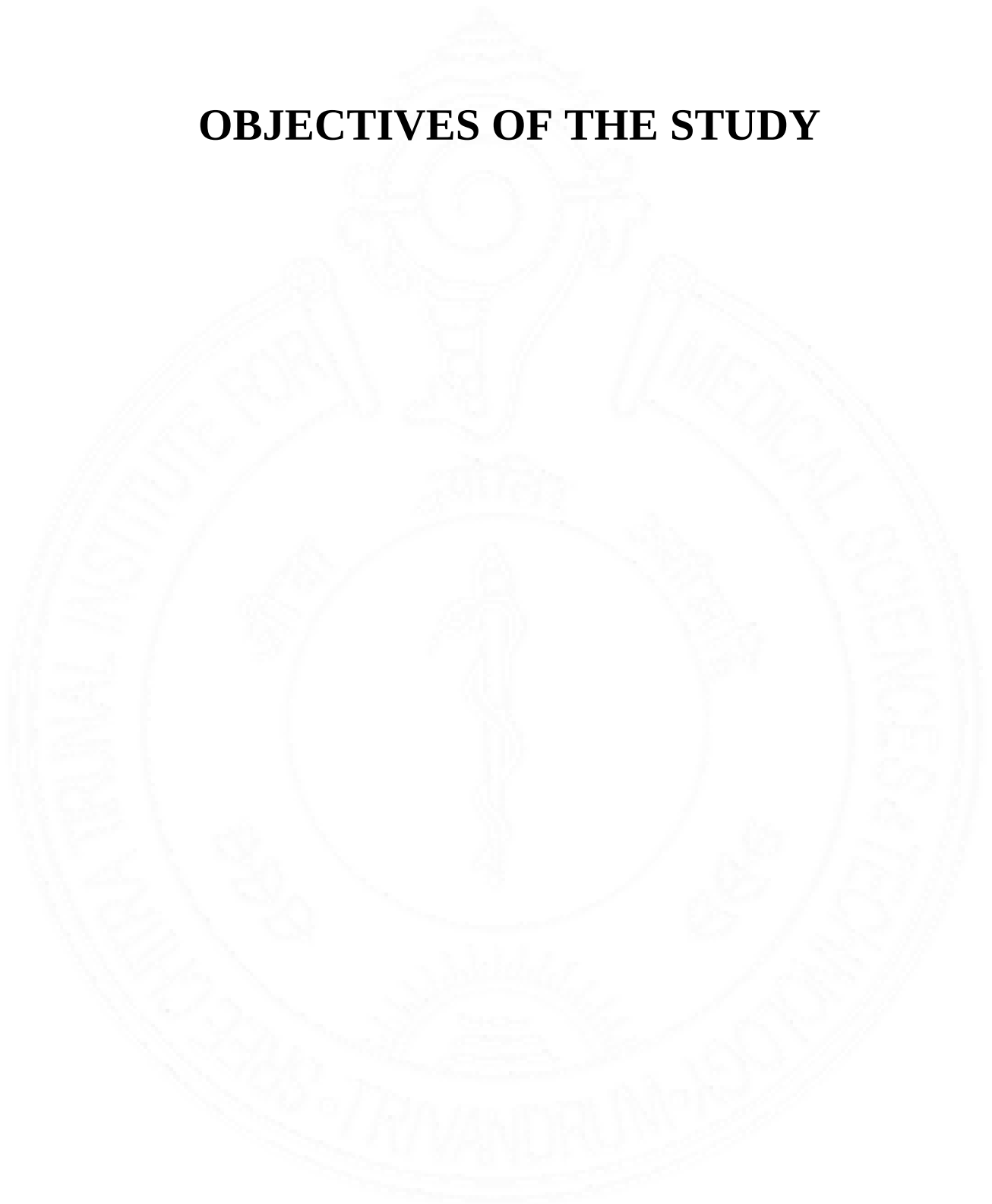
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INTRODUCTION

INTRODUCTION

There is an emergent need of potential imaging biomarkers predicting succesful recanalisation following Endovascular thrombectomy (EVT), which is the mainstay of treatment in acute ischaemic stroke (AIS) with large vessel occlusion (LVO). Thrombus is the ultimate target of any reperfusion therapy in large vessel occlusion and delineation of appropriate thrombus imaging characteristics could guide a better selection of patients for EVT. Thrombus imaging features like hyperdense artery sign and thrombus length less than 8 mm are associated with a favourable recanalisation after intravenous thrombolysis (1) (2). Previous studies have shown that a shorter thrombus length, lower Clot burden score (CBS) value and a permeable thrombus were associated with better functional outcome and a faster mechanical thrombectomy (3) (4). EVT procedural factors like duration, number of passes, combined aspiration for retrieval are associated with the recanalisation and functional outcome. Recent studies have shown conflicting data regarding the combined use of stent retriever and aspiration with the outcome (5). Hence the aim of our study is to evaluate the thrombus imaging characteristics on non contrast CT brain and CT angiography and the various procedural factors and correlate with the degree of recanalisation after mechanical thrombectomy in acute ischaemic stroke.

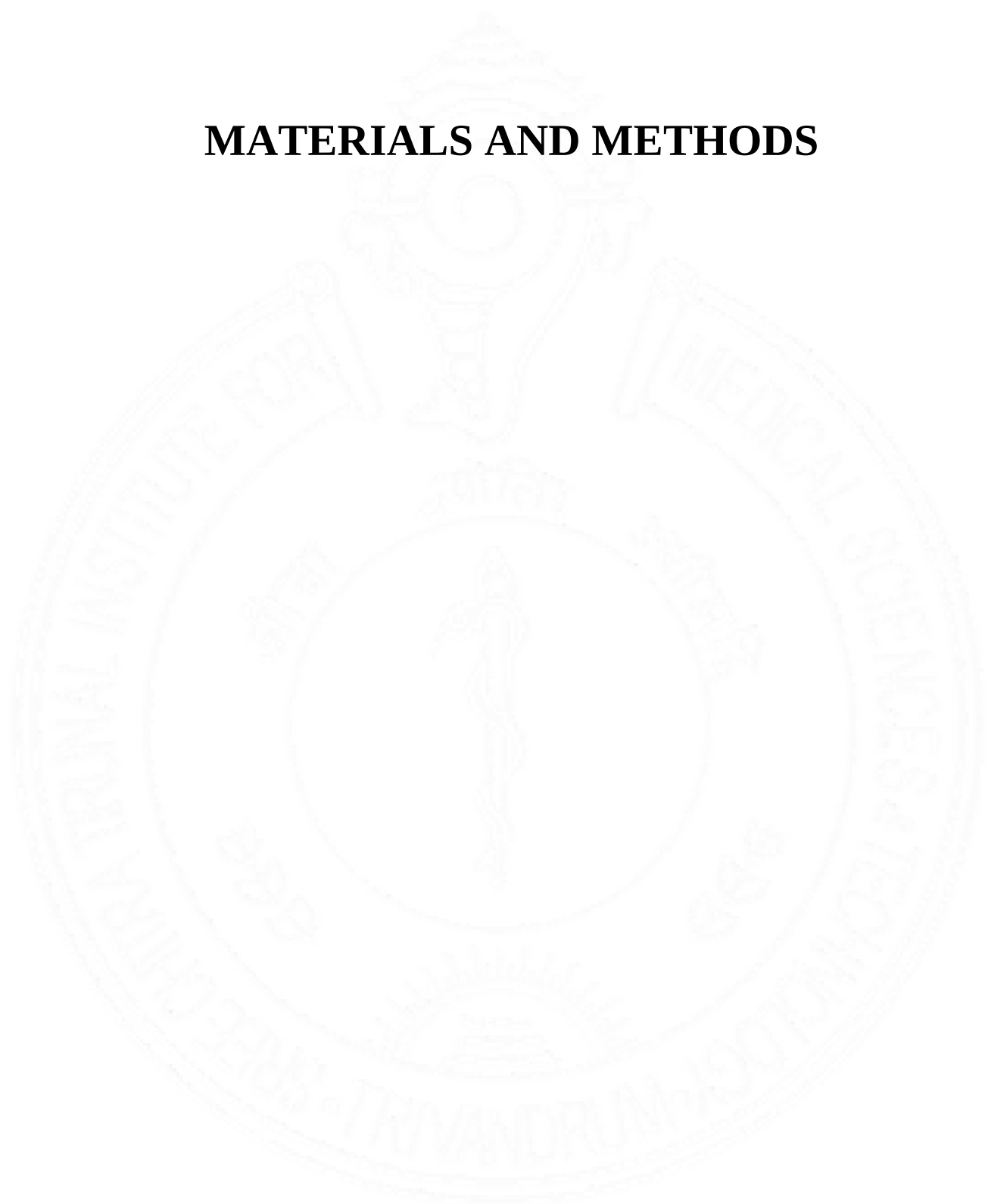
OBJECTIVES OF THE STUDY



AIM OF THE STUDY

To evaluate the thrombus imaging characteristics on non contrast CT brain and CT angiography and the various procedural factors and correlate with the degree of recanalisation after mechanical thrombectomy in acute ischaemic stroke.

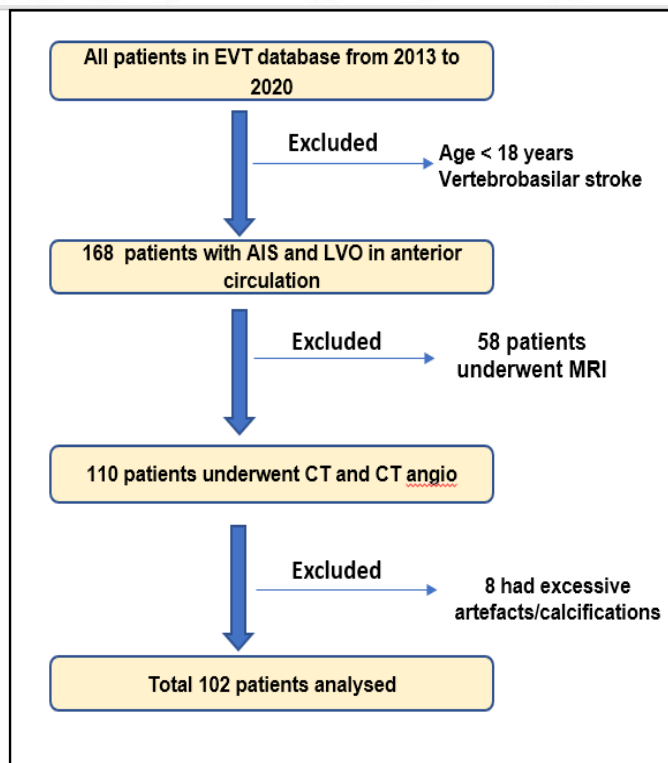
MATERIALS AND METHODS



MATERIALS AND METHODS:

All patients more than 18 years of age with AIS and LVO in the anterior circulation who underwent EVT within 24 hours of onset of the stroke from 2013 to 2020 were identified from our prospectively maintained EVT database. The patients who underwent a noncontrast CT brain and a CT angiogram were included in the study. Patients with images having motion artefacts and excessive calcifications were excluded. The flowchart indicating the selection process of patients is depicted in figure 1. The data on demographics, risk factors, prior medications, admission and 24 hours National Institute of Health Stroke Scale (NIHSS) score, baseline, discharge and 3month modified Rankin scale (mRS) score were collected. Stroke etiology was classified based on TOAST (Trial of ORG 10172 in Acute Stroke Treatment) criteria.

Figure 1. Flowchart showing the selection of patients for the study



Imaging analysis:

All images were analysed by a neurologist and neuroradiologist blinded to the clinical details. Noncontrast computed tomography (NCCT) thick (5 mm) and thin sections (1 mm) and computed tomography angiography (CTA) acquired before EVT were analysed. Images with motion artefacts and calcified thrombus were excluded. Baseline and 24 hours CT ASPECTS and hyperdense MCA sign (absolute MCA attenuation value > 43 HU and a ratio of HU in the affected to contralateral MCA > 1.2 in thin sections) were assessed from plain CT (6). Thrombus imaging characteristics (thrombus location, clot burden score, thrombus length and permeability) and collateral status (Tan grading) were assessed from CT angiogram. Thrombus location was classified as occlusions in the internal carotid artery (ICA), middle cerebral artery (proximal M1, distal M1, M2 or M3) or anterior cerebral artery (A1, A2), based on the most proximal vascular segment which got occluded. Thrombus length was measured in millimetres in MCA M1 segment from the axial CT angiogram and length ≤ 8 mm was considered as a short thrombus. Clot burden score was calculated by assigning points for the presence of thrombus on CTA within the intracranial internal carotid artery and MCA M1 and M2 branches, and anterior cerebral artery A1 segment. A CBS of 10 indicates absence of a visible large vessel occlusion (LVO), whereas a score of 0 corresponds to a complete multisegmented occlusion of anterior circulation arteries, and a score <6 was considered as poor (7). Thrombus permeability was assessed by the degree of contrast permeation through thrombus in CTA and graded as 0 (impermeable) and 1 and 2 (permeable thrombus) (8) (9). Collateral status was graded from 0 (absent collateral supply in the occluded MCA territory) to 3 (100% collateral supply of the occluded MCA territory)(10).

Procedural factors:

The angiographic procedural factors (onset to groin puncture and groin puncture to recanalisation time, number of passes for EVT, technique of EVT- stent retriever alone or a multimodal procedure using combination of stentriever with aspiration) were analysed. Primary outcome was defined as the degree of recanalization after EVT as assessed by mTICI score which indicates the degree of reperfusion in the distal territory (11) (12). TICI grade 2b,2c and 3 were taken as a good outcome. A 3 month modified Rankin scale score (mRS) of 0-2 was considered as a good functional outcome.

Ethical considerations

This study has the approval of the Institutional Ethics Committee and individual consent was waived as this was a retrospective study.

STATISTICAL ANALYSES

The baseline clinical and demographic parameters are expressed as mean, median and interquartile range (IQR) for continuous variables and frequencies and percentages for categorical variables.

The association between thrombus imaging characteristics and angiographic procedural factors with primary and secondary outcomes were analysed using binary logistic regression analysis. The association was tested using Chi square test and Odds ratio (OR) and confidence intervals were estimated using binary logistic regression models. The characteristics which showed 'p' value ≤ 0.10 were included in the multiple logistic regression model. Hyperdense MCA sign was excluded from this analysis as it was a nonsignificant factor when considering all thrombus locations. All statistical analyses were performed using **STATA/IC 14.1(Texas USA)**.

RESULTS

RESULTS

The demographic and clinical characteristics are shown in **table 1**. The mean age of 102 patients was 60.5 ± 11.8 years. About 42 (41.2%) patients were females. The median NIHSS at admission was 16 (IQR 12-20). Median CT ASPECTS at admission was 6 (IQR 5-8) and at 24 hours, 6 (IQR 4-8). Bridging intravenous thrombolysis was given to 33/102 (34.3 %) patients before mechanical thrombectomy. Cardioembolism was the most common etiology (46.1%) and about 27.5 % patients had their etiology undetermined. After EVT, a good recanalisation was achieved in 84/102 (82.4%) patients and around half (47.1%) of the 102 patients attained a good 3 month functional outcome.

Table 1. Demographic and Clinical Characteristics of 102 patients

Baseline characteristics	n=102
Mean Age	60.5 ± 11.8 (SD)
Sex - females	42(41.2%)
Mean NIHSS at admission	16 (IQR 12-20)
Hypertension	
Diabetes Mellitus	57 (55.9%)
Coronary artery disease	39 (38.2%)
Peripheral occlusive vascular disease	19 (18.6%)
Dyslipidemia	18 (17.6%)
Smoking	20 (19.6%)
Sick sinus syndrome	27 (26.5 %)
Rheumatic heart disease	4 (3.9%)
Past TIA/stroke	15 (14.7%)
Malignancy	20 (19.6%)
Using dual antiplatelet	3 (2.9%)
	8 (7.8%)

TOAST Etiology	
Large artery atherosclerosis	23 (22.5%)
Cardio embolism	47 (46.1%)
Other determined etiology	3 (2.9%)
Undetermined	28 (27.5%)
Baseline CT ASPECTS (median)	6 (IQR 6-8)
Hyperdense MCA sign	40/84 (47.6%)
Thrombus location	
Proximal ICA	3 (2.9 %)
Distal ICA	15 (14.7%)
Proximal M1	26 (25.5 %)
Mid M1	28 (27.5 %)
Distal M1	28 (27.5 %)
M2	2 (1.9 %)
Thrombus length ≤8 mm	47/84 (56 %)
Clot burden score <6	79/102 (77.5 %)
Permeability	
Grade 0	24 (23.5%)
Grade 1	68 (66.7%)
Grade 2	10 (9.8 %)
Collateral score (Tan)	
Grade 0	2 (1.9 %)
Grade 1	46 (45.1 %)
Grade 2	50 (49 %)
Grade 3	4 (3.9 %)
Received bridging IV thrombolysis	35 (34.3%)
Symptomatic ICH	5 (4.9%)
Procedural factors	
Mean groin puncture to recanalization (min)	55.3 ± 29.4 (SD)
Number of EVT passes	
1 pass	44 (43.1 %)
2 passes	29 (28.4 %)
≥ 3 passes	29 (28.4 %)

Multimodal technique- Stentriever with aspiration	25 (24.5 %)
Good recanalization (TICI 2b,2c,3)	84 (82.4%)
3month mRS (0-2)	48 (47.1%)
In hospital mortality	9 (8.8%)

Of the 40 patients showing a hyperdense MCA sign, 90% had a good recanalisation ($p=0.07$) showing a tendency for statistical significance and 45% with the sign in NCCT had a good functional outcome (**table 2**). Shorter thrombus was seen in 47 patients and 79 % among them had favourable recanalisation. Of 78 patients who had a permeable thrombus (grade 1 and grade 2), 86% had good recanalisation ($p= 0.09$). Similarly, 81.5% patients having a good Tan collateral grade had favourable recanalisation. Among the thrombus imaging characteristics, hyperdense MCA sign and permeable thrombus was showing a tendency for statistical significance to be associated with good recanalisation. None of the thrombus imaging characteristics showed a statistically significant interaction with the secondary outcome.

Coming to the angiographic procedural factors (**table 2**), 95 % of the 61 patients with a shorter groin puncture to recanalisation (≤ 60 minutes) attained a good recanalisation with strong statistical significance (p value <0.001) with unadjusted OR 11.2 (95 % CI 2.97-41.9). Among the 73 patients requiring lesser than 3 passes, 90 % attained good TICI score (90% vs 62 %) showing a statistically significant interaction ($p= 0.001$). Compared to patients undergoing a combined use of stentriever and aspiration, 90 % patients among whom a stent retriever alone was used attained good recanalisation ($p=0.002$). Coming to the secondary outcome, requirement of fewer passes ($p=0.003$) and a shorter groin puncture to recanalisation time ($p=0.03$) were associated with a good functional outcome.

Table 2. Binary logistic regression analysis showing association of thrombus imaging characteristics and angiographic procedural factors with primary and secondary outcomes

	n	Good recanalisation	p value	Good functional outcome	p value
Imaging characteristics					
Hyperdense MCA sign					
Present	40	36 (90%)	0.07	18 (45 %)	0.8
Absent	44	33 (75 %)		19 (43.2%)	
Thrombus location					
ICA thrombus	18	15(83.3 %)	0.9	11 (61.1%)	0.1
Others	84	69(82.1%)		37 (44.1%)	
Thrombus length in MCA					
≤ 8 mm	47	37(78.7 %)	0.35	20 (42.6 %)	0.75
>8 mm	37	32 (86.5 %)		17(46 %)	
Clot burden score					
≥6	23	17(73.9 %)	0.2	11(47.8 %)	0.9
<6	79	67(84.8%)		37(46.8 %)	
Thrombus permeability					
Grade 0	24	17 (70.8 %)	0.09	10(41.7 %)	0.5
Grade 1 and 2	78	67(85.9 %)		38(48.7 %)	
Collateral status					
Good	54	44(81.5 %)	0.8	27(50 %)	0.5
Poor	48	40 (83.3%)		21(43.8 %)	
Procedural factors					
Groin puncture to recanalisation time					
≤ 60 min	61	58 (95.1%)	<0.001	34(55.7%)	0.03
>60 min	41	26 (63.4%)		14 (34.2%)	
EVT passes					
<3 passes)	73	66(90.4%)	0.001	41(56.2 %)	0.003
≥3 passes	29	18(62.1%)		7 (24.14 %)	
Technique					
Stent retriever alone	73	66 (90.4%)	0.002	36 (49.3 %)	0.4
Stentriever plus aspiration	25	16 (64 %)		10 (40 %)	

Table 3. Multiple logistic regression analysis showing association of imaging and procedural factors with primary and secondary outcomes

	Good recanalisation			Poor functional outcome		
	OR	95 % CI	p value	OR	95 % CI	p value
Permeable thrombus	5.9	1.3-26.6	0.02			
EVT <3 passes	1.7	0.45-6.9	0.41			
EVT ≥3 passes				3.4	1.2-9.8	0.02
Technique- stent retriever alone	5.4	1.3-22.5	0.02			
Groin puncture to recanalisation ≤ 60 min	7.95	1.7-36.8	0.008	1.46	0.6 – 3.3	0.42

Multiple logistic regression analysis (**table 3.**) showed thrombus permeability (p= 0.02; aOR 5.9; 95 % CI 1.3-26.6), usage of a stent retriever alone (p=0.02; aOR 5.4; 95 % CI 1.3-22.5) and a groin puncture to recanalisation time ≤60 minutes (p=0.008; aOR 7.95; 95 % CI 1.7-36.8) were independently associated with good recanalisation. Requirement of lesser number of passes (p=0.02; aOR 3.4; 95 % CI 1.2-9.8) was independently associated with a good 3 month functional outcome.

DISCUSSION

DISCUSSION

In our study, majority of patients with hyperdense MCA sign and a permeable thrombus had a favourable recanalisation after mechanical thrombectomy. Requirement of ≥ 3 passes for EVT was associated with a poor recanalisation. Presence of a permeable thrombus, requirement of lesser passes and use of stent retriever alone (without aspiration) were independently associated with a good recanalization. The requirement of ≥ 3 passes was independently associated with a poor 3 month functional outcome after EVT.

Presence of hyperdense MCA sign (HMCAS), its persistence and disappearance have been studied previously predicting successful reperfusion, but there are only limited studies assessing its value in predicting successful recanalisation after EVT. A recent systematic review found a higher Odds of poor functional outcome by 1.43 fold in the presence of HMCAS by any treatment modality (13). Our study accurately assessed the prevalence of HMCAS (47.6%) from thin sections and previous estimates vary from 20-40 %. There was a tendency for statistical significance for good recanalisation in the presence of HMCAS in our study and we feel the sign should be employed along with other imaging biomarkers in prognostication. Another parameter showing significance was thrombus permeability. Permeability or perviousness is indicated by the contrast material percolating through the thrombus and has been shown to be associated with good recanalisation after IVT (due to increased clot area amenable to lysis) than EVT (9). Recent analysis from COMPASS study showed good first pass recanalisation in a pervious thrombus by an aspiration first approach (14). Majority of our subjects underwent stent retriever thrombectomy and was showing marginal statistical significance with recanalisation which could be due to a small sample size. MR CLEAN registry data analysis by Dutra et al done in 408 patients has shown that distal thrombus, shorter thrombus, higher CBS value and a permeable thrombus were associated with better functional outcome and faster EVT (3). We did not find any significant association of other imaging biomarkers with recanalisation or 3 month mRS.

Recanalisation achieved after a first pass (first pass effect) has been found to be associated with a good outcome (15). Our study showed that requirement of more number of passes for EVT was independently associated with poor recanalisation and poor functional outcome. About 43% patients achieved good recanalisation with first pass in our group emphasising this first pass effect. It has been conclusively shown that the rate of recanalisation sequentially gets reduced with increasing number of passes approaching less than 10 % recanalisation with five

passes (16)(17). This could be due to increasing coefficient of friction of the clot and clot compaction after more passes. It could also be attributed to thrombus fragmentation and distal cortical branch migration adversely affecting the functional outcome. The benefit of thrombectomy by successful recanalisation after more number of passes may not get translated to a clinical benefit; as in our study, 82.4% patients had good TICI recanalisation but only marginally more than half (47.1%) of them had a good functional outcome. There may be a critical point at which procedure needs to be abandoned as recanalisation may be meaningless after a certain critical number of passes which is currently not well established. More research is needed in this aspect regarding the optimal number of passes to be attempted and why this recanalisation benefit is not getting translated into a meaningful clinical benefit. Of the 102 patients in our study, 72 had fewer passes and an overall recanalisation rate attained in our patients is more than 80%, but a good functional outcome achieved only in nearly half of them. Our data strongly supports the first pass effect and the detrimental effect on the functional outcome after 3 or more number of passes.

Using stent retriever alone was associated with good recanalisation, indirectly suggesting that multimodal approach using combined aspiration with stent retriever is usually employed when there is difficulty in extracting thrombus. Stent retriever is deployed initially as per the existing protocol in our institute. Using stent retriever initially or contact aspiration first or a combined approach is beneficial, producing a first pass effect as discussed above, is a source of ongoing trials. The ASTER RCT failed to demonstrate any superiority of contact aspiration over stent retriever as first technique (successful reperfusion rates contact aspiration, 85.4% vs 83.1%) and ASTER 2 trial is ongoing to address the superiority of a combination therapy assuming a synergistic benefit of 2 modalities (5). The COMPASS study yielded noninferiority of aspiration first pass thrombectomy(18). A systematic review by Tsang et al showed that stent retriever first was associated with a superior reperfusion (74.9% vs 66.4%; OR 1.53)(19). Majority of our patients underwent stent retriever approach with a good recanalisation in concordance with the results of metaanalysis. A combined procedure was employed in 25 patients to attain recanalisation but majority of them were difficult procedures requiring more than 3 passes. This confounding element and a small sample size makes the interpretation of this statistical significance difficult. However we can clearly conclude that a first stent retriever approach helps to attain the maximum possible recanalisation, in concordance with the current evidence, and a combined approach already confounded by more number of passes with doubtful clinical benefit. A lesser groin puncture

to recanalisation is affected by multiple factors like skill of the interventionist and technical difficulty of the procedure. We found that faster puncture to recanalisation was associated with a good recanalisation and good functional outcome.

Merits and limitations

All the images were meticulously reviewed by the neurologist and neuroradiologist who were blinded to the clinical data. No patients in our study was lost to followup. The limitation of our study includes a small sample size which could have influenced the statistical significance of certain imaging characteristics.

Conclusions

- Thrombus permeability was a predictor of successful recanalisation after EVT.
- Requirement of 3 or more passes during EVT was associated with poor recanalisation and poor functional outcome.

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APPENDIX

ABBREVIATIONS

EVT- Endovascular thrombectomy

AIS- Acute ischaemic stroke

LVO- Large vessel occlusion

CT – Computed tomography

CTA- CT angiogram

NIHSS- National institute of Health stroke scale

mRS- modified Rankin scale

HMCAS- Hyperdense MCA sign

ASPECTS- Alberta stroke program early CT score

PROFORMA

Age:

Sex:

Date and time of onset of symptoms:

Date and time of reaching the hospital

If wake up stroke: 1-Yes/2-No If yes, time last seen normal:

Diabetes:

Hypertension:

Dyslipidemia:

Coronary artery disease:

Chronic kidney disease:

Previous stroke/TIA:

Rheumatic heart disease:

Peripheral occlusive vascular disease:

Prior antiplatelet use: If yes, single or dual

Prior oral anticoagulation:

Prior malignancy:

Smoking: current vs exsmoker

Alcohol intake:

NIHSS at admission:	Post procedure:	Discharge:	3
months:			

mRS at admission:	Post procedure:	Discharge:	3
months:			

Left hemisphere/ Right hemispheric

Imaging characteristics

Baseline CT ASPECTS:

24 hours CT ASPECTS:

Haemorrhagic transformation:

HI-1/HI-2/PH-1/PH-2

Symptomatic ICH:

Hyperdense MCA sign (section thickness <2.5 mm):

1=yes/2=no

Absolute MCA attenuation HU:

CT angio: Multiphase/single phase

Thrombus location: Extracranial ICA/intracranial ICA / MCA- proximal
M1, mid M1, distal M1, M2 or M3/ACA-A1/A2

Clot burden score:

(10-point scoring system; One point is subtracted for M2, A1 or infra-clinoid ICA occlusions.

Two points are subtracted for proximal M1, distal M1, or supra-clinoid ICA occlusions)

Involved regions: Extracranial ICA/Intracranial ICA/MCA M1 and M2
branches/ ACA A1 segment:

Thrombus length (in mm):

Thrombus permeability –

Grade 0 - no contrast permeation of the thrombus; Grade 1 - contrast permeating diffusely through thrombus; Grade 2 - tiny hairline lumen or a streak of well-defined contrast within the thrombus extending either through its entire length or through part of the thrombus.

Absolute thrombus attenuation (NCCT):

Relative thrombus attenuation:

Mean thrombus attenuation in NCCT:

Mean thrombus attenuation in CECT:

Thrombus attenuation increase:

Thrombus density:

Collateral status (Tan grade): 0/1/2/3

(0 - Absent collateral supply in occluded MCA territory; 1 – Collateral supply filling $\leq 50\%$ but $> 0\%$ of occluded MCA territory; 2 - Collateral supply filling $> 50\%$ but $< 100\%$ of occluded MCA territory; 3 - 100% collateral supply of occluded MCA territory)

CT perfusion done: Yes/No If yes, mismatch present: Yes/No

Bridging thrombolysis done: Yes/No

Angiographic characteristics

Door to needle time:

Door to groin puncture time:

Groin puncture to recanalisation time:

Number of passes required:

TICI grade:

(Grade 0: no perfusion; Grade 1: penetration with minimal perfusion; Grade 2: partial perfusion - Grade 2A: only partial filling (less than two-thirds) of the entire vascular territory is visualized; Grade 2B: complete filling of all of the expected vascular territory is visualized but the filling is slower than normal; Grade 3: complete perfusion)

EVT technique Stent retriever/Aspiration:

Thrombus histopathology: RBC/Fibrin platelet rich

Etiology of stroke (TOAST classification):

Mortality: In hospital/ At 3 months

Cause of death – Vascular / Nonvascular

If vascular – stroke/ cardiac



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम

तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

Thiruvananthapuram - 695 011, Kerala, India

(An Institute of National Importance under Govt. of India)

Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1706 /August/ 2021

16.09.2021

Dr. Harikrishnan R

PDF, Stroke

Department of Neurology

SCTIMST, Thiruvananthapuram

Dear Dr. Harikrishnan,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "THROMBUS IMAGING CHARACTERISTICS AS A PREDICTOR OF OUTCOME AND RECANALIZATION AFTER ENDOVASCULAR THROMBECTOMY IN ACUTE ISCHAEMIC STROKE (IEC/1706)" on 18th August, 2021.

The following members of the Ethics Committee were present at the meeting held on 18th August, 2021 at Residences and Offices of IEC Members via Video Conference

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Prof. C.C. Kartha	MBBS,MD	Male	Basic Medical Scientist (Chairman)	No
2.	Dr. Kala Kesavan P	MBBS,MD	Female	Basic Medical Scientist	No
3.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
4.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
5.	Dr. Achuth Sankar S. Nair	Ph.D (i.Engineering ii.Music)	Male	Social Scientist	No
6.	Dr. Rejnish Kumar	MBBS,MD ,DNB	Male	Clinician	No
7.	Adv. N Anand	BAL, L.LB	Male	Legal Expert	No
8.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
9.	Dr. Harikrishna Varma P. R	Ph.D (Materials Sciences)	Male	Medical Technology	Yes
10.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
11.	Dr. Narayanan Namboodiri. K K	MBBS,MD,DM	Male	Clinician	Yes
12.	Dr. Biju Soman	MBBS,MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
13.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:Original submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST dated 17.07.2021
2. IEC Application Form
3. Project Proposal
4. Proforma
5. TAC Approval Letter
6. CV of PI and Co-PIs

Revised submission

1. Covering letter addressed to the Member Secretary, IEC, SCTIMST dated 14.09.2021
2. Covering letter addressed to Chairman, IEC, SCTIMST dated 14.09.2021
3. IEC Application Form
4. Project Proposal
5. Proforma
6. TAC Approval Letter
7. CV of PI and Co-PIs

IEC Decision

The IEC approved the conduct of the study in the present form

This approval is in continuation of IEC Regn No. ECR/189/Inst/KL/2013/RR-16, subject to IEC Renewal pending process with CDSCO

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,



G. Srinivas

Member Secretary, IEC

