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Higher Annual Operator Volume is Associated with Better Reperfusion Rates in Stroke Patients Treated by Mechanical Thrombectomy in the ETIS Registry

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ABSTRACT

Background: Mechanical thrombectomy (MT) is a level IA treatment in acute ischemic stroke (AIS) patients. The operator's effect has been found to be an independent predictor for clinical outcome and technical performance in interventional cardiology.

Purpose: The aim of this study was to determine if individual operator characteristics have an impact on reperfusion and procedural complication rates.

Methods: From the ETIS (Endovascular Treatment in Ischemic Stroke) study, a prospective, multicenter, observational real world MT registry, we included all AIS patients consecutively treated by MT between January 2012 and March 2017 in 3 high volume comprehensive stroke centers by 19 operators. We assessed the effect of individual operator characteristics on successful reperfusion, defined as modified Thrombolysis In Cerebral Infarction 2b/3 at the end of MT, and procedural complications using a multivariable hierarchical logistic regression models.

Results: A total of 1541 anterior and posterior AIS patients were enrolled (mean age 67 years; median NIHSS 16). There was a significant operator effect on successful reperfusion, with an intraclass correlation coefficient (ICC) of 0.036 (P=0.046), but not on complications (ICC=0). There was a dose response relationship between annual operator volume and successful reperfusion rate (P=0.003) with an adjusted Odds Ratio for successful reperfusion equal to 2.52 (95% CI, 1.37-4.64) for patients treated by an operator with annual volume ≥ 40 MT/year compared to those treated by operator with less than 14 MT per year (first tertile). Nevertheless, this result did not translate to better clinical outcomes.

Conclusions: Our data suggest that operator volume of MT per year have a positive impact in AIS patients on successful reperfusion but not on clinical outcomes nor on complication rate. Further studies are warranted to investigate threshold procedure numbers associated with better outcomes.

KEY WORDS: Mechanical thrombectomy; Acute Ischemic Stroke; Operator Volume; ETIS register

CONDENSED ABSTRACT

What is the impact of operator's characteristics on reperfusion and procedural complication rates in acute ischemic stroke (AIS) treated by mechanical thrombectomy (MT)? In this prospective, multicenter, observational study, from the ETIS register, 1541 AIS patients were consecutively treated by MT. There was a significant operator effect on successful reperfusion but not on complications. There was a dose response relationship between annual operator volume and successful reperfusion rate. Successful reperfusion in AIS patients treated with MT is dependent on the operator volume of MT per year. Further studies are warranted to investigate threshold procedure numbers associated with better outcomes.

ABBREVIATIONS AND ACRONYMS

MT = Mechanical Thrombectomy

AIS = Acute Ischemic Stroke

ETIS = Endovascular Treatment in Ischemic Stroke

ICC = Intraclass Correlation Coefficient

mTICI = modified Thrombolysis In Cerebral Infarction

PCI = Percutaneous Coronary Intervention
NIHSS = National Institutes of Health Stroke Scale
PLAAC = Percutaneous Left Atrial Appendage Closure
ICH = Intracranial Hemorrhage
ASPECT = Alberta Stroke Program Early CT Score

INTRODUCTION

Endovascular mechanical thrombectomy (MT) is considered a class I, level of evidence A, recommendation for immediate revascularization of proximal intracranial arterial occlusion of the anterior circulation (1-6). According to the Joint Commission in the collaboration with the American Heart Association/American Stroke Association, stroke centers must present precise standards and advanced stroke certification to be considered as a MT-capable stroke centers. Moreover, the Joint Commission propose a minimum volume of 12 MT procedures per year or 24 over the past 2 years accomplished by 2 to 3 experienced operators (7). Nevertheless, these thresholds aren't supported by strong evidence. There is a need for studies assessing the relationship between operator experience, operator volume, success reperfusion, and complications rates.

Robust data support the association of higher complications rate with low operator's experience in several cardiological interventions such as percutaneous coronary intervention (PCI), coronary stent placement, and Percutaneous Left Atrial Appendage Closure (PLAAC) (8-10). The main purpose of our study was to analyse the impact of the individual operator characteristics on reperfusion and complication rates at the end of MT procedure.

METHODS

Patient population

The study population was selected from the prospective observational multicenter ETIS (Endovascular Treatment in Ischemic Stroke) registry referred to three large comprehensive stroke centers in France. All patients were identified from ETIS between January 2012 and March 2017(11). The number of operators in this registry was 19. Patients enrolled in this study presented an acute ischemic stroke (AIS) with occlusion of the internal carotid artery or the

middle cerebral artery (M1 and M2 segments) or vertebro-basilar arteries and were treated with MT by either contact aspiration or stent retrievers. A more detailed description of the technique has been published previously (11). A local ethics committee and the French Data Protection Agency approved the use of patient data for this research protocol. In accordance with the French legislation, informed consent was not needed from patients because this study used analysis of anonymized data collected prospectively as a part of routine clinical care.

Patient's characteristics

The following clinical characteristics of each patient were analyzed: age, gender, vascular risk factors, treatments before the procedure, vital signs before treatment, the severity of the acute ischemic stroke using the National Institutes of Health Stroke Scale (NIHSS) score at admission and 24 hours after the initiation of treatment assessed by a certified medical professional or by a stroke neurologist implicated in the acute management of patient post MT, and the degree of disability or dependence in the daily activities using the modified Rankin Scale at day 90. Furthermore, the following radiological imaging characteristics were identified: 1) DWI-ASPECT score and CT brain ASPECT score each ASPECTS region was scored 0 if abnormal and 1 if normal, 2) site of occlusion in the middle cerebral artery M1 or M2, 3) mTICI score, 4) imaging results 24 hours after MT to evaluate the presence of a hemorrhagic transformation.

Concerning treatment and procedure, we assessed: 1) time from symptom onset to initiation of intravenous thrombolysis, to groin puncture, and to final reperfusion, 2) the use of general or local anaesthesia during the MT.

Operator's experience characteristics

Operator characteristics were defined according to the number of MT performed per year during the study and according to the year of the first MT. The name of the operator was checked on signed interventional report. The experience of operator was estimated by the year of first MT. Operator were divided in 2 groups (≤ 2010 or > 2010), according to the median year of first MT in this sample.

Outcome

The primary study outcome was the angiographic success rate defined by a reperfusion of the occluded artery evaluated by the modified Thrombolysis In Cerebral Ischemia (mTICI) scores of 2b/3 (considered as restoration of flow to more than 50% of the involved brain territory at the end of the MT procedure). Secondary outcomes include the favourable outcome and procedural complications. Favourable outcome was evaluated by the modified Rankin Scale (mRS) at 90 days post MT, during face-to-face interviews or via telephone conversations with the patient, their relatives, or their general practitioner.

The procedural complications during and post MT collected from register were: intracranial hemorrhage (ICH), subarachnoid hemorrhage (SAH), groin complication (formation of a groin hematoma, retroperitoneal hematoma, femoral artery pseudo-aneurysm), distal limb artery occlusion by migrated emboli, recurrent AIS, vessel perforation or dissection, vasospasm, device fracture, infection, death. We grouped ICH according to the classification of the European Cooperative Acute Stroke Study (ECASS) 1 criteria: parenchymal hematoma type 1 and 2, hemorrhage infarction type 1 and 2 (12). Symptomatic ICH was considered in patients presenting within 24 hours an increase of 4 or more points in their NIHSS score caused by the hemorrhage.

Statistical Analysis

Continuous variables are expressed as means (standard deviation) in the case of normal distribution or medians (interquartile range) otherwise. Categorical variables are expressed as numbers (percentage). Normality of distributions was assessed using histograms and the Shapiro-Wilk test. Main patient's level characteristics were compared between patients with and without successful reperfusion, with and without a favourable outcome, and between patients with and without procedure complications using Student t test (or Mann-Whitney U test) for continuous variables and Chi-Square test for categorical variables.

To assess the effect of operators on each outcome (successful reperfusion, favourable outcome and procedural complications), we used a multivariable mixed (hierarchical) logistic regression model including all patient-level characteristics associated with outcome in bivariate analyses ($P < 0.20$) as fixed effects and operators as a random effect. We derived from this model the intraclass correlation coefficient (ICC) which represents the outcome variability attributable to individual operator. We further investigate the association of the two main operator characteristics (annual volume categorized into 3 levels and operator experience categorized in two levels using date of January 2010) with each outcome by including the annual operator volume as covariate into the previous multivariable hierarchical logistic regression model. Odds ratios (OR) for middle and upper relative to lowest tertile of annual operator volume were calculated as effect size. Statistical testing was conducted at the two-tailed α -level of 0.05. Data were analyzed using the SAS software version 9.4 (SAS Institute, Cary, NC).

RESULTS

From January 2012 to March 2017, 1541 AIS patients treated by MT in 3 French comprehensive stroke centers. During the study period, a total of 19 operators performed MT with a median

number of MT per year of 27 (range from 5 to 69MT per operator per year). Patient's characteristics are reported for overall study population.

Successful Reperfusion and Clinical Outcome

The overall rate of successful reperfusion was 76.6% (n=1175; 95%CI, 74.5-78.7). As shown in Table 1, intravenous thrombolysis, local anaesthesia, diabetes and higher ASPECTS score were significantly associated with successful reperfusion in univariate analyses. In multivariable hierarchical logistic regression model controlling for all patient-level characteristics associated with successful reperfusion (P<0.20), the effect of operator on successful reperfusion was significant (P=0.046), with an ICC of 0.037 meaning that 3.7% of the successful reperfusion variability was due to interoperator variation.

When annual operator annual volume was included in multivariable hierarchical logistic regression model as covariate, we found a dose response relationship between annual operator volume and successful reperfusion (P=0.003 associated with one-level increase) (Table 2A). Compared with patients treated by operator with annual volume less than 14 MT, the patient-level characteristic adjusted OR of successful reperfusion was 1.75 (95%CI, 1.02-2.99) for patients treated by an operator with annual volume between 14 and 39 and was 2.52 (95%CI, 1.37-4.64) for patients treated by an operator with annual volume equal or greater than 40 MT. No association was found between the year of the first MT (≤ 2010 or > 2010), taken as a marker of operator experience, and the rate of successful reperfusion (P=0.85).

Clinical favourable outcome was achieved in 44.1% (n=680; 95%CI, 41.7-46.6). In multivariable hierarchical logistic regression model controlling for all patient-level characteristics associated with clinical favourable outcome (P<0.20), the effect of operator on

successful reperfusion was not significant ($P=0.13$), with an ICC of 1.5%. In addition, operator characteristics had no effect on clinical favourable outcome rate (Table 2B).

Procedural Complications

Two hundred and forty seven patients (16.4%, 95%CI, 14.5-18.2) presented at least one procedural complication. Embolization in new territory ($n=102$) was the most frequent complication followed by arterial perforation ($n=67$), arterial dissection ($n=63$) and spasm ($n=24$). As shown in Table 3, higher rate of procedural complications was associated with no prior history of antiplatelet medication, higher admission NIHSS score, lower ASPECTS score, and less often M1 middle cerebral artery occlusion. In multivariable hierarchical logistic regression model controlling for patient-levels characteristics associated with procedure complications ($P<0.20$), we found no effect of operator (ICC=0). In addition, when annual operator volume was included in multivariable hierarchical regression model, we found no change in odds ratio of procedural complication with increasing annual operator volume ($P=0.67$, Table 4) nor with the year of first MT ($P=0.91$). Of note, none of the MT complications needed an urgent neurosurgical intervention directly related to the procedure.

DISCUSSION

Our large multicenter real-world MT cohort, including 1541 consecutive anterior and posterior AIS patients documented the correlation between higher operator's volume and successful reperfusion rate with an intraclass correlation coefficient of 0.037 ($P=0.046$), but not on complications. We observed dose response relationship between annual operator volume and successful reperfusion ($P=0.003$). This finding is in line with previous studies in other interventions. For example, characteristics of operators such as volume of procedures per year and number of years of practice, have been found to be an independent clinical and radiological

outcome predictor in interventional cardiology for myocardial infarction syndromes in several studies (8,9,13,14). Moreover, several studies, such as CAPTURE 2, analyzing the association of the physician variables and outcomes in CAS, showed that one of the most important determinants of perioperative carotid artery stenting outcomes was the operator carotid stenting volume (15). However, this annual volume operator effect on successful reperfusion rates was not found to have an impact on mRS \leq 2 at 90 days in our study. We can hypothesize that our study was underpowered to observe an effect on clinical outcome, as the 90-day mRS scores integrate other factors that the sole success of MT such as individual and environmental factors (16).

To date, only one study performed on the MR CLEAN registry based on 313 patients showed no significant relation between the level of experience, neurological adverse events and poor outcomes in operators with less than 50 MT procedures (17).

In our study, two hundred and forty seven patients had complications. The most common one was embolization in a new territory (7%). The overall rate of complications was not statistically significant between the operators' experience and volume. There was no significant operator variation for complications. This finding is somewhat controversial in the literature for other interventions. In the randomized CREST trial, there was no association between operator's volume and rate of complications in carotid revascularization (18). In contrast, experience and high volume had better prognosis on many procedures such as carotid artery stenting, coronary stenting, and percutaneous left atrial appendage closure (9,10, 19-22).

Our analysis also demonstrated a better reperfusion rate associated with female gender, patients on antiplatelet therapy, high ASPECT score before MT and M1 segment of the middle cerebral artery occlusion as previously reported (23-27).

Our findings should not be taken as a guideline, but we noted that a volume of at least 40 MT procedures per operator per year, that is less than one per week, was associated with better reperfusion rate. Currently, the Joint Commission has suggested a minimum of 12 MT during the previous year, or 24 MT over the past 2 years to certificate a thrombectomy-capable stroke center (28). Based on the minimum number of 75 coronary interventions/operator/year required to obtain formal certification in coronary interventional procedures, it is important to establish a minimal number of procedures/operator/year to accredit each operator and MT-capable stroke centers (22). Our results didn't allow to establish a threshold volume for accreditation but added valuable data on this topic.

Our study has several limitations. First, it was done in 3 large volume stroke centers. It will be interesting to compare in the future our results with other stroke centers with a lesser volume of MT per year. Secondly, the majority of our patients enrolled in this study were treated during the first 6 hours. Several studies such as DAWN and DEFUSE 3 studies showed the benefit of MT beyond 6 hours of last seen well (29,30). It will be interesting to compare in the future, the operator volume effect on reperfusion and complication rate between 6 and 24 hours after AIS onset. Thirdly, in our study, we analyzed only the volume of mechanical thrombectomy and not all kind of interventions on brain vessels such as embolization of intracranial aneurysm or AVM. This issue could be assessed in further studies in particular if the volume of all intervention on brain vessel have and added value on better outcomes than the sole volume of mechanical thrombectomy. Lastly, no formal sample size was calculated for the present study's objectives. We calculated that with 1500 patients, we have a precision greater than 2.55% to estimate the primary outcome rate (successful reperfusion).

CONCLUSIONS

Our data suggest that successful reperfusion in AIS patients treated with MT is dependent on the operator volume of MT per year. We did not find any relation between operator volume and complication rates, and the better procedure outcome did not translate into better clinical outcomes. Further studies are warranted to confirm these findings and investigate threshold procedure numbers associated with better outcomes."

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Table 1. Patient's characteristics according to successful reperfusion at the end of the procedure.

	Successful reperfusion (mTICI 2b/3)		P-value
	No (n=359)	Yes (n=1175)	
Age, mean (SD)	67.5 (15.8)	67.1 (14.9)	0.61
Men	206/359 (57.4)	618/1175 (52.6)	0.11
Medical History			
Hypertension	194/358 (54.2)	636/1170 (54.4)	0.96
Hypercholesterolemia	101/355 (28.5)	346/1168 (29.6)	0.67
Diabetes	44/356 (12.4)	201/1169 (17.2)	0.030
Current smoking	85/326 (26.1)	258/1115 (23.1)	0.27
Antithrombotic use	140/335 (41.8)	449/1096 (41.0)	0.79
Antiplatelet use	87/335 (26.0)	298/1096 (27.2)	0.66
Anticoagulants	64/335 (19.1)	182/1096 (16.6)	0.29
Current stroke event			
Wakeup stroke	81/359 (22.6)	263/1175 (22.4)	0.94
Pre-stroke rankin \geq 1	58/340 (17.1)	184/1143 (16.1)	0.67
NIHSS score, median (IQR) ¹	18.0 (12.0 to 21.0)	16.0 (11.0 to 21.0)	0.070
ASPECTS, median (IQR) ²	7.0 (5.0 to 8.0)	7.0 (6.0 to 8.0)	<.001
<8	211/333 (63.4)	563/1124 (50.1)	<.001
Initial Imaging			
MRI	287/359 (79.9)	970/1174 (82.6)	0.25
CT scan	72/359 (20.1)	204/1174 (17.4)	
M1-MCA Occlusion	165/358 (46.1)	571/1771 (48.8)	0.38
Cardio-embolic etiology	158/335 (47.2)	564/1061 (53.2)	0.056
Acute treatment characteristics			
Thrombolysis IV	187/359 (52.1)	771/1175 (65.6)	<.001
Onset to groin puncture, min , median (IQR) ³	244.0 (184.0 to 306.0)	240.5 (190.0 to 295.0)	0.78
General anaesthesia	141/359 (39.3)	337/1175 (28.7)	<.001

Values expressed as number (%) unless otherwise indicated. Abbreviations: ASPECTS= Alberta Stroke Program Early Computed Tomography Score; CT= Computed Tomography ; IQR=interquartile range;MCA=middle cerebral artery; MRI=magnetic resonance imaging; NIHSS=National Institutes of Health Stroke Scale; SD=standard deviation. ¹16 missing data (6 in no successful reperfusion group), ²77 missing data (26 in no successful reperfusion group), ³17 missing data (4 in no successful reperfusion group).

Table 2A. Relationship between annual operator volume (by tertiles), operator experience and successful reperfusion controlling for associated patient-levels characteristics.

	Operator (n)	Successful Reperfusion	Adjusted OR(95%CI)	Pvalue
Annual volume, MT/year				0.003*
<14	6	87/142 (61.3)	1.00 (reference)	-
14-39	7	691/910 (75.9)	1.75 (1.02 to 2.99)	0.040
≥40	6	397/482 (82.4)	2.52 (1.37 to 4.64)	0.003
Year of first MT				
<2010	8	530/677 (78.3)	1.00 (reference)	-
≥2010	11	645/857 (75.3)	1.34 (0.87 to 2.06)	0.18

Successful reperfusion was defined as a TICI 2b/c at the end of endovascular procedure. OR and P-value calculated in multivariate hierarchical logistic regression model including patient-levels characteristics associated with successful reperfusion in univariate analyses (p<0.20).

* calculated by including annual al operator volume levels as an ordinal variable.

Abbreviations: CI=confidence interval; MT=mechanical thrombectomy; mTICI=*modified treatment in cerebral infarction*; OR=odds ratio.

Table 2B. Relationship between annual operator volume (by tertiles), operator experience and favourable outcomes at 3 months after controlling for associated patient-levels characteristics.

	Operator (n)	Favorable outcome	Adjusted OR* (95%CI)	P-value
Annual volume, MT/year				0.80*
<14	6	65/143 (45.4)	1.00 (reference)	-
14-39	7	409/915 (44.7)	0.84 (0.48 to 1.50)	0.41
≥40	6	206/483 (42.7)	0.81 (0.43 to 1.52)	0.42
Year of first MT				
<2010	8	271/680 (40.0)	1.00 (reference)	-
≥2010	11	409/861 (47.5)	1.37 (0.99 to 1.89)	0.06

Favorable outcome was defined as a 90-day modified Rankin score 0 to 2. OR and P-value calculated in multivariate hierarchical logistic regression model including patient-levels characteristics associated with favourable outcome in univariate analyses ($p < 0.20$).

* calculated by including annual al operator volume levels as an ordinal variable.

Abbreviations: CI=confidence interval; MT=mechanical thrombectomy; OR=odds ratio.

Table 3. Patient's characteristics associated with procedural complications.

	No complication (N=1262)	Complications (N=247)	P-value*
Risk Factors			
Age, mean (SD)	67.2 (15.0)	66.9 (16.0)	0.82
Men	668/1262 (52.9)	139/247 (56.3)	0.34
Medical History			
Hypertension	687/1257 (54.7)	128/246 (52.0)	0.45
Hypercholesterolemia	378/1252 (30.2)	60/246 (24.4)	0.067
Diabetes	203/1254 (16.2)	35/246 (14.2)	0.44
Current smoking	285/1188 (24.0)	53/228 (23.2)	0.81
Antithrombotic use	487/1179 (41.3)	88/237 (37.1)	0.23
Antiplatelet use	330/1179 (28.0)	49/237 (20.7)	0.020
<i>Anticoagulants</i>	195/1179 (16.5)	43/237 (18.1)	0.55
Current stroke event			
Wakeup stroke	274/1262 (21.7)	66/247 (26.7)	0.085
Pre-stroke rankin≥1	197/1221 (16.1)	43/240 (17.9)	0.50
NIHSS score, median (IQR) ¹	16.0 (11.0 to 21.0)	18.0 (12.5 to 21.0)	0.036
ASPECTS, median (IQR) ²	7.0 (6.0 to 8.0)	7.0 (5.0 to 8.0)	0.001
<8	628/1201 (52.3)	138/230 (60.0)	0.032
Initial Imaging			
<i>MRI</i>	1039/1261 (82.4)	201/247 (81.4)	0.70
<i>CT Scan</i>	222/1261 (17.6)	46/247 (18.6)	
M1-MCAOcclusion	617/1258 (49.0)	98/246 (39.8)	0.008
Acute treatment characteristics			
Thrombolysis IV	793/1262 (62.8)	146/247 (59.1)	0.27
Onset to groin puncture, min, median (IQR) ³	245.0 (190.0 to 300.0)	235.5 (185.0 to 285.0)	0.12
General anaesthesia	387/1262 (30.7)	89/247 (36.0)	0.097

Values expressed as number (%) unless otherwise indicated. * P-value were obtain using Chi-square test and Mann-Whitney U test. Abbreviations: ASPECTS= Alberta Stroke Program Early Computed Tomography Score; CT scan=Computed Tomography; IQR=interquartile range; MRI=Magnetic Resonance Imaging; NIHSS=National Institutes of Health Stroke Scale; SD=standard deviation. ¹14 missing data (11 in no complication group), ²78 missing data (61 in no complication group) ³17 missing data (12 in no complication group).

Table 4. Relationship between annual operator volume (by tertiles), operator experience and procedural complication outcome controlling for associated patient characteristics.

	Operator (n)	Complications	Adjusted OR (95%CI)	P-value
Annual volume, MT/year				0.67*
<14	6	24/138 (17.4)	1.00 (reference)	-
14-39	7	150/897 (16.7)	1.07 (0.60 to 1.89)	0.64
≥40	6	73/474 (15.4)	0.95 (0.51 to 1.76)	0.57
First thrombectomy				
<2010	8	111/675 (16.4)	1.00 (reference)	-
≥2010	11	136/834 (16.3)	0.98 (0.72 to 1.34)	0.91

OR and P-value calculated in multivariate hierarchical logistic regression model including patient-levels characteristics associated with complication outcome in univariate analyses ($p < 0.20$).

* calculated by including annual operator volume as an ordinal variable.

Abbreviations: OR=odds ratio; MT=mechanical thrombectomy; mTICI=*modified treatment in cerebral infarction*.