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The effect of operator's experience on mechanical thrombectomy outcomes: A systematic review

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Abstract

Background: Mechanical thrombectomy (MT) has become the standard of care for stroke patients. The majority of the clinical trials and publications analyzing the outcomes related to the procedures report interventional performance by experienced practitioners. However, few of them individualize their preliminary metrics according to the operator's experience.

Objective: To summarize the literature and report safety and efficacy outcomes following MT procedures and correlate them with the operator's experience. Primary outcomes were successful recanalization, defined as modified thrombolysis in cerebral infarction greater or equal to 2b or 3, duration of the procedure measured in minutes, and serious adverse event.

Methods: This systematic review was performed according to the PRISMA guidelines. The PubMed, Embase, and Cochrane databases were utilized.

Results: There were six studies comprising 9348 patients (mean age 69.8 years; 51.2% males), and 9361 MT procedures were included. Each publication used for this review used a different experience definition to report their data. Higher interventionists' experience demonstrated a positive relationship with the possibility of successful recanalization and an inverse relationship with the duration needed for the operation in almost all of the included studies. As for the complications, none of the authors reported a statistically significant risk reduction of an adverse event, except Olthuis et al. correlating increasing training with lower odds of stroke progression.

Conclusions: A higher experience level is associated with better recanalization rates and shorter procedural duration in MT operations. Further studies are warranted to define the minimum required level of experience for operational autonomy.

Keywords

Operator's experience, mechanical thrombectomy, successful recanalization, procedural duration

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Introduction

Mechanical thrombectomy (MT) is a life-saving and disability-preventing procedure that has been the gold standard therapeutic approach for stroke cases within the appropriate time window. Although the bibliography contains analyses about the association of the operator's experience with EVTs for other pathologies such as intracranial aneurysms[1] or carotid stenting,[2,3] the available data for the corresponding relationship with MT are minimal. American Heart Association/American Stroke Association[4] and European Stroke Organization/European Society of Minimally Invasive Neurological Therapy[5] have proposed minimal experience required by the interventionist before autonomous EVT performance ability is certified. However, experience is unclear, yet the minimum number of procedures required for neurointerventional certification has not been established.

A recently published study indicates that cumulating the annual total number of procedures performed in a single center is associated with better MT safety and efficacy outcomes.[6] However, their results associate the whole center's increasing caseload without individualizing the operator's experience performing in each case. Large clinical trials[7–9] have been conducted to test different MT techniques' efficacy and safety outcomes. In addition, many systematic reviews and meta-analyses have taken place to synthesize the bibliographic data to conclude the most efficient treatment option.[10,11] However, very few correlate their results with the interventional operator's experience.

This study systematically reviews the publications correlating efficacy and safety outcomes of neurointerventions

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for stroke with the operator's experience and examines the relationship between them.

Methods

This systematic review was performed according to the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines.[12]

Search strategy and selection criteria

PubMed, Embase, and the Cochrane Central databases were queried without language restrictions. The search algorithm was the following: ("interventionist's experience" OR "operator's experience" OR "interventional radiologist experience" OR "interventionalist's") AND (EVT OR "endovascular therapy" OR "mechanical thrombectomy" OR "stentriever" OR "stent retriever" OR "direct aspiration" OR Penumbra) for published articles until March 2022. Two independent investigators searched. The references of the included studies were also manually reviewed to identify further eligible articles.

A study was included in this systematic review if it fulfilled all predefined criteria: (i) RCTs or prospective or retrospective observational studies that report MT efficacy and safety outcomes and complications in correlation to interventional operator's experience, (ii) publication date up to March 2022.

Data extraction and outcomes

Two reviewers with previous experience, blinded to each other, extracted relevant data from the eligible studies. Data extracted included first author, title, date of publication, country of origin, patient number, demographic characteristics, age, gender, National Institutes of Health Stroke Scale (NIHSS), level of vessel occlusion, symptom onset to groin puncture, and intravenous thrombolysis with alteplase (IVt). Primary study endpoints are successful recanalization, defined as modified thrombolysis in cerebral infarction (mTICI) greater or equal to 2b or 3, duration of the procedure measured in minutes, and serious adverse events (SAEs). In addition, stroke progression, new ischemic stroke (disabling, fatal, or nondisabling), embolus to a new territory, distal thrombus formation, symptomatic intracranial hemorrhage (sICH), vessel dissection, and vessel perforation were considered SAEs. Two investigators evaluated the risk of bias according to the ROBINS-1 tool for observational studies.[13]

Results

Literature search

The search strategy identified 19 studies after duplicates were removed. After irrelevant studies were excluded, ten studies underwent full-text evaluation. Six studies fulfilled our selection criteria[14–19] and were included in this review as presented in the flow diagram (Figure 1). All of them were retrospective observational cohort analyses. None of the included studies was found to have a high risk of bias (Supplementary Table 1).

Characteristics of the included studies and patients

Six studies comprising 9348 patients who underwent 9361 interventional procedures were included. The mean age of this cohort was 69.8 (±12.1) years, and the percentage of female patients was similar to male patients (51.2%, male/female = 2730/5336), based on the studies with available data (Table 1). The average time from symptom onset to groin puncture was 233.2 min with a standard deviation of 61.9 min and the mean NIHSS was 15.9 ± 2.9. According to the publications with the corresponding information, the level of vessel occlusion was most commonly located at the M1 branch of the middle cerebral artery (MCA) (2706 cases), followed by proximal internal carotid artery (848 cases) and M2 branch of MCA (554 cases) or other location (29 cases) (Table 2). In addition, the studies reported intravenous alteplase use in 5665 patients, comprising 60.6% of the cases.

Definition of experience

Each study differently defined the level of experience of individual interventionists. Olthuis et al.[16] used the total number of previously performed EVTs (EXPno) using 45 procedures (median EXPno) as a cutoff value for descriptive purposes to divide the patients into two groups EXPno $\geq$45 procedures and EXPno $<$ 45 procedures, the number of EVT procedures performed in the preceding year (EXPfreq), and years of experience since the first EVT (EXPyears) and performed multivariate regression analysis for each definition individually. Weylan et al.[17] divided the patients into three groups according to the primary interventionist's experience during the MT procedure. Group A comprised patients treated as one of the first 25 MT cases of the respective primary neurointerventionalist. Patients receiving MT as one of the 26th to 50th cases of the primary neurointerventionalist were allocated to group B. Patients treated beyond the 50th case of the primary neurointerventionalist were pooled in group C. Beharry et al.[18] analyzed the procedural outcomes of EVTs performed by five peripheral vascular interventional radiologists without a formal neurointerventional certification; two of them had some previous experience with an annual caseload of 60–70 procedures; one of them had significant neurointerventional training during the fellowship without completing a dedicated interventional neuroradiology fellowship; the other two had no previous experience on neurointerventional procedures. Moreover, Zhu et al.[19] defined the operator's experience as a continuous variable by cumulating the number of EVTs performed since January 2015. El Nawar et al.[14] utilized a multivariable mixed (hierarchical) logistic regression model using operator's annual volume as a covariate to assess the effect of interventionists' experience on successful reperfusion and

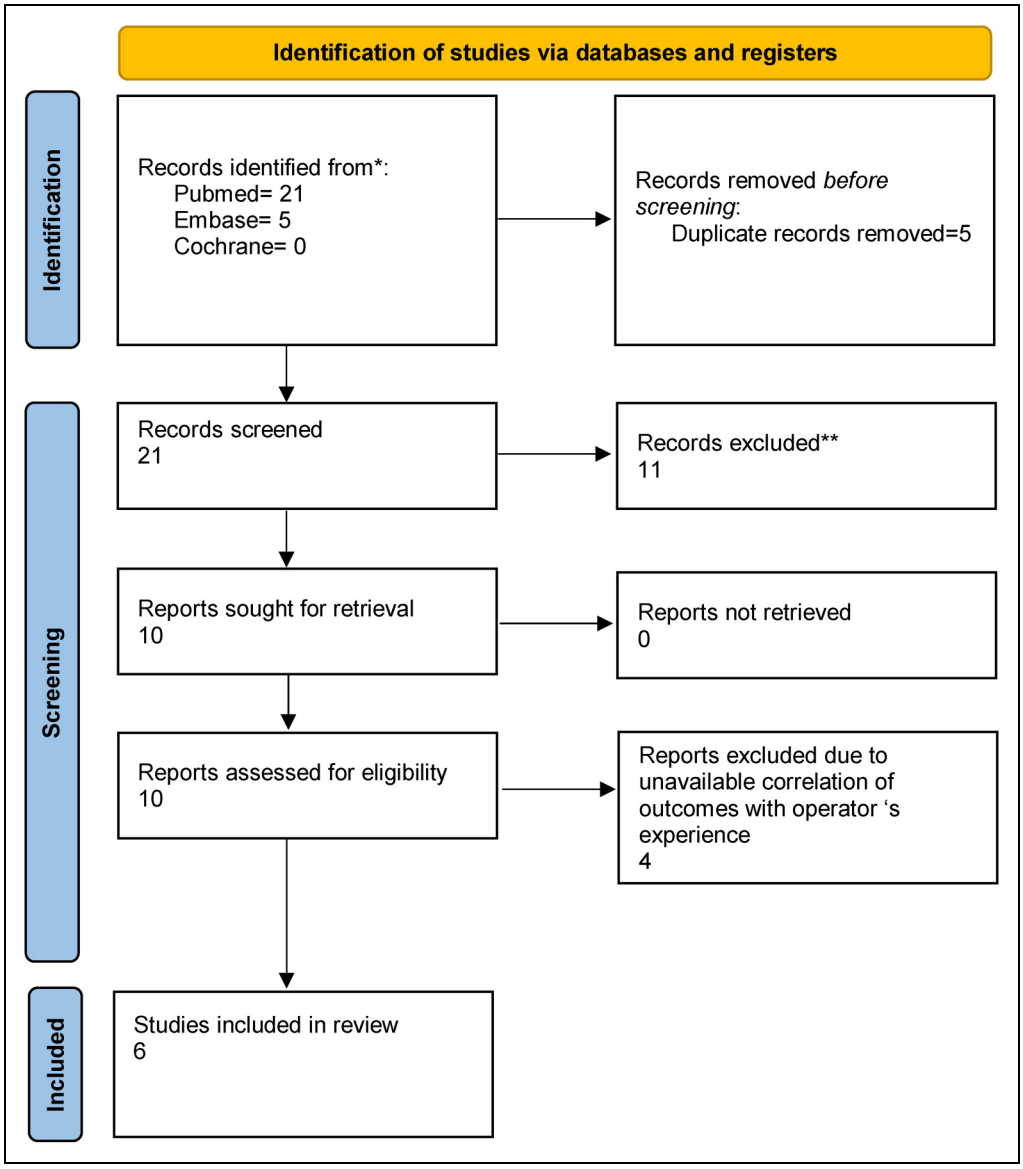

Figure 1. PRISMA search flow diagram.

procedural complication; three groups were examined: operators with less than 14 MT procedures per year, operators conducting from 14 up to 39 MT procedures per year and operators performing 40 or more MT procedures per year. Similarly, Beumer et al.[15] used logistic regression models expressing the association between experience and outcomes with adjusted odd ratios and created three different groups according to the operator's previous caseload: group 1 defined as "low experience" consisted of performers with no more than 5 previously performed MT procedures, group 2 interventionists with "minimal experience" had participated from 6 up to 15 procedures, and group 3 operators with "moderate experience" had conducted 16 up to 49 interventions.

Recanalization rate

Almost all publications with available data demonstrated a relationship between the increasing level of experience and successful recanalization rates. Olthuis et al.[16] reported 71% successful recanalization in the EXPno ≥45 versus 59% in the EXPno <45. Adjusted odds ratios (aORs) with the corresponding confidence intervals (95% CIs) correlated with higher EXPno and EXPfreq with a greater chance of recanalization (aOR = 1.08, 95% CI: 1.04–1.12, and aOR = 1.20, 95% CI: 1.11–1.31, respectively). In Weylan et al.[17] study group C achieved 87% mTICI 2b-3 followed by 82% of group B and 83% of group A. Moreover, the operator with significant experience in neurointerventions ended up with a 92% success rate, while the two operators with less previous experience reached 80% and 86% in Beharry et al.[18] publication (Table 3). Furthermore, Zhu et al.[19] multivariable regression analysis demonstrated that raising the interventionist's experience significantly increases the chances for complete recanalization (OR = 1.02, 95% CI: 1–1.04) (Table 4). Operators that had previously performed less than 14 MT procedures experience at El

Table 1. Baseline characteristics.

	Total *N* of patients	Total *N* of procedures	Male sex	Age		IV Alteplase
				Mean	SD	
Olthuis et al.	2589	2589	1351	71	5.5	1945
Weylan et al.	696	696	287	73	13	377
Beharry et al.	197	210	101	74.8	5.5	103
Zhu et al.	4012	4012	NA	70	15.3	2225
El nawar et al.	1.541	1541	824	67.2	15	958
Beumer et al.	313	313	167	61	14	57
Overall	9348	9361	2730	69.8	12.1	5665

N: number; SD: standard deviation; IV: intravenous.

Table 2. Baseline characteristics.

	NIHSS		Level of occlusion				Symptom onset to groin puncture	
	Mean	SD	ICA-T	M1	M2	Other	Mean	SD
Olthuis et al.	15.8	2.6	675	1476	330	15	204	72
Weylan et al.	16	2.9	132	380	174	9	274	74.6
Beharry et al.	15	2.9	41	114	50	5	292.8	80
El nawar et al.	16.2	2.8	NA	736	NA	NA	242.5	35.2
Beumer et al.	16	5.8	NA	NA	NA	NA	300	70
Overall	15.9	2.9	NA	NA	NA	NA	233.2	61.9

SD: standard deviation; ICA-T: proximal internal carotid artery; M1: M1 branch of middle cerebral artery; M2: M2 branch of middle cerebral artery; NIHSS: National Institutes of Health Stroke Scale.

Nawar et al.[14] achieved successful reperfusion at 61.3% of the cases, a percentage that was raised to 75.9% by the physicians with moderate experience (14–39 MT procedures) and to 82.4% by the most experienced (≥40 MT procedures); the corresponding odd ratios were 1.75 (95% CI: 1.02–2.99) and 2.52 (95% CI: 1.37–4.64), respectively. Beumer et al.[15] failed to statistically significantly associate operator's experience with complete reperfusion (aOR = 0.99, 95% CI: 0.97–1.02), reporting 41% rate at group 1, 50% at group 2, and 39% at group 3.

Procedural duration

The duration of the interventional procedure was inversely related to the operator's experience according to all of the included studies, except from Beumer et al.[15] (aOR = −0.55, 95%CI: −1.14 to 0.04) (Table 4). The average time spent for the operation by EXPno < 45 group was 72 min (min) [SD = 35 min], while EXPno ≥ 45 needed a mean of 67 min (SD = 34 min) in Olthuis et al.[16] publication. Effect estimates for the same study confirmed the inverse relationship between experience and procedural duration (EXPno: aOR = −1.34, CI: −1.84 to −0.85 and EXPfreq: aOR = −3.08, CI: −4.32 to −1.8). Weylan et al.[17] reported a mean duration of 89.3 min (SD = 22.2 min) in group A, 71.3 min (SD = 15.9 min) in group B, and 63.3 min (SD = 18.2 min) in the more experienced group C. Following the same pattern, Beharry et al.[18] interventionists' with no experience operated for a mean of 60.3 min (SD = 18.2 min) and 43.3 (SD = 13.6 min) followed by 40 min (SD = 10.4 min) and 40.8 min (SD = 7.8 min) for the interventionists with some previous experience. The operator with significant previous training demonstrated the shortest mean procedural duration of 34 min (SD = 8.1 min) (Table 3). Lastly, Zhu et al.[19] multivariable regression analysis demonstrated that raising the interventionist's experience is related to procedure duration (OR = −3.98, 95% CI: −5.15 to −2.8) (Table 4).

Procedure-related complications

The majority of the included studies that provided data related to procedural complications did not show an association between the operator's experience and the possibility of an adverse event taking place. Olthuis et al.[16] associated higher experience with decreased probability of stroke progression (aOR = 0.88, 95% CI: 0.82–0.95). On the other hand, new ischemic stroke (aOR = 1.00, 95% CI: 0.80–1.27), sICH (aOR = 0.98, 95% CI: 0.87–1.09), vessel perforation(aOR = 1.06, 95% CI: 0.87–1.30), vessel dissection(aOR = 0.89, 95% CI: 0.71–1.11), or embolization to a new territory(aOR = 0.96, 95% CI: 0.84–1.09) had no statistically significant relation to the interventionist's experience in the same study. El Nawar et al.[14] demonstrated no statistically significant association by reporting a 17.4% procedural complication rate during the performance of the least experienced interventionists (<14 MT procedures), 16.7% by the moderately trained (14–39 MT procedures), and 15.4% by the most trained operators (≥40 MT procedures); the aORs for the moderately and most experienced physicians were 1.07 (95% CI: 0.60–1.89) and 0.95 (95% CI: 0.51–1.76), respectively. In line with the latter study, Beumer et al.[15] failed to achieve statistical significance with group 1 adverse event rate of 57%, group 2 of 53%, group 3 of 58% and resulting in aOR = 1.00 (95% CI: 0.98–1.02). Similarly, increasing the operator's previous caseload did not seem to prevent sICH or embolization to a new territory and vessel dissection or vessel perforation from happening in Beharry et al.[18] and Zhu et al.[19] publication, respectively.

Discussion

This systematic review summarized all available studies of patients who underwent interventional procedures with

Table 3. Procedural outcomes.

Study	Experience status	Successful Recanalization		Procedure Duration	
		N	%	Mean	SD
Olthuis et al.	EXPno ≥45 procedures	900	71*	67	34
	EXPno < 45 procedures	741	59*	72	35
Weylan et al.	Group A	127	83	89.3	22.2
	Group B	124	82	71.3	15.9
	Group C	342	87	63.3	18.2
Beharry et al.	Some previous experience in neurointerventions operator 1	65	80	40	10.4
	Some previous experience in neurointerventions operator 2	38	86	40.8	7.8
	Significant previous neurointerventinal training	43	92	34	8.1
El Nawar et al.	< 14 MT procedures per year	87	61.3	NA	NA
	14 −39 MT procedures per year	691	75.9	NA	NA
	= or > 40 MT procedures per year	397	82.4	NA	NA
Beumer et al.	Group 1: < 6 previously performed MT procedures	34	41	NA	NA
	Group 2: 6–15 previously performed MT procedures	46	50	NA	NA
	Group 3: 16–49 previously performed MT procedures	39	39	NA	NA

*Number of patients with available data for Olthuis et al. was 1263 for EXPno ≥45 procedures and 1262 for EXPno < 45 procedures for successful recanalization.
N: number; SD: standard deviation.

Table 4. Effect estimates of procedural outcomes.

Study	Experience definition	Successful recanalization		Procedure duration	
		OR	95% CI	OR	95% CI
Olthuis et al.	EXPno	1.08	1.04–1.12	−1.34	−1.84 to −0.85
	EXPfreq	1.20	1.11–1.31	−3.08	−4.32 to −1.8
Zhu et al.	Cumulating number of procedures performed since January 2015	1.02	1–1.04	−3.98	−5.15 to −2.8
El Nawar et al.	14–39 MT procedures per year	1.75	1.02–2.99	NA	NA
	= or > 40 MT procedures per year	2.52	1.37–4.64	NA	NA
Beumer et al.		0.99	0.97–1.02	−0.55	−1.14 to 0.04

OR: odds ratio; CI: confidence interval.

available metrics of operators' experience, including 9348 patients and 9361 interventions. The interventionist experience was differently defined in each study and associated with the duration of the procedure, successful recanalization, and procedural complications. Increasing the operator's caseload seems to be associated with higher recanalization rates and a lower probability of an adverse event. The mean duration of the interventions varied from 34 to 89.3 min across this patient cohort. In addition, escalating interventionists' experience had an inverse relationship with procedural duration. This review supports that experience is related to the operator's efficacy compared to previous studies with preliminary metrics that indicate no association.[15]

One of the included publications demonstrated no association between previous training and procedural outcomes.[15] Beumer et al.[15] reported that during the research conduction they followed very strict inclusion criteria and did not take into account other intracranial and extracranial procedures that the study subjects underwent for indications other than stroke. We assume that these points might have led to the underestimation of the true effect that the experience might have had the results of the MT procedures. Also, the authors of the same study report this notification at their publication.[15]

Our study suggests cumulating interventionist experience for better clinical and safety EVTs outcomes. However, the optimal balance between procedural efficiency and safety has not yet been established. In addition, the number of previously performed MT and the annual caseload rate has not been strictly defined to decide when the practitioner is qualified to operate with autonomy. More studies with available preliminary metrics are warranted to conclude the most appropriate education and training plan for future interventionists.

This urge appeals not only to neurointerventions; radiology-guided minimal invasive procedures have replaced many treatment options[20–24] in the settings of emergency as well as for patients not eligible for surgical approaches due to comorbidities.[25] Studies with specified records for the same interventions are essential to define the minimal baseline experience level and the appropriate certification process for future operators.

Minimizing the duration of interventions is a challenging matter of high interest. Radiation is associated with

a significant number of different long-term morbidities and complications. Qualified health care personnel of medical centers which receive high annual caseloads are vulnerable to exposure to a significant amount of radiation. Reducing procedural time by recruiting operators with a higher level of experience before proceeding in autonomy will retain lower exposure of the interventional team staff and the patients. Moreover, defining the appropriate baseline of experience and achieving the lowest possible duration of an intervention is also a subject of deep concern for pediatric procedures[26,27] as the children population constitutes a group of patients highly vulnerable to radiation-related consequences.[28]

Limitations

Our results should be interpreted in the context of several limitations. First, the retrospective design and nature of the included studies have an inherent risk of bias that cannot be accounted for. Secondly, choice of patient, treatment method and device type at the discretion of the treating interventionist according to experience can lead to selection bias. In addition, clinical, imaging, and safety outcomes were not available for all patients, and the variable experience definitions rendered data synthesis impossible. Moreover, no records correspond to the MT technique used in each case; recent bibliography demonstrated that direct aspiration is associated with significantly shorter procedural time than stent retriever for both anterior and posterior[29] circulation vascular pathologies. Finally, modifications in MT international guidelines, including more than one interventionist or probable supervision in certain cases, and changes in hospital staff and technicians' contribution to EVTs constitute possible and hardly measurable confounders.

Conclusion

There is an evident heterogeneity in how thrombectomy studies define "experience." Appropriate operator's experience is associated with higher recanalization rates and shorter procedural duration; however, the number of previously performed interventions does not seem to be associated with a lower probability of an adverse event. Further studies are warranted to evaluate the potential baseline level of experience and define the necessary certification process to enable future operators to proceed safely in autonomy.

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Supplemental material

Supplemental material for this article is available online.

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