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Stroke: A Single-Center Cohort Study**

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Predictors of Endovascular Treatment Procedural Complications in Acute Ischemic Stroke: A Single-Center Cohort Study

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ABSTRACT

BACKGROUND AND PURPOSE: Procedural complications occur in 4%–29% of endovascular treatments in acute ischemic stroke. However, little is known about their predictors and clinical impact in the real world. We aimed to investigate the frequency and clinical impact of procedural complications of endovascular treatment and identify associated risk factors.

MATERIALS AND METHODS: From 2015–2019, we retrospectively reviewed all patients with acute ischemic stroke receiving endovascular treatment within 24 hours included in the Acute STroke Registry and Analysis of Lausanne. We identified patients having an endovascular treatment procedural complication (local access complication, arterial perforation, dissection or vasospasm, and embolization in a previously nonischemic territory) and performed logistic regression analyses to identify associated predictors. We also correlated procedural complications with long-term clinical outcome.

RESULTS: Of the 684 consecutive patients receiving endovascular treatment, 113 (16.5%) had at least 1 procedural complication. The most powerful predictors were groin puncture off-hours (OR = 2.24), treatment of 2 arterial sites (OR = 2.71), and active smoking (OR = 1.93). Patients with a complication had a significantly less favorable short-term clinical outcome (Δ -NIHSS score of -2.2 versus -4.33 , P -value adjusted $< .001$), but a similar long-term clinical outcome (mRS at 3 months = 3 versus 2, P -value adjusted = .272).

CONCLUSIONS: Procedural complications are quite common in endovascular treatment and lead to a less favorable short-term but similar long-term outcome. Their association with treatment off-hours and at 2 arterial sites requires particular attention in these situations to optimize the overall benefit of endovascular treatment.


ABBREVIATIONS: AIS = acute ischemic stroke; EVT = endovascular treatment


Endovascular treatment (EVT) with stent retrievers or the direct aspiration first-pass technique is considered the criterion standard procedure for eligible patients with acute ischemic stroke (AIS) with proximal intracranial large-vessel occlusion.^{1–3} Even though complication rates of 4%–29% have been reported,^{4–10} they do not eliminate its global beneficial effect.

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Procedural complications during EVT include local-access complications (ie, hemorrhage or arterial lesion at the access site) and cerebrovascular complications (ie, arterial dissection, embolization in a previously nonischemic territory, arterial perforation, or vasospasm). The occurrence of procedural complications carries the risk of additional diagnostic and therapeutic procedures, longer hospital stays, and increased illness, mortality, and costs.

Awareness of the frequency and clinical impact of EVT procedural complications and of the independently associated risk factors could guide stroke teams in patient selection and complication's prevention during the procedure. In addition, the presence of such risk factors should intensify intraprocedural monitoring, which may permit a more proactive management of complications. Although the timing of AIS and EVT cannot be chosen by patients or the medical system, recent reports described longer door-to-reperfusion delays at night and on weekends¹¹ and poorer outcomes in patients treated in the afternoon.¹²

Given the paucity of clinical data,¹³ we aimed to investigate the frequency and clinical impact of the overall EVT procedural

complications and identify associated risk factors in a consecutive real-world AIS population in the modern EVT era.

MATERIALS AND METHODS

Study Design and Cohort Selection

We retrospectively reviewed all patients with AIS receiving EVT from January 2015 to December 2019 in the prospectively constructed Acute STroke Registry and Analysis of Lausanne (ASTRAL), which collects all adults with AIS admitted to the stroke unit and/or intensive care unit of Lausanne University Hospital (CHUV).¹⁴

For this analysis, we selected all patients receiving EVT within 24 hours, with or without preceding IV thrombolysis, including patients for whom the target occlusion was not reached for technical reasons or in whom the target occlusion on DSA was already re-canalized at the time of the EVT attempt. We excluded patients receiving rescue endovascular procedures, ie, EVT after secondary worsening and/or >24 hours after stroke onset.

Acute Neuroimaging, EVT Eligibility, and Procedure

Acute brain imaging on admission was based mainly on CT until April 2018 using a 64-detector row CT scanner and mainly on MR imaging from May 2018 with 3T MR imaging scanners. We obtained at least 1 arterial study of the cervical and cerebral arteries before EVT, mostly CTA, alternatively MRA, followed by DSA with the intention to perform EVT. A senior vascular neurologist and senior neuroradiologist assessed all noninvasive neuroimaging, and an interventional neuroradiologist, all DSAs to identify procedure-related cerebrovascular complications in a nonblinded manner. A tandem lesion was defined as the simultaneous presence of an arterial occlusion or stenosis ($\geq 70\%$ extracranially, $\geq 50\%$ intracranially) in both the extra- and intracranial circulation in the same vascular axis.

Since October 2014, we have offered EVT in our center within 6 hours for a disabling deficit and an ASPECTS of ≥ 5 , similar to the Multicenter Randomized Clinical trial of Endovascular treatment for Acute Ischemic stroke in the Netherlands (MR CLEAN)⁷ and initial European criteria.² Since May 2017, patients were treated up to 8 hours using the same criteria.¹⁵ After 8 hours, treatment was given following the modified Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention with Trevo (DAWN) criteria, ie, in the presence of an NIHSS score of ≥ 10 and an ASPECTS of ≥ 7 or, if the stroke was disabling, an NIHSS score of 1–10 and an ASPECTS of ≥ 8 .^{4,16} Since January 2018, late treatment was alternatively based on any NIHSS, a core <70 mL and a mismatch ratio [(penumbra + core)/core] of > 1.8, according to the Endovascular Therapy Following Imaging Evaluation for Acute Ischemic Stroke 3 (DEFUSE-3) criteria, in accordance with the updated Swiss,¹⁷ European,¹ and American recommendations.³

We treated basilar artery occlusions until April 2017 with EVT up to 6 hours in the absence of extensive brainstem infarct on imaging. From May 2017, the treatment window was extended to 8 hours if the posterior circulation ASPECTS was ≥ 7 , and to 24 hours if no transverse irreversible brainstem ischemia was present on MR imaging or if the posterior circulation ASPECTS was ≥ 8 on plain CT.

We performed femoral access under sonographic guidance. The type of sedation was recorded (local versus general anesthesia), with the latter being the preferred method in our center. We routinely add 2 mg of nimodipine in the flushing line of the guiding catheter to prevent vasospasm during the intervention. The degree of recanalization at the end of the procedure was recorded according to the modified TICI grading scale.¹⁸

During working hours, there is a board-certified neurologist on-site and available any time, whereas during off-hours, there is a neurology resident-in-training on site who is supervised by phone by a board-certified neurologist. During working hours, there are always 3–4 board-certified interventional neuroradiologists in-house; during off-hours, the on-call board-certified interventional neuroradiologist arrives within 20 minutes at the hospital when called for an EVT. Finally, there are 2 interventional technicians available in-house during working hours, and only 1 after hours. Emergency department staffing by the physician residents and nurses is identical at all times, but during working hours, there are twice as many board-certified internists present.

EVT Procedural Complications

We defined procedural complications related to EVT in accordance with the current literature.^{19,20}

Access Complications

- 1) Hemorrhage in the arterial puncture area: any important external bleeding or internal hematoma (ie, femoral, retroperitoneal)
- 2) Arterial access damage: symptomatic or radiologic pseudoaneurysm, arterial dissection, occlusion or embolization in a peripheral territory, and floating thrombus at the punctured artery.

Procedural Cerebrovascular Complications

- 1) Embolization in the nonischemic cerebral territory: any embolization in a previously not occluded artery (with the exclusion of clot fragmentation and embolization in a distal segment of the already affected artery)
- 2) Iatrogenic dissections of cervical or intracranial arteries or vasospasms requiring therapeutic interventions by intra-arterial vasodilator drugs
- 3) Intracranial arterial perforation or postprocedural SAH: contrast extravasation observed during the procedure or SAH in the territory of the treated artery on any control neuroimaging within 24 hours.

We did not consider the occurrence of parenchymatous hemorrhage and cerebral edema as procedural complications because their proportion was not increased in large, randomized, controlled trials of EVT^{21,22} and most of these occur in the postprocedural phase. Therefore, they were not included in the current analysis.

Post-EVT monitoring in our stroke unit is described in the Online Supplemental Data.

Primary End Points

As primary outcomes, we evaluated the frequency and predictors of EVT procedure-related complications.

Table 1: Frequency of EVT procedural complications

EVT Procedural Complications	Frequency (No.) (%)
Significant at access site <7 days	13 (1.9%)
External bleeding	6 (46.2%)
Internal hematoma	7 (53.8%)
Any local arterial damage at access site <7 days	9 (1.3%)
Cerebral arterial complications, ie, dissection (<i>n</i> = 27) and treated vasospasm (<i>n</i> = 1)	28 (4.1%)
Embolization in previously normal territory	21 (3.1%)
Arterial intracranial perforation during EVT (observed acutely, SAH on subacute imaging)	42 (6.1%)
Total EVT procedure complications	113 (16.5%)

Table 2: Multivariate analysis of significant factors associated with EVT procedural complications

Predictors of EVT Procedural Complications	OR	95% CI	P Value
Two sites treated	2.71	1.49–4.86	<.001
Groin puncture off-hours	2.24	1.37–3.69	<.001
Smoking	1.93	1.10–3.33	.02

Secondary End Points

In patients with procedural complications, we assessed the short-term outcome using the 24-hour Δ -NIHSS, defined as the difference between the NIHSS score at 24 hours and the NIHSS score at admission. We decided to analyze the NIHSS as an ordinal variable, to increase the power of the study to identify independent associations with dependent variables. The Δ -NIHSS was preferred over early neurologic deterioration, which lacks a uniform definition in the literature.

In these patients, we used the mRS for evaluation of the long-term outcome at 3 months.

For patients with-versus-without complications, we compared the length of hospitalization, the disposition after acute hospitalization, early ischemic stroke or TIA recurrence up to 7 days, and mortality at 7 days and 3 and 12 months using univariate analysis.

Statistical Analysis and Ethics Considerations

Differences between patients with and without EVT procedural complications were explored using appropriate statistical testing such as the Mann-Whitney *U*, χ^2 , or Fisher Exact tests.

To identify factors independently associated with the occurrence of any procedural complication, we used logistic regression models. We initially performed unadjusted univariate analyses, fitting models with the complications/no complications indicator as the only explanatory variable. Variables that were significant in the univariate approach (using a threshold *P* value of .20) were then used for the multivariate analysis, in which a stepwise variable-selection method based on the Akaike information criterion was performed to obtain the final multivariate logit model. The following variables were entered into the final model: active smoking, hypertension, diabetes mellitus, groin puncture during regular working hours (8:00 AM–5:59 PM) versus off-hours (6:00 PM–7:59 AM), and 2 arterial sites treated.

For short-term outcome (24-hour Δ -NIHSS), a multivariate linear model was used and well-known factors associated with clinical outcome such as covariates, ie, age, admission NIHSS,

admission level of consciousness, pre-stroke modified Rankin Scale (mRS) score, acute ASPECTS (CT or DWI-MR imaging), pretreatment with intravenous thrombolysis, acute blood glucose, and stroke mechanism (grouped into cardioembolic, atheromatous, and other categories).

For the 3-month outcome (mRS as an ordinal variable, 0–6), a multivariate ordinal logistic model was used. Factors included in this outcome analysis were age, admission NIHSS, admission level of consciousness, prestroke mRS score, acute ASPECTS (CT or DWI), proximal-versus-distal site of large-vessel occlusion, and peripheral artery disease.

A *P* value < .05 was considered significant for all analyses.

ASTRAL follows the institutional regulations on clinical and research registries. Before analysis, the data were anonymized following the principles of the Swiss Human Research Ordinance from 2013 (HRO, Art.25). Given that only anonymized data were used, there was no need for local ethics committee approval or patient consent according to the Swiss Federal Act on Research involving Human Beings from 2011 (HRA, Art.3) and the applicable data protection legislation. Patients were informed in writing about the potential scientific use of their routinely collected data in anonymized form and their right to refuse scientific use of personal data for research purposes; any such refusal was honored before data extraction.

The anonymized data of this study are available from the authors on reasonable request.

For reporting, we used the Strengthening the Reporting of Observational Studies in Epidemiology checklist.²³

RESULTS

During the study period, 684 consecutive patients with EVT were included, with a median age of 72 years. The median NIHSS score was 14, and women were nonsignificantly underrepresented (47.3%). In total, 113 (16.5%) patients experienced an EVT procedure-related complication. The baseline characteristics of these patients are summarized in the Online Supplemental Data, and the frequency of EVT procedural complications, in Table 1.

Predictors for Procedural Complications during EVT

In the univariate analysis (Table 1), patients with a procedural complication during EVT had higher admission NIHSS scores and more cerebrovascular risk factors such as smoking; and more often had a tandem lesion, thus 2 arterial sites were treated. The number of device passages in the recanalization attempt of the occluded artery seemed to also be associated with EVT procedural complications in the univariate analysis.

In the multivariate analysis, we identified 3 independent associations of EVT with any procedural complication: groin puncture off-hours, treatment of 2 arterial sites, and active smoking (Table 2).

Table 3: Adjusted primary outcomes for patients with AIS with versus patients without EVT procedural complications

Clinical Outcome	AIS with Procedural Complications (n = 113)	AIS without Procedural Complications (n = 571)	Adjusted OR or β Coefficient (95% CI)	Adjusted P Value
Short-term clinical consequences (24-hour Δ -NIHSS)	-2.21 (10.06)	-4.33 (7.89)	2.73 (1.09–4.37)	<.001 ^a
Long-term functional outcome at 3 months (mRS) (median) (IQR)	3 (2–5)	2 (1–4)	1.32 (0.81–2.16)	.272

^aSignificant.

Secondary Outcomes

Patients with procedural complications had a significantly less favorable short-term clinical outcome in the adjusted analysis than patients without a procedural complication (24-hour Δ -NIHSS of -2.2 versus -4.33 , $P < .001$). However, this difference did not persist when evaluating the adjusted long-term clinical outcome (mRS at 3 months = 3 versus 2, P -value adjusted = .272) (Table 3).

Concerning secondary outcomes, the unadjusted analysis between patients with or without a procedural complication (early stroke recurrence within 7 days of stroke onset, duration of hospitalization, discharge orientation, mortality at 7 days and 3 and 12 months and mRS score at 12 months) found no statistically significant differences (Online Supplemental Data).

DISCUSSION

Of 684 consecutive patients receiving EVT in the modern thrombectomy era in our hospital, 16.5% had a procedural complication. The most powerful predictors were EVT performed off-hours, treatment of 2 arterial sites, and a history of smoking. While short-term clinical outcome was significantly worse in patients with a procedural complication, it did not affect long-term outcome.

Our frequency of 16.5% for EVT procedural complications is in line with the literature, reporting a wide range of complications in randomized controlled trials (4%–29%). Lack of a uniform definition hampers comparability, however. In our study, we used a more liberal definition for some complications, in particular by considering any postprocedural SAH on neuroimaging as a complication. However, in some cases, the SAH may not be related to the procedural perforation but to arterial lacerating when pulling back the endovascular device or thrombolysis-facilitated rupture of an ischemic superficial artery.

Groin puncture off-hours was strongly associated with procedural complications. This could potentially be explained by the operator's fatigue due to sleep deprivation leading to impairment of motor, cognitive, and attention skills. Another explanation could be less staff, which is particularly prevalent after hours. Hajdu et al¹² demonstrated that EVT for AIS performed in the morning hours leads to a more favorable outcome at 3 months than EVT at the end of the workday, highlighting the potential influence of stroke unit staff fatigue. Another important factor could perhaps be that during off-hours, less experienced emergency and neurology physicians perform the pre-EVT management of patients with stroke.

Another powerful predictor of occurrence of EVT procedural complications was the treatment of 2 arterial sites. Such treatment

may be challenging, requiring particular neurointerventional skills. It also demands a higher number of EVT device passages, increasing the risk of dissection or perforation of the cervicocerebral arteries as well as the risk of embolization in a previously nonischemic territory. This variable seems to be more powerful in predicting complications than the number of device passes, which was associated with procedural complications in our univariate but not multivariate analysis.

Among patient characteristics, we identified active smoking as contributing to a higher procedural complication risk. Smoking has been demonstrated to increase the total calcification index of the carotid arteries and arterial stiffness and endothelial dysfunction and is associated with poorer control of other cerebrovascular risk factors, again potentially contributing to such arterial problems.²⁴

Most interesting, age, diabetes mellitus, stroke mechanism (Trial of Org 10172 in Acute Stroke Treatment [TOAST]),²⁵ and the type of anesthesia were not significantly associated with an increased occurrence of procedural complications. A higher stroke severity (admission NIHSS score) was associated with complications in the univariate but not multivariate analysis.

The fact that the 24-hour neurologic status was worse in patients with procedural complications highlights the need for close monitoring and proactive management of the complications. This initial disadvantage of problematic EVT did not translate into a statistical difference of the functional status at 3 months in the adjusted analysis. Similarly, other large series of patients with EVT, which did not analyze the rate of complications, showed no association of the time of treatment with clinical outcome.^{26,27} This reassuring observation is a further argument in favor of the relative safety of EVT.

Additional important findings of our study were the absence of statistically significant differences in the length of hospitalization, posthospital disposition, early ischemic event recurrence, and early or late mortality rates between patients with and without EVT procedure-related complications.

The main clinical implication of our study is the identification of predictors of EVT procedural complications. Given that the treating physicians cannot influence the 3 identified variables, they can at least inform patients and their next of kin of the additional risk. Furthermore, the interventional neuroradiologist may use special care or techniques in the recognized patients to avoid procedural complications to maximize the benefit of EVT. Third, awareness of these complication predictors may allow a closer monitoring during and after the EVT procedure for their early detection and treatment.

The main strength of our study is the enrollment of consecutive real-world patients, which makes our results more generalizable.

Furthermore, prespecified and liberal definitions of EVT complications by noninterventional neurologists decrease the risk of underreporting. Third, we considered only procedures from the modern EVT era (2015–2019) using mainly stent retrievers and the direct aspiration first-pass technique, which are the currently preferred revascularization methods.

The main limitations are, first, the retrospective, observational, nonrandomized, and single-center character of our study. Second, our results need to be confirmed in other populations because ASTRAL contains a predominantly elderly, white population. Third, the definitions of some of the procedural complications are debatable, given the lack of complete consensus.¹⁹ Similarly, the causal association of a “complication” and the EVT is not always certain, for example in the case of SAH, which can also occur spontaneously or due to IV thrombolysis. Finally, we did not include postprocedural parenchymal hemorrhage and cerebral edema in this analysis because we do not consider these procedure-related.^{10,22}

CONCLUSIONS

Procedural complications are quite common in endovascular treatment and lead to a less favorable short-term but similar long-term outcome. The most powerful predictors of procedural complications are EVT performed off-hours, treatment of two arterial sites, and a history of smoking. These situations require particular attention in order to optimize the overall benefit of endovascular treatment.

Disclosure forms provided by the authors are available with the full text and PDF of this article at www.ajnr.org.

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