ORIGINAL RESEARCH

Acute Recanalization of Thrombo-Embolic Ischemic Stroke with pREset (ARTESp): the impact of occlusion time on clinical outcome of directly admitted and transferred patients

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ABSTRACT

Objectives Acute Recanalization of Thrombo-Embolic Ischemic Stroke with pREset (ARTESp) is a prospective multicenter study assessing the efficacy and safety of the pREset stent retriever for the treatment of intracranial vessel occlusion. Determination of the effect of transfer status on clinical outcome was a secondary objective.

Methods Efficacy was measured by recanalization success (Thrombolysis in Cerebral Infarction score 2b) and favorable clinical outcome at 90 days (modified Rankin Scale 0–2). Intracranial hemorrhage (ICH) and death at 90 days were safety measures. The outcome of directly admitted (DAP) and transferred (TP) patients was investigated using multivariable regression models.

Results Four study centers included 100 patients (mean age 68.3 years, median National Institutes of Health Stroke Scale score 15). Recanalization success was achieved in 84.4% after a mean of 1.7 passes. ICH was detected in 14.0%, with 2.0% being symptomatic. At 90 days, 62.5% of the patients had a favorable outcome and 7.3% died. TP had longer occlusion times (289 vs 180 minutes, p<0.001) and a lower rate of favorable outcome (58.0% vs 78.4%, p=0.046) than DAP. Multivariable regression revealed occlusion time as the critical determinant (OR=0.963, 95% CI 0.931 to 0.997, p=0.032), whereas transfer status itself showed no significant association (OR=0.565, CI 0.133 to 2.393, p=0.438).

Conclusions pREset proved to be safe and effective for the treatment of acute intracranial vessel occlusion. Increased occlusion time impaired clinical outcome in TP.

Trial registration number NCT02437409; Results.

INTRODUCTION

The efficacy of mechanical thrombectomy (MT) in patients with acute ischemic stroke caused by embolic proximal vessel occlusion was recently proved by five randomized controlled trials (RCTs).1–5 The positive results of these trials were mainly driven by the use of very effective stent-like retrievers, which were first introduced in 2008,6 and barely used in previous trials.7–9 Currently, several devices belonging to the family of ‘stent retrievers’ are available but each has undergone very different stages of scientific evaluation. The performance of the Trevo retriever (Stryker, Kalamazoo, Michigan, USA) and the Solitaire FR revascularization device (Covidien/Medtronic, Dublin, Ireland) has been evaluated in multicenter studies.10 11 For the pREset thrombectomy device (phenox, Bochum, Germany), data of retrospective single-center studies demonstrated a safety and efficacy profile comparable to that of other stent retrievers.12 13 Prospective data from a multicenter study with defined inclusion and exclusion criteria and core-laboratory evaluation are lacking. Thus the primary purpose of the Acute Recanalization of Thrombo-Embolic Ischemic Stroke with pREset (ARTESp) study was to assess the safety and outcome after MT with the pREset device under controlled study conditions.

Similar to treatment with IV thrombolysis (IVT), it is assumed that the odds for favorable outcome after MT substantially depend on the occlusion time of cerebral arteries.14 19 Since MT is less widely available than IVT, a relevant proportion of patients needs a secondary transfer after the diagnosis of large vessel occlusion. Thus, MT is delayed in transferred patients compared with patients directly admitted to an endovascular stroke center. This hypothetically results in less favorable clinical outcome. Since in all study centers a relevant proportion of patients with stroke are secondary referrals, data of ARTESp were used to investigate the impact of secondary transfer on clinical outcome.

MATERIALS AND METHODS

Study design

ARTESp is a prospective, multicenter, single-arm, post-market clinical follow-up study to evaluate the safety and clinical outcome of MT with the pREset thrombectomy device in eligible patients. The study was approved by the local ethics committees of all participating centers and registered at ClinicalTrials.gov (NCT02437409).

Study subjects

Between February 2013 and February 2015, consecutive patients undergoing MT in four centers were screened for ARTESp inclusion and exclusion criteria. Key inclusion criteria were proven occlusion of the internal carotid artery (ICA), M1 or M2 segments of the middle cerebral artery (MCA), vertebral artery or basilar artery, a National Institutes of Health Stroke Scale (NIHSS) score of 8–30 and groin puncture within 6 hours after symptom onset. Patients <18 and >85 years of age and/or...
with extended infarct demarcation according to the judgment of
the local investigator were excluded. Patients provided informed
written consent before study inclusion. If patients were unable
to provide informed consent, their legal guardian acted on behalf. A comprehensive list of inclusion and exclusion criteria
is provided as online supplementary material.

Participating centers
All study centers introduced MT between 2007 and 2009 and
perform at least 60 procedures annually. Participating interven-
tionalists were trained in device handling and independently
completed at least 25 procedures with pREset before study entry.

The pREset device
pREset is a laser-cut nitinol stent retriever with a closed-cell
design (figure 1). A helical slit along the device body allows for
optimal adaptation to the vessel diameter, while preserving the
closed-cell configuration. The proximal cells are connected with
a ring to maintain a stable opening and to reduce tapering in
vessel curves. There are one proximal and two distal radiopaque
markers. pREset 4–20 and 6–30 were evaluated in ARTESp,
with the first number representing the maximum diameter in
millimeters and the latter the usable length between the distal
marker and the proximal ring. pREset was approved in Europe
in August 2011.

Endovascular treatment
Procedures were performed either under local anesthesia, con-
scious sedation, or general anesthesia, according to the respect-
ive institutional guideline. The interventionalist chose the access
site, access material, microcatheter, and micro-guidewire, taking
device compatibility into account. The use of a balloon-guide
catheter or intermediate catheter was not mandatory. The pro-
cedure was performed according to the official instructions for
use of pREset.

Imaging evaluation and technical outcome
All imaging data were subject to independent and blinded core-
laboratory evaluation. Pretreatment imaging was evaluated for
compliance with inclusion and exclusion criteria. Collateral flow
was assessed on angiographic images according to the Higashida
score. Recanalization results were rated after the final pass
with pREset and in the final angiographic series using the ori-
ginal Thrombolysis in Cerebral Infarction score (o-TICI). All
possible procedure- and device-related events were recorded.

Post-treatment imaging was performed at 24–48 hours and
evaluated for hemorrhagic events, including subarachnoid hem-
orrhage and parenchymal hematoma (PH) types II and I,
according to the European Cooperative Acute Stroke Study
definition. Clinical assessment
The modified Rankin Scale (mRS) was assessed before the inter-
vention, at discharge, and at 90 days either during a follow-up
visit or by telephone interview. The pre-stroke mRS was esti-
Figure 1  Study device pREset 4–20.
rated according to the information provided by the patient,
relatives, or legal guardian. The NIHSS was assessed before
treatment, at 24–72 hours after treatment, and after 7 days or
discharge, whichever came first.

Study endpoints
The primary clinical endpoint was the degree of stroke-related
dependency at 90 days measured using the mRS. For analysis
the score was categorized defining mRS 0–2 as favorable, mRS
0–1 as very good, and mRS 0 as excellent outcome.

Secondary endpoints were recanalization success achieved
with the study device, defined as o-TICI ≥2b after a maximum
of five passes and the average number of passes required for suc-
cessful recanalization.

Imaging hemorrhage and death rate at 90 days served as
safety measures. Symptomatic hemorrhage was defined as any
hemorrhage leading to deterioration of the NIHSS score of >3
points or death within 24 hours.

The secondary objective was assessment of process time pa-
rameters, which were compared between directly admitted (DAP)
and transferred patients (TP).

Statistical analysis
Baseline demographic and medical history data, process time
parameters, technical and clinical outcome, and adverse events
were assessed for the complete study population using descript-
ive statistics.

For comparison of DAP and TP patients with a pre-stroke
mRS >1 were excluded in order to minimize a bias on clinical
outcome. Further, logistic regressions were used to model the
probability of the different possible functional outcomes (mRS after 90 days
of the different possible functional outcomes (mRS after 90 days
– 1) vs all others; very good (mRS=0
– 1) vs all others, and favorable (mRS=0–2) vs all other mRS) and all
baseline as well as procedural and process time parameters were
tested for significant differences between these outcome groups.
All variables showing a difference with a p value <0.10 were
included into three separate multivariable logistic regression
models, with excellent, very good, and favorable outcome as the
dependent variable, respectively. p<0.05 was used as a cut-off
level for statistical significance.

All statistical analyses were performed using SPSS V.22 (IBM,
Armonk, New York, USA).

RESULTS
Subjects and occlusion patterns
Between February 2013 and February 2015, 100 patients
were treated with pREset for acute embolic stroke were included into
the study. Eight patients had multiple intracranial occlusions
resulting in 109 target vessels. Baseline clinical data are summar-
ized in table 1.

Recanalization success
After the last pass with pREset, a successful recanalization
(o-TICI 2b/3) was achieved in 92 of 109 treated vessels (84.4%)
with a mean of 1.7 (SD 0.96; median 1, range, 1–5) passes.
Ischemic stroke

Table 1  Baseline characteristics for all patients and separately for directly admitted and transferred patients

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>All patients (n=100)</th>
<th>Transferred patients (n=53)</th>
<th>Directly admitted patients (n=38)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>68.3 (13.8)*</td>
<td>69.2 (11.5)</td>
<td>66.1 (16.4)</td>
<td>0.292</td>
</tr>
<tr>
<td>Female sex, % (n/n)</td>
<td>55.0% (55/100)</td>
<td>54.7% (29/53)</td>
<td>53.3% (21/38)</td>
<td>0.959</td>
</tr>
<tr>
<td>NIHSS score at admission</td>
<td>Median (n; range)</td>
<td>15 (99; 5–29)†</td>
<td>15 (53; 6–29)</td>
<td>0.278</td>
</tr>
</tbody>
</table>

Medial history

| atrial fibrillation, % (n/n) | 57.1% (56/98) | 59.6% (31/52) | 52.6% (20/38) | 0.509  |
| systemic hypertension, % (n/n) | 67.3% (66/98) | 69.2% (36/52) | 62.2% (23/37) | 0.487  |
| diabetes, % (n/n) | 17.2% (17/99) | 15.4% (8/52) | 13.2% (5/38) | 0.767  |
| former stroke, % (n/n) | 16.3% (13/80) | 20.0% (9/45) | 10.0% (3/30) | 0.247  |

Pre-stroke mRS, % (n/vn) | 83.0% (83/100) | 92.5% (49/53) | 89.5% (34/38) | 0.715  |
| 0–1 | 91.0% (91/100) | 100.0% (53/53) | 100.0% (38/38) | NA |
| 0–2 | 96.0% (96/100) | NA | NA | NA |
| >2  | 4.0% (4/100) | NA | NA | NA |

ASPECTS, % (n/n) | 8–10 | 95.8% (91/95) | 96.0% (48/50) | 94.4% (34/36) | 1.000  |
| 5–7 | 4.2% (4/95) | 4.0% (2/50) | 5.6% (2/36) | 1.000  |
| 0–4 | 0.0% (0/95) | 0.0% (0/50) | 0.0% (0/36) | NA |

Preprocedure IV lysis, % (n/n) | 63.0% (63/100) | 66.0% (35/53) | 60.5% (23/38) | 0.590  |

General anesthesia, % (n/n) | 88.0% (88/100) | 90.6% (48/53) | 81.6% (31/38) | 0.211  |

Higashida collateral score median (n; range) | 2 (9; 0–4) | 2 (49; 0–4) | 1 (35; 0–3) | 0.339  |

Occlusion site, % (n/n vessels) | MCA | 74.3% (81/109) | 73.7% (42/57) | 71.7% (33/46) | 0.825  |
| ICA | 13.8% (15/109) | 15.8% (9/57) | 13.0% (6/46) | 0.694  |
| BA | 7.3% (8/109) | 5.3% (3/57) | 10.9% (5/46) | 0.462  |
| PCA | 3.7% (4/109) | 5.3% (3/57) | 2.2% (1/46) | 0.626  |
| ACA | 0.9% (1/109) | 0.0% (0/57) | 2.2% (1/46) | 0.447  |
| Multiple occlusions, % (n/n vessels) | 8.3% (9/109) | 8.8% (5/57) | 8.7% (4/46) | 0.715  |
| Stenting cervical ICA, % (n/n) | 14% (14/100) | 17.0% (9/53) | 13.2% (5/38) | 0.618  |

Patients with pre-stroke mRS >1 were excluded for further analysis of outcome in the last two groups.

†Three patients had a NIHSS score <8.

According to the performing interventionalist’s individual decision, other devices were used after pREset, treating 6.4% of the vessel occlusions (n=5 MCA, n=2 ICA). Supplementary devices were Solitaire FR (n=4), Trevo (n=1), Eric (MicroVention, Tustin, California, USA) (n=1), or angioplasty (n=1). In one of these cases recanalization could be improved to o-TICI 2b/3. Thus, the overall rate of successfully recanlalyzed vessels was 93 of 109 (85.3%).

Safety

Ten (10%) potentially device-related complications occurred (n=2 extravasations, n=3 vasospasms, n=2 emboli to a new territory, n=3 emboli to the same territory) but none was associated with a clinical deterioration. Post-treatment imaging revealed seven focal subarachnoid hemorrhages around the target vessel (7%), four (4%) PH I, and three (3%) PH II. Two patients developed a remote subdural hematoma (2%), probably owing to trauma in combination with IVT. Two (2%) hemorrhages were classified as symptomatic.

Clinical outcome

At 24–72 hours after recanalization, patients showed a median NIHSS score of 5 (n=99; range, 0–42). At this time, a great clinical improvement of at least 10 points, according to the NIHSS, was seen in 36 of 98 patients (36.7%). At discharge the median NIHSS score was 2 (n=94; range, 0–27), and 23 of 94 patients (24.5%) showed complete remission of neurological symptoms (NIHSS 0).

Follow-up at 90 days was available for 96 of 100 patients. Favorable clinical outcome was found in 62.5% (60/96) of the patients, 54.2% (52/96) showed a very good outcome, and 24.0% (23/96) an excellent outcome.

Death rate at 90 days was 7.3% (7/96). Of these, four patients died during the hospital stay, three were caused by malignant cerebral infarction and one was caused by the development of contralateral MCA occlusion. Of the remaining three patients, one died owing to the severity of the stroke, one presumably developed a recurrent stroke, and in one patient the cause of death was unknown.

Comparison of DAP and TP

After exclusion of nine patients with pre-stroke mRS >1, 38 DAP and 53 TP remained for further analysis. The two groups did not differ in baseline clinical data (table 1). In TP, the time from stroke onset to admission in the endovascular stroke center was significantly increased, whereas the time from


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admission to groin puncture was shorter than for DAP. The time from groin puncture to reperfusion did not differ. Overall, the vessel occlusion time (stroke onset to reperfusion) was significantly longer in TP (table 2). Regarding clinical results the NIHSS at 24–72 hours and at discharge was significantly higher in TP and the rate of favorable (mRS=0–2), very good (mRS=0–1), and excellent (mRS=0) outcome was significantly lower, yet the death rate remained equal (table 3). DAP were more than twice as likely to achieve a favorable outcome than TP (OR=2.63, CI 1.002 to 6.879, p=0.046).

Assessing the process time parameters, no significant differences were found between the four study centers (each p>0.07). Analogously, no significant differences were found in the rates of excellent (p=0.354), very good (p=0.564), or favorable clinical outcome (p=0.282) at 90 days, suggesting a negligible center bias. However, the proportion of transferred

| Table 2 | Process time parameters for all, transferred and directly admitted patients |
|---------------------------------|-----------------------------|-----------------------------|-----------------------------|
| Process time parameters         | All patients (n=100)        | Transferred patients (n=53) | Directly admitted patients (n=38) |
| (min)                            |                             |                             | p Value                     |
| Stroke onset to admission       | Median (n; range) 145 (92; 9–396) | 188 (51; 73–369) | 61 (34; 9–220) <0.001 |
| Admission to groin puncture     | Median (n; range) 58.5 (92; 5–187) | 45 (51; 5–150) | 76 (34; 15–187) <0.001 |
| Groin puncture to reperfusion   | Median (n; range) 40 (100; 6–159) | 49 (53; 6–159) | 36 (38; 8–116) 0.943 |
| Stroke onset to reperfusion     | Median (n; range) 247 (99; 112–469) | 289 (53; 172–469) | 180 (38; 112–386) <0.001 |

Admission refers to admission in the endovascular stroke center. Significant p values are shown in bold. Min, minutes; mRS, modified Rankin Scale.

| Table 3 | Technical and clinical outcome for all, transferred and directly admitted patients |
|---------------------------------|-----------------------------|-----------------------------|-----------------------------|
| Technical/clinical outcome      | All patients (n=100)        | Transferred patients (n=53) | Directly admitted patients (n=38) |
|                                 |                             |                             | p Value                     |
| Final o-TICI 2b-3 only pRSet    | % (n/n vessels) 84.4% (92/109) | 84.2% (48/57) | 82.6% (38/46) 0.828 |
| Final o-TICI 2b–3 overall      | % (n/n vessels) 85.3% (93/109) | 86.0% (49/57) | 82.6% (38/46) 0.640 |
| Passages until final o-TICI overall | Mean (n vessels; SD) 1.91 (109; 1.31) | 1.95 (57; 1.38) | 1.91 (46; 1.30) 0.898 |
| Intraprocedural complications  | % (n/n) 10.0% (10/100) | 9.4% (5/53) | 13.2% (5/38) 0.575 |
| Emboli to new or same territory| % (n/n) 5.0% (5/100) | 1.9% (1/53) | 10.5% (4/38) 0.157 |
| Hemorrhage post                 | Any hemorrhage, % (n/n) 14.0% (14/100) | 13.2% (7/53) | 18.4% (7/38) 0.497 |
| Parenchymal, % (n/n) 6.0% (6/100) | 7.5% (4/53) | 5.3% (2/38) 1.000 |
| Subarachnoid, % (n/n) 7.0% (7/100) | 3.8% (2/53) | 13.2% (5/38) 0.124 |
| Subdural, % (n/n) 2.0% (2/100) | 3.8% (2/53) | 0.0% (0/38) 0.508 |
| Symptomatic, % (n/n) 2.0% (2/100) | 1.9% (1/53) | 2.6% (1/38) 1.000 |
| NIHSS at 24–72 hours            | Median (n; range) 5 (99; 0–42) | 6 (52; 0–42) | 3 (38; 0–22) 0.005 |
| NIHSS at discharge=0            | % (n/n) 24.5% (23/94) | 16.7% (8/48) | 36.8% (14/38) 0.033 |
| mRS after 90 days; % (n/n) 0    | 24.0% (23/96) | 16.0% (8/50) | 40.5% (15/37) 0.010 |
| 0–1 54.2% (52/96) | 48.0% (24/50) | 73.0% (27/37) 0.019 |
| 0–2 62.5% (60/96) | 58.0% (29/50) | 78.4% (29/37) 0.046 |
| 3–5 30.2% (29/96) | 36.0% (18/50) | 18.9% (7/37) 0.082 |
| 6 7.3% (7/96) | 6.0% (3/50) | 2.7% (1/37) 0.633 |

Significant p values are shown in bold. mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; o-TICI, original Thrombolysis in Cerebral Infarction score.
DISCUSSION

In this study, we analyzed technical and clinical outcome as well as adverse events in patients treated with the pREase thrombectomy device for acute ischemic stroke caused by occlusion of a proximal cerebral vessel either in the anterior or posterior circulation.

The rate of successful recanalization was 84.4% and therefore single-center studies using the same device. Intraprocedural potentially device-related complications were seen in 10% but none were clinically relevant, which is in agreement with the low complication rates of the SWIFT PRIME trial and the retrospective analyses of the pREase thrombectomy device. Similarly, the overall rates of all and symptomatic hemorrhages were in line with data on other stent retriever studies.

The 90-day mortality of 7.3%, as found in this study, is close to the lower end of the mortality rates reported by most recent RCTs, which range between 9% and 21%, and thus is comparable to these.

Recent RCTs reported rates of a favorable clinical outcome, represented by a 90-day mRS of 0–2, ranging between 33% (MR CLEAN) and 71% (EXTEND-IA). Functional outcome is critically determined by successful reperfusion, which was lowest in MR CLEAN (59% m-TICI 2b/3) and highest in EXTEND-IA (86% modified Thrombolysis in Cerebral Infarction score (m-TICI) 2b/3). The superior effect of stent retrievers on recanalization results and clinical outcome has been proved previously in two device comparison studies (TREVO 2, SWIFT).

Another important factor influencing outcome is patient selection. Inclusion and exclusion criteria of our study were similar to those of MR CLEAN. Although the purpose of this study was to assess the performance of a specific device, MR CLEAN allowed for any endovascular approach. Also, in contrast, we included patients with occlusions in the posterior circulation; nevertheless, rates of successful recanalization were substantially higher. Hence, comparatively high rates of favorable functional outcome might be due to high recanalization rates achieved with the pREase thrombectomy device. However, in contrast to the MR CLEAN trial the interventionalists of our study had to perform at least 25 procedures with the study device before enrolling patients, whereas only five procedures were required for the MR CLEAN trial. It should be noted that these comparatively higher requirements for the interventionalists participating in our study might have caused a training bias, leading to a better technical and clinical outcome in comparison with the outcome of other trials, such as the MR CLEAN trial. Additionally, the median NIHSS score at admission was slightly lower (15 vs 17), which might also have contributed to the better clinical outcome in our study compared with the MR CLEAN trial, which might affect the generalizability of our results. Moreover, 95.8% of the patients selected for this study had ASPECT scores of ≥8 and 91% of these patients had a pre-stroke mRS of 0 or 1, which might have caused an additional selection bias.

An additional objective of this study was the subgroup analysis comparing referred patients with those who were directly admitted to one of the endovascular stroke centers. In referred patients, the median time from symptom onset to arrival at a stroke center was significantly longer. This substantial delay was attributable to additional transportation time and medical measures taken at the peripheral hospitals as well as IVT in eligible patients. MT was started significantly more quickly in TP after arrival at a stroke center, because imaging was already available. However, this could not compensate for the loss of time caused by the secondary transport and thus the time from symptom onset to recanalization was significantly longer in TP.

In patients directly admitted to one of the endovascular stroke centers, a favorable clinical outcome was more than twice as likely as in referred patients. In the multivariable logistic regression analysis, only the time from symptom onset to...
reperfusion, diabetes mellitus, and the NIHSS at admission were identified as independent predictors for excellent, very good, and favorable outcome. Since the NIHSS and presence of diabetes mellitus did not differ between the subgroups, the longer duration of vessel occlusion in referred patients can be regarded as the main reason for the significantly lower rate of a favorable outcome. This association of time parameters and functional outcome is well known for IVT and it also applies to endovascular stroke treatment: a post hoc analysis of IMS-III, MR CLEAN, and SWIFT PRIME showed a significant association between time to reperfusion and clinical outcome.16–21 In a retrospective single-center study, Sun et al18 previously reported a similar correlation between long occlusion times and less favorable outcome in referred patients. This effect seems to be particularly distinct in patients with poor collaterals.14 Also, in the recent SWIFT study, the time between symptom onset and admission of <3 hours was associated with favorable functional outcome at 90 days.19

Our study clearly underlines the association of a shorter time between symptom onset and recanalization and a better functional outcome. This effect becomes more pronounced for stricter outcome measures, such as very good and excellent functional results (figure 2).

Our results have implications for future healthcare organization of endovascular treatment of patients with acute stroke. Endovascular stroke therapy requires dedicated technical equipment suitable for cerebral angiography and highly trained interventionalists to perform the procedure safely and effectively. Thus, a nationwide coverage comparable to IVT cannot be achieved. A direct transfer of all patients with stroke to centers with endovascular treatment expertise might serve as a solution at first glance. On the other hand, only about 10% of stroke victims are potential candidates for thrombectomy and functional outcome after acute ischemic stroke: an analysis of data from the Interventional Management of Stroke (IMS III) phase 3 trial. Lancet Neurol 2014;13:567–74. Further, pre-hospital triage of patients with stroke based on clinical scales might solve this problem, but this still needs further validation.24–28 Yet, very fast brain and vessel imaging in the primary admitting hospital is necessary, allowing for quick identification of candidates for endovascular therapy and instantaneous transfer. Ambulance services need to set these patients at top priority and, possibly, new structures for transportation need to be established, especially in rural areas (eg, increasing capacities for day and night helicopter transportation).

CONCLUSIONS

pRESST proved to be safe and effective for the treatment of acute embolic intracranial vessel occlusion. Increased occlusion time impaired clinical outcome in TP. Reorganization of healthcare is urgently required to minimize this obvious disadvantage.

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