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Comparison of Solitaire-FR and Trevo-ProVue Thrombectomy in Patients with Anterior Circulation Large Artery Occlusion

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Abstract

Background: Recent randomized controlled trials have recommended stentriever thrombectomy as an important modality in treating acute ischemic stroke.
Objectives: This study compares Solitaire-FR (ST) and Trevo-ProVue (TV) in terms of their angiographic recanalization rates and clinical outcomes in acute ischemic stroke patients with anterior circulation large artery occlusion.
Patients and Methods: Forty-seven patients who underwent stentriever thrombectomy using ST or TV were retrospectively reviewed. Successful angiographic recanalization was defined as a modified treatment in cerebral ischemia (mTICI) score of 2b-3 and a good outcome was defined as a modified Rankin scale score (mRS) of 0 - 2 at 3 months. We compared angiographic and clinical outcomes of ST- and TV-treated patients.
Results: Twenty-one patients (mean age $\pm$ SD: 67.7 $\pm$ 13.5 years; 14 men) were treated with ST and 26 patients (70.7 $\pm$ 9.7 years; 13 men) were treated with TV. There were no differences in baseline characteristics, initial national institute of health stroke scale score, location of occlusion, onset to puncture time, or total procedure time between groups. The rate of successful recanalization and symptomatic intracranial hemorrhage (sICH) between ST and TV groups were not different. [for ST group, mTICI 2b-3: 19 (90.55%) and sICH: 2 (9.5%); for TV group, mTICI 2b-3: 23 (88.5%) and sICH: 3 (11.5%)]. Good outcomes (mRS 0 - 2) were not significantly different between the groups [ST: 10 (47.7%) and TV: 13 (50%); P = 0.81].
Conclusion: The two stentriever devices showed similar recanalization rates and clinical outcomes in patients with anterior circulation large artery occlusion.

Keywords: Ischemic Stroke, Stentriever Thrombectomy

1. Background

Expedient administration of intravenous recombinant tissue plasminogen activator (IV rtPA) within 4.5 hours was the first treatment approved for acute ischemic stroke (1-3). However, this treatment has drawbacks, which not only include a low recanalization rate but also a small range of application because of the limited time window and extensive exclusion criteria (4, 5). Recently, randomized controlled trials have demonstrated the improved efficacy and safety of endovascular mechanical thrombectomy for acute ischemic stroke. The stentriever thrombectomy in particular is poised to play an important role in acute anterior circulation large artery occlusions (6-10). Although mechanical thrombectomy using stentrievers, such as the Solitaire-FR (ST; ev3, Irvine, CA, USA) or Trevo-ProVue (TV; Stryker, Fremont, CA, USA), has been proven effective in treating acute ischemic stroke, few studies have directly compared each stentriever (11).

2. Objectives

In this study, we directly compare ST and TV in terms of angiographic recanalization and clinical outcomes in acute ischemic stroke patients with anterior circulation large artery occlusions.

3. Patients and Methods

3.1. Patients

We retrospectively collected data from acute ischemic stroke patients with anterior circulation large artery occlusion who underwent endovascular stentriever thrombectomy in a single institution between June 2014 and March 2016. The indication for stentriever thrombectomy was an initial national institute of health stroke scale (NIHSS) score of $\geq$ 4 within 6 hours of symptom onset and confirmation of large artery occlusion on multiphase com-

puted tomography (CT) angiography. The collateral circulation was classified into three clinically relevant categories on multiphase CTA (i.e., good (> 50%), intermediate (25% - 50%), poor (< 25%) pial arterial filling) (12). If indicated, IV rtPA was administered (0.9 mg/kg), and stentriever thrombectomy was subsequently performed in the non-responders to rtPA. The stentrievers, either ST or TV, were used as monotherapy according to the preference of the neurointerventionalist. Patients in whom more than one retriever or other devices such as the Penumbra (Penumbra, Alameda, CA, USA) were used were excluded from the study. The cause of stroke was classified into various subtypes by using the trial of org 10172 in acute stroke treatment classification on the basis of the etiopathologic mechanisms (13). This retrospective study was approved by the Institutional Review Board, which waived the requirement for written informed consent from the participants.

3.2. Interventional Procedures

All procedures were performed by two neurointerventionalists (B.H.L and J.W.K) with 8 years and 3 years of experience. Stentriever thrombectomy was performed under local anesthesia. The femoral artery was punctured and an 8Fr or 9Fr balloon-guiding catheter was placed in the relevant cervical internal carotid artery (ICA). The occluding clot was instantly confirmed on the control angiogram. A 0.014-inch microguidewire (Traxcess, Synchro, or Transend) and microcatheter (Rebar 18, Prowler Select Plus, or Prowler Plus) were navigated distal to the occluded intracranial vessel, passing through the clot. Subsequent angiography using a microcatheter was performed to confirm its placement distal to the clot and to determine the length of the occluded segment. A stentriever (ST 4/20 or TV 4/20) was introduced through the microcatheter and fully deployed in the occluded segment. After waiting for 3 to 5 minutes after stentriever deployment, the balloon-guiding catheter was inflated, and the stentriever was then retrieved. During the retrieval of the stentriever, negative suction was performed by an assistant through the balloon-guiding catheter using a 50 mL syringe. In cases of reocclusion or incomplete recanalization, the procedure would be repeated up to six or seven times to achieve successful recanalization, which was defined as a modified treatment in cerebral infarction score (mTICI) of 2b-3 on the final angiogram.

3.3. Follow-Up and Outcome Measures

Magnetic resonance imaging including gradient echo sequences, fluid-attenuated inversion recovery, diffusion weighted image, and time of flight angiography was performed within 24 hours in almost all patients who underwent stentriever thrombectomy. If the patient's neurological status declined rapidly, a CT scan was instantly acquired to detect hemorrhagic complications. Symptomatic intracranial hemorrhage (sICH) was defined as the presence of a large parenchymal hematoma and an increase of 4 points or more in the NIHSS score compared to the score on admission. Mortality was defined as death within 90 days of treatment administration.

All patients had standard assessments of demographic characteristics and stroke severity using the NIHSS score. The NIHSS score was reappraised within 24 hours after treatment and at discharge. Successful angiographic recanalization was defined as mTICI 2b-3. The total procedure time was defined as the time interval from puncture of the femoral artery to acquisition of final angiography. Functional outcome was assessed by the modified Rankin Scale (mRS) at 3 months. A good outcome was defined as an mRS score $\leq$ 2 at 3 months. Statistical analysis was performed using SPSS version 20.0 (IBM, Chicago, IL, USA) and a two-tailed $P < 0.05$ was considered significant.

3.4. Statistical Analysis

We analyzed differences between the groups using χ^2 tests for categorical variables and the Mann-Whitney test or Fisher's exact test for continuous variables, as appropriate. Quantitative variables were expressed as mean $\pm$ standard deviation and categorical variables are indicated as numbers (percentages). Multivariable analysis was used to evaluate associations between good outcome at 3months with following potential prognostic factors (initial NIHSS, hypertension, diabetes, smoking, cause of stoke, site of occlusion, IV rtPA, collateral flow, onset to puncture time, procedure time, number of passes, successful recanalization, two different stentrievers (ST vs. TV)). Statistical analysis was performed using SPSS version 20.0 (IBM, Chicago, IL, USA) and a two-tailed $P < 0.05$ was considered significant.

4. Results

4.1. Demographic and Clinical Characteristics

Forty-seven patients with anterior circulation large artery occlusion who underwent stentriever thrombectomy were included in the analysis. Twenty-one patients (mean age $\pm$ standard deviation (SD): 67.7 $\pm$ 13.5 years; 14 men and 7 women) were treated with ST and 26 patients (mean $\pm$ SD: 70.7 $\pm$ 9.7 years; 13 men and 13 women) were treated with TV. There was no difference in the initial NIHSS score between the ST group (median, range: 15, 8 - 24) and TV group (median, range: 15, 5 - 25). In the ST group, the present cardiovascular risk factors were hypertension in

61.9%, diabetes in 38.1%, smoking in 33.3%, and atrial fibrillation in 38.1% of patients. Seventeen of the twenty-one patients underwent IV rtPA before stentriever thrombectomy. The occlusion site was identified in the ICA in six patients (I:1, L:2, T:3) and in the middle cerebral artery (MCA) in 15 patients (M1: 13, M2: 2). In the TV group, the present cardiovascular risk factors were hypertension in 65.4%, diabetes in 34.6%, smoking in 26.9%, and atrial fibrillation in 26.9% of patients. Twenty-one of the twenty-six patients underwent IV rtPA before the stentriever thrombectomy. The occlusion site was identified in the ICA in six patients (I:2, L:0, T:4) and in the MCA in 20 patients (M1: 17, M2: 3). There was no difference in the collateral flow and cause of stroke between two groups. The clinical characteristics of the patients in each group are summarized in Table 1.

4.2. Angiographic and Clinical Outcomes

In the ST group, the mean time from onset to puncture was 167.2 ± 54.6 minutes and total procedure time was 49.3 ± 29.1 minutes. The median number of passes needed to achieve maximum recanalization was 2.1 ± 1.7. Successful recanalization (mTICI 2b-3) was achieved in 19 patients (90.5%). In the TV group, the mean time from onset to puncture was 152.2 ± 70.2 minutes and total procedure time was 42.4 ± 20.6 minutes. The median number of passes needed to achieve maximum recanalization was 1.67 ± 1.1. Successful recanalization (mTICI 2b-3) was achieved in 23 patients (88.5%). No distal embolization, arterial ruptures, or dissections caused by the stentrievers were observed.

There was no difference in the rate of sICH between the ST group (n = 2, 9.5%) and the TV group (n = 3, 11.5%). In the ST group, the mean NIHSS score on discharge was 5 (0 - 30). Ten patients (47.7%) showed a good clinical outcome (mRS score $\leq$ 2) at 3 months. In the TV group, the mean NIHSS score on discharge was 5 (0 - 27). Thirteen patients (50%) showed a good clinical outcome (mRS score $\leq$ 2) at 3 months. There was no difference in the mortality between the ST group (n = 3, 14.3%) and the TV group (n = 4, 15.4%). The differences in outcomes between each group did not reach statistical significance. The angiographic and clinical outcome analysis are summarized in Table 2. The multivariable analysis models showed that good collateral was the only significant factor in good outcome at 3 months (odds ratio, 2.16 (0.96 - 4.75); P = 0.03). There was no significant difference for good outcome at 3 months between ST and TV (odds ratio, 0.92 (0.72 - 1.76); P = 0.83).

5. Discussion

We found that the two stentriever devices (ST and TV) showed similar recanalization rates and clinical outcomes in patients with anterior circulation large artery occlusion. Recently, randomized controlled studies of endovascular treatments for acute ischemic stroke due to anterior circulation large artery occlusion have demonstrated their improving efficacy and safety (6-10). Stentriever devices play an important role in the modern era of endovascular thrombolysis, but there have been only a limited number of case series directly comparing the stentriever devices (11, 14). Our study was a direct comparative study of a relatively large number of ischemic stroke patients treated using two different stentriever devices.

In our study, there was no difference in terms of baseline demographic characteristics (including stroke risk factors), stroke severity, occlusion location, procedure time, sICH, or mortality between the ST and TV groups. Recent large randomized controlled studies reported effective clinical outcomes (mRS score $\leq$ 2 in 32.6% - 71.0% of patients) at 3 months, with a relatively high rate of recanalization (mTICI 2b-3 in 58.7% - 88.0%) and a low mortality rate (9.0% - 21.0%) (6-10). Compared with previous large randomized controlled studies, there was a similar trend in terms of overall recanalization rate (89.4%) and good clinical outcome (48.9%). Furthermore, there was also no difference in outcomes observed between the two groups. However, overall sICH tended to be slightly higher in both groups compared to those studies (6-10). The slightly higher sICH rate probably occurred because the sample size was relatively small. No permanent device-related complications, such as a failure to deploy the stentriever, perforation, dissection, or thrombus formation, occurred in either group. In the evaluation of the independent predictors of good clinical outcomes, there was no difference between the two different stentrievers (ST vs. TV). The good collateral was the only significant factor in good outcome at 3 months. The sufficient baseline collateral status in acute ischemic stroke patients was associated with improved functional recovery and decreased mortality rate at 3 months after stroke (15). Our study showed similar results that collaterals are important for the clinical outcome of acute ischemic stroke patients.

The TV was designed to facilitate proper visualization of the complete device by integrating the platinum wires into the stent struts itself (16-18). Full structural visibility of the stent during deployment and retrieval allow procedural adaptation or modification by enhancing the operator's understanding of the actual stent-clot or stent-vessel interaction (16). Subjectively, proper visualization of the stent helped to position the TV stentriever in the correct position at emergency situations where the patient was not cooperative.

Early reperfusion through recanalization is an important factor in the treatment of acute ischemic stroke (1, 2).

Table 1. Patients' Characteristics[a]

Variables	Solitaire-FR (N = 21)	Trevo-ProVue (N = 26)	P Value
Age, y; mean ± SD	67.7 ± 13.5	70.7 ± 9.7	0.42
Male Sex	14 (66.7)	13 (50)	0.41
Initial NIHSS, median (range)	15 (8 - 24)	15 (5 - 25)	0.85
Hypertension	13 (61.9)	17 (65.4)	0.87
Diabetes	8 (38.1)	9 (34.6)	0.85
Smoking	7 (33.3)	7 (26.9)	0.77
Atrial fibrillation	8 (38.1)	7 (26.9)	0.21
Cause of Stroke			0.73
Cardioembolic	16 (76.2)	21 (80.8)	
Large-artery atherosclerosis	2 (9.5)	3 (11.5)	
Undetermined cause	3 (14.3)	2 (7.7)	
IV rtPA	17 (80.9)	21 (80.7)	1.0
Collateral flow			0.28
Good	11 (52.4)	11(42.3)	
Intermediate	7 (33.3)	12 (46.2)	
Poor	3 (14.3)	3 (11.5)	
Occlusion site			0.66
ICA (I, L, T)	6 (28.6) (1, 2, 3)	6 (23.1) (2, 0, 4)	
M1[b]	13 (61.9)	17 (65.4)	
M2[c]	2 (9.5)	3 (11.5)	

Abbreviations: ICA, Internal Carotid Artery; IV rtPA, Intravenous Recombinant Tissue Plasminogen Activator;; NIHSS, National Institutes of Health Stroke Scale.
[a]Values are expressed as No. (%).
[b]M1, horizontal middle cerebral artery segment.
[c]M2, insular middle cerebral artery segment.

Table 2. Angiographic and Clinical Outcomes[a]

Variables	Solitaire-FR (N = 21)	Trevo-ProVue (N = 26)	P Value
Onset to puncture time, min; mean ± SD	167.2 ± 54.6	152.2 ± 70.2	0.41
Procedure time, min; mean ± SD	49.3 ± 29.1	42.4 ± 20.6	0.43
Number of passes, mean ± SD	2.1 ± 1.7	1.67 ± 1.1	0.31
Successful recanalization (mTICI, 2b- 3)	19 (90.5)	23 (88.5)	0.73
sICH	2 (9.5)	3 (11.5)	1.0
Mortality	3 (14.3)	4 (15.4)	1.0
NIHSS discharge	5 (0-30)	5 (0-27)	0.90
Good outcome at 3 months (mRS, 0-2)	10 (47.7)	13 (50)	0.81

Abbreviations: mRS, Modified Rankin Scale; mTICI, Modified Thrombolysis in Cerebral Ischemia; NIHSS, National Institutes of Health Stroke Scale; sICH, Symptomatic Intracranial Hemorrhage.
[a]Values are expressed as No. (%).

Intracranial atherosclerotic disease, which is more common in Asian populations, has limited treatment options because of the tendency of stenotic lesions to reocclude (4, 19, 20). There is a report demonstrating that stentriever thrombectomy can achieve partial recanalization, allowing the planning of subsequent rescue treatments

(21). However, there is a published case where stentriever thrombectomy fails to obtain satisfactory recanalization (22). If successful recanalization fails, permanent stenting may be a rescue modality for anterior circulation large artery occlusion (22, 23). Because the ST has a detachable property, permanent stenting using ST may be effective when rapid rescue treatment is needed (23).

This study had some limitations. This study was a retrospective study based on a database at a single institution. In order to minimize the effect of selection bias, all cases were registered in the prospectively maintained neurointervenional database with descriptions of the procedural details and complications in our institution. Another limitation is that selection of the device was not randomized but was left to the discretion of the individual neurointerventionalist. Nevertheless, baseline characteristics of the patients were well balanced in terms of occlusion location, cause of stroke, collateral flow, and initial stroke severity. Furthermore, this study is unique in comparing the performance of each stentriever device in a relatively large number of patients with anterior circulation large artery occlusion. Recently, various devices that are effective and safe have been introduced for the treatment of acute ischemic stroke. However, there is still a lack of comparative studies on ischemic stroke treatment using these devices. Consequently, we plan to perform a further large prospective study evaluating the effectiveness and safety of these new devices.

In conclusion, our study suggests that the two stentriever devices show similar recanalization rates and clinical outcomes in patients with anterior circulation large artery occlusion. Recently, various devices that are effective and safe have been introduced. Further well-designed, randomized prospective studies of the different devices are necessary to determine their role in the effective and safe treatment of acute ischemic stroke.

Footnotes

Authors' Contributions: Jin Woo Kim, design of the study, patient enrollment, data acquisition, data analysis/interpretation, and manuscript preparation; Byung Hoon Lee, patient enrollment, data acquisition, and data analysis; Yoon Joon Hwang, data acquisition, and data analysis/interpretation.

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