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Efficacy of Solitaire™ Stent Arterial Embolectomy in Treating Acute Cardiogenic Cerebral Embolism in 17 Patients

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Background: Thrombolysis with rtPA is the only accepted drug therapy for acute ischemic stroke. Since acute cerebral stroke is so pervasive, newly developed recanalization methods have the potential for wide-ranging impacts on patient health and safety. We explored the efficacy and safety of Solitaire stent arterial embolectomy in the treatment of acute cardiogenic cerebral embolism.

Material/Methods: Between October 2012 and June 2015, 17 patients underwent Solitaire stent arterial embolectomy, either alone or in combination with rtPA intravenous thrombolysis, to treat acute cardiogenic cerebral embolism. Sheath placement time, vascular recanalization time, number of embolectomy attempts, and IV rtPA dose and time were recorded. Success and safety of the recanalization procedure, as well as clinical outcomes, were assessed. These results were compared to 16 control patients who were treated using only rtPA IV thrombolysis.

Results: Full recanalization of the occluded arteries was achieved in 15 (88.2%) of the Solitaire stent patients. NIH Stroke Scale scores of embolectomy patients improved by an average of 12.59±8.24 points between admission and discharge, compared to 5.56±5.96 in the control group ($P<0.05$). Glasgow Coma Score improvement between admission and discharge was also significantly higher in the embolectomy group ($P<0.05$). There was no significant difference in symptomatic intracerebral hemorrhage, high perfusion encephalopathy, incidence of hernia, or mortality between the 2 groups ($P>0.05$).

Conclusions: Solitaire stent embolectomy is a safe and effective alternative to simple venous thrombolytic therapy, and it can significantly improve short-term neurological function and long-term prognosis in acute cardiogenic cerebral embolism.

MeSH Keywords: Anesthesia, Intravenous • Embolectomy • Intracranial Embolism • Stroke • Thrombectomy

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Background

Acute stroke ranks among the leading causes of death and adult disability worldwide [1,2]. Ischemic stroke accounts for about 80% to 85% of acute stroke, and cardiac cerebral embolism accounts for approximately one-fifth of the incidence of ischemic stroke [1]. Thrombolysis with rtPA is the only accepted drug therapy for treating acute ischemic stroke, but advances in this treatment have stalled in recent years [3]. Since acute cerebral stroke is such a pervasive condition, newly developed recanalization methods have the potential for wide-ranging impacts on patient health and safety.

The Solitaire™ stent, a mechanical thrombectomy device, is one such method. Previous research has suggested that the Solitaire stent is associated with high recanalization rates and improved clinical outcomes in a significant proportion of patients [3–5]. In this study, we observed the recanalization extent and time, recovery of neurological function, and long-term clinical outcomes of patients who underwent Solitaire stent arterial embolectomy to treat acute cardiogenic cerebral embolism. We hoped to investigate the safety and efficacy of this technology, and to confirm an effective basis for clinical treatment.

Material and Methods

Patient selection

All patients who were admitted to the Emergency Department at our institution from October 2012 to June 2015 for cardiogenic cerebral infarction were prospectively recruited. Acute cardiogenic cerebral embolism was diagnosed using the following 3 criteria: 1) acute onset; 2) CT or MRI examination upon admission confirming acute cerebral infarction; and 3) medical history, electrocardiogram, or cardiac color Doppler ultrasound examination confirming persistent or paroxysmal atrial fibrillation, heart valve disease, prosthetic valve replacement surgery, infective endocarditis, rheumatic heart disease, myocardial infarction in the preceding four weeks, cardiac myxoma, left ventricular aneurysm, sick sinus syndrome, dilated cardiomyopathy, congenital heart disease, patent foramen ovale, or other heart disease. Patients with intracranial atherosclerosis were excluded.

Every patient in this study was managed according to the stroke emergency green channel process. The research was approved by our institutional review board. All patients provided written informed consent prior to inclusion in this study.

Control and embolectomy groups

For the purposes of post-treatment analysis, patients were categorized into control and embolectomy groups. However, all hospitalized patients were considered for intravenous thrombolytic therapy. Select patients admitted to our department with cardiac cerebral embolisms who were only treated with intravenous (IV) rtPA thrombolysis were used as the control group.

Patients whose condition either worsened or remained unchanged after intravenous thrombolytic therapy were considered for arterial embolectomy. In addition, a small group of patients with severe stroke symptoms or thrombolytic contraindications, such a surgery within the preceding 3 months, open wounds, or bleeding conditions and tumors, were not treated by IV rtPA thrombolysis and directly underwent intervention. Inclusion criteria for the experimental group was as follows: 1) anterior circulation infarction identified within 6 hours of onset OR posterior circulation infarction identified within 12 hours of onset; 2) obvious neurological dysfunction, with symptoms persisting for over 1 hour; 3) US National Institutes of Health Stroke Scale (NIHSS) score ≥8 points; 4) rapid progression of symptoms after onset, decreased NIHSS, or altered state of consciousness; and 5) suspected intracranial large vessel occlusion that is not improved by rtPA recanalization treatment. Patients whose head CT indicated intracranial hemorrhage or who suffered vital organ failure were excluded.

Once a patient was identified as a candidate for arterial embolectomy, informed consent was obtained and the patient was transported directly to the intervention room.

Thrombolytic therapy protocol

Patients were screened for cerebral hemorrhage and thrombolytic contraindications before drug therapy was considered. If indications complied with intravenous thrombolytic therapy, it was applied within 4.5 hours of anterior circulation infarction or within 12 hours of posterior circulation infarction onset. Actilyse (BoehringerIngelheim Pharmaceutical Companies, Germany) is the trade name for a recombinant tissue plasminogen activator (rtPA) that was administered to 10 of the stent patients and all 16 of the control patients. Patients had 10% of the total dose initially intravenously injected over the course of 1 minute, followed by the remaining 90% infused through a micro-injection pump over the course of 1 hour.

Surgical protocol

Local anesthesia was used in all 17 surgical cases. The 7 patients who did not undergo preoperative intravenous thrombolytic therapy were also administered 300 mg Aspirin (Bayer, Italy) and 300 mg hydrogen clopidogrel film-coated tablets (Sanofi, France), either orally or via gastric tube. Patients who became agitated in surgery and were unable to cooperate with the inspection and treatment were either given 5 to 10 mg of diazepam intravenously or underwent further sedation.

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The Seldinger technique was used to puncture the patient's right femoral artery and place a 6F or 8F arterial sheath. The left femoral artery was used if right femoral artery puncture failed. The guiding catheter (6F or 8F, Cordis Corporation, USA) was placed under the guidance of a loach guide wire to the proximal position of the occluded blood vessel. The occlusion was passed with a microcatheter and microguidewire, after which point the microguidewire was removed. Microcatheter angiography was used to determine the distal patency, and the Solitaire stent (4×15 mm, EV3 Corporation, USA) was released through the microcatheter to the distal end of the vascular occlusion. Approximately 3 to 5 minutes after the stent was fully released, the stent and the microcatheter were retraced and the clot was removed. The connection pipe was teed with a 20-mL syringe during removal to withdraw broken blood clots and reduce the incidence of secondary embolism caused by thrombus fragmentation.

Angiography was performed following stent retrieval to determine whether the vessel was successfully recanalized. If not, then the thrombectomy procedure was repeated. The thrombectomy was performed a maximum of 4 times on a single patient. After a successful puncture, patients who had not undergone IV rtPA thrombolysis received a single dose of 6000 U IV heparin, followed by 2000 U per hour thereafter. Patients were closely monitored postoperatively for changes in condition, including neurological function, consciousness, breathing, pulse, blood pressure, and urine.

Postoperative care

Adjuvant therapy was recommended for patients with residual stenosis of the occluded blood vessel after revascularization. If this condition significantly affected the distal perfusion, auxiliary balloon dilatation and stent implantation were considered.

Patients in the embolectomy group received microinjections of nimodipine (5 mL/h) for 1 to 3 days postoperatively, based on blood pressure and vascular spasms. If angiography showed no signs of cerebral hemorrhage 24 hours postoperatively, patients were started on platelet aggregation inhibitors in the form of film-coated hydrogen clopidogrel tablets (75 mg/d). Stent patients who did not receive low molecular weight heparin subcutaneous injections (5000 U/d) after discharge were also started on anticoagulant therapy at the same time. Patients also received 60 mg of atorvastatin calcium tablets nightly postoperatively. This dose was reduced to 40 mg per night after 3 days, and 20 mg per night after 7 days.

Hypertension was strictly controlled in recovering patients, and the systolic blood pressure was kept at between 100 and 120 mmHg. Head CT or MRI scans were performed at 24 hours, 72 hours, 1 week, and 2 weeks postoperatively. If high-perfusion encephalopathy, symptomatic intracranial hemorrhage, upper gastrointestinal bleeding, or other complications were detected, patients were taken off of antiplatelet and anticoagulation agents. Patients were considered for decompressive craniectomy in cases of cerebral edema, brain stem compression, midline shift, or herniation.

Data collection and statistical analysis

For thrombolysis patients, rtPA time was defined as the period between acute onset and the start of medication. For stent patients, the time periods from onset to successful arterial sheath placement and from onset to recanalization were recorded. NIH Stroke Scale (NIHSS) and Glasgow Coma Scale (GCS) tests were administered at admission and discharge for both groups, as well as at 1 hour, 24 hours, 72 hours, 1 week, and 2 weeks post-treatment. These tests were conducted even more frequently on postoperative stent patients.

We used the Thrombolysis in Cerebral Infarction scale (TICI) [1] to evaluate vascular recanalization. Levels 2b and 3 denote full recanalization, while levels 0 to 2a indicate insufficient recanalization. The modified Rankin Scale score (mRS) was used to evaluate the long-term clinical prognosis of patients. A good outcome was defined as a mRS score of<2. Excluding cases of patient mortality, all patients were followed up for at least 3 months.

SPSS 20.0 Statistical software (IBM, USA) was used for all statistical analysis. Due to the small total sample size (<40), Fisher's Exact Test was used to compare differences in sex, prevalence of hypertension, and diabetes rates between the 2 groups, as well as other rates and proportions. Shapiro-Wilk tests were used to determine normality of distribution. Comparisons of means used independent-sample t-tests, while nonparametric tests (Mann-Whitney U test) were used for comparison when the conditions to conduct a t-test were not satisfied. A *P*-value <0.05 was deemed statistically significant.

Results

Patient characteristics

In total, 17 patients underwent Solitaire stent thrombectomy. All patients had intracranial large artery occlusions, including 6 cases of middle cerebral artery occlusion, 3 cases of internal carotid artery occlusion, 7 cases of basilar artery occlusion, and 1 case of posterior cerebral artery occlusion. The time from stroke onset to arterial sheath placement ranged from 2.67 to 8.33 hours, with an average of 4.97 ± 1.84 hours. The time from acute onset to recanalization ranged from 3.33 to 10 hours, with an average of 5.97±2.01 hours. Embolectomies

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Table 1. Group characteristics.

Group	No. of cases (n)	Sex (male/female)	Age (years)	High blood pressure n (%)	Diabetes n (%)	NIHSS score during disease
Embolectomy group	17	9/8	55.24±12.55	5 (29.4)	2 (11.8)	20.64±4.96
Control group	16	9/7	63.31±13.40	6 (37.5)	1 (6.3)	17.88±5.80
t value	–	–	–1.788	–	–	1.479
P value	–	1.000	0.084	0.721	1.000	0.149

Age and NIHSS scores were analyzed using an independent sample t-test. Gender, high blood pressure, and diabetes were analyzed using Fisher's Exact test.

Table 2. Comparison of the rtPA time and dose*.

Group	No. of cases (n)	rtPA time (hours)	rtPA dosage (mg)
Embolectomy group	10	3.45±1.48	49.5±2.99
Control group	16	3.74±0.66	47.81±3.64
z	–	–1.519	–0.735
P value	–	0.129	0.465

* Mann-Whitney U test.

were performed on each patient 1–4 times, with an average of 2.53±0.87 times.

Of these patients, 7 simply underwent thrombectomy and 10 underwent IV rtPA thrombolysis with bridging arterial embolectomy. There were 9 males and 8 females in this group, ranging in age from 31 to 79 years old, with an average age of 55.24±12.55 years.

The 16 patients in the control group only underwent IV rtPA thrombolysis. There were 9 females and 7 males in this group, ranging in age from 46 to 85 years, with an average age of 63.31±13.40 years. There were no significant differences in sex, hypertension prevalence, diabetes rate, average age, or average NIHSS score between the stent and the control groups (Table 1).

Treatment

The time from acute onset to the start of IV rtPA treatment ranged from 2 to 7 hours, with an average of 3.63±1.03 hours, for all patients. For the subset of patients who underwent both embolectomy and thrombolytic therapy, the range of times from onset to treatment was the same, and the average time was 3.45±1.48 hours. Time from onset to treatment in the control group ranged from 2.5 to 4.5 hours, and the average was 3.74±0.66 hours. While the rtPA times of the experimental group were normally distributed ($P>0.05$), the rtPA times of the control group were not ($P<0.05$). However, no significant difference in rtPA time was observed between groups ($Z=-1.519$, $P\geq0.05$, Table 2).

For all patients who underwent IV thrombolytic therapy, the rtPA dosage ranged from 40 to 55 mg, with an average dose of 48.46±3.44 mg. Dose for the stent patients who received thrombolytic therapy ranged from 45 to 53 mg, with an average dose of 49.5±2.99 mg. The dose range for the control group was from 45 to 50 mg, with an average dose of 47.81±3.64 mg. The dose of the control group were not normally distributed ($P<0.001$), while the dose of the stent group were normally distributed ($P>0.05$). However, the difference in rtPA dose between the two groups was not statistically significant ($Z=-0.735$, $P\geq0.05$, Table 3).

Short-term clinical outcomes

NIHSS scores for all patients were measured at admission and discharge. The NIHSS scores of stent patients at admission ranged from 13 to 29 points, with an average score of 20.65±4.96 points. The discharge scores of these patients ranged from 0 to 30 points, with an average of 7.94±9.20 points. Overall, the average improvement in NIHSS score at discharge was 12.59±8.24 points.

The NIHSS scores of the control group at admission ranged from 9 to 27 points, with an average score of 17.87±5.80 points. The scores at discharge ranged from 0 to 30 points, with an

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Table 3. Comparison of short- and long-term clinical outcomes*.

Test	Score at admission	Score at discharge	Change in score	*t* value	*P* value
NIHSS outcome					
Embolectomy group	20.65±4.96	7.94±9.20	12.59±8.24	2.792	0.009
Control group	17.87±5.80	12.31±8.74	5.56±5.96	–	–
GCS outcome					
Embolectomy group	7.88±2.60	12.82±3.84	4.94±3.47	3.070	0.004
Control group	10.63±2.39	12.12±3.56	1.50±2.92	–	–

* Independent sample t-test.

Table 4. Clinical prognosis of surviving patients*.

Group	No. of cases (n)	mRS score after 3 months	*z*	*P* value
Embolectomy group	17	1.71±1.86	–2.120	0.034
Control group	16	3.13±2.00	–	–

* Mann-Whitney U test.

average of 12.31±8.74 points. The average improvement in NIHSS score at discharge was 5.56±5.96 points.

The score change values of both the embolectomy and the control groups were normally distributed ($P>0.05$). However, the improvement in NIHSS score for the group that underwent Solitaire stent embolectomy was significantly larger than for the group that underwent thrombolytic therapy alone ($T=2.792$, $P<0.01$, Table 3). No statistically significant difference in the duration of hospitalization between the embolectomy and control groups was observed.

GCS scores were also measured for all patients at admission and discharge. The GCS scores of the stent group at admission ranged from 4 to 12 points, with an average score of 7.88±2.60 points. The GCS scores at discharge ranged from 3 to 15 points, with an average score of 12.82±3.84 points. The average improvement in GCS score between admission and discharge was 4.94±3.47 points.

GCS scores of control group at admission ranged from 7 to 14 points, with an average score of 10.63±2.39 points. The scores at discharge were similar, ranging from 3 to 15 points, with an average score of 12.12±3.56 points. The average improvement in GCS scores between admission and discharge 1.50±2.92 points for the control group. The results GCS improvement of embolectomy group was significantly better than for the group undergoing IV rtPA treatment alone ($P<0.05$, Table 3).

Clinical outcome at three months

Long-term functional outcome was assessed for all patients by measuring the mRS score at 3 months after acute onset. For the stent group, the mRS score after 3 months averaged 1.71±1.86 points. The control group had a higher average – 3.13±2.00 points. The scores for the control group were normally distributed ($P>0.05$), unlike the scores for the embolectomy group ($P<0.01$). The long-term outcome of stent patients was determined to be significantly better than the long-term outcome for control patients ($Z=-2.120$, $P<0.05$, Table 4).

Safety

None of the stent patients experienced hematoma at the puncture site or other complications related to the interventional procedure. In addition, none of the patients in either group experienced upper gastrointestinal bleeding problems during the follow-up period. The incidences of mortality, symptomatic intracerebral hemorrhage, and high-perfusion encephalopathy and brain herniation for both groups are shown in Table 5. There was no statistically significant difference between the 2 groups for any of these factors ($P>0.05$).

Discussion

Cardiogenic cerebral embolism is a serious condition with high incidence, disability, fatality, and recurrence rates [6,7]. Resultant neurological symptoms are acute and critical, and the low recanalization rate and high bleeding risks can temper

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Table 5. Comparison of complications*.

Group	Embolectomy group	Control group	*P* value
Symptomatic intracerebral hemorrhage	17.6% (n=3)	18.8% (n=3)	1.000
High perfusion encephalopathy and cerebral herniation	11.8% (n=2)	6.3% (n=1)	1.000
Mortality	11.8% (n=2)	12.5% (n=2)	1.000

* Using a Fisher's Exact test.

the therapeutic effects of even very timely treatment. In addition, the overall prevalence of this potentially devastating condition is probably severely underestimated. Long-term and invasive ECG monitoring has led to the discovery that some cryptogenic strokes are the result of cardiogenic cerebral embolisms [8,9]. As Professor Wang Yongjun pointed out in the Eighth Beijing Wuzhou International Cardiovascular Disease Conference in 2014, most cryptogenic stroke patients are assumed to have suffered cardiac strokes, when in fact cardioembolic strokes account for more than one-third of all cases [10].

Cardioembolisms often cause blockages in large intracranial vessels, such as the end of the internal carotid artery, the middle cerebral artery, the anterior cerebral artery, or the basilar artery. When only rtPA thrombolytic therapy is used, the rate of recanalization of such occluded vessels is very low – approximately 10%. In addition, the approximate bleeding conversion rate is a very high 10.23%. Using IV rtPA thrombolysis alone to treat cerebral embolism often does not achieve satisfactory results [6,11].

The rapid development of catheter and neural intervention techniques, endovascular mechanical recanalization technology are increasingly being applied as a first-line treatment for acute cerebral infarction, particularly in patients with occluded large cerebral vessels. This technology uses embolectomy devices, microcatheters, and microguidewire to mash, cut, and wind around the thrombus by mechanical means. This allows for the removal of clots blocking blood vessels and the rapid opening of occluded vessels, actively rescuing ischemic penumbra. Such methods can improve clinical prognosis, as well as reducing patient morbidity and mortality.

A number of clinical studies have demonstrated the feasibility and safety of various intravascular mechanical recanalization techniques. The MERCI trial [11,12] demonstrated that mechanical arterial embolectomy using the Merci device could quickly open occluded vessels for patients with occlusions in the distal end of internal carotid artery, the proximal end of middle cerebral artery and other large vessels. The recanalization rate was reported to reach up to 53%, far higher than the 10% of simple intravenous thrombolysis therapy. The subsequent SWIFT study determined that the Solitaire stent was not associated with an increased risk of symptomatic intracranial hemorrhage when compared to the Merci device. The recanalization rate using the Solitaire stent was 61% [4]. The STAR study reported an even higher revascularization rate of 79.2% using the Solitaire stent [13].Finally, the TREVO 2 study reported a recanalization rate of 86% using the Trevo device, which is one of the highest rates yet% [14].

In addition, rapid blood vessel intervention treatment can improve the functional outcome of patients with cerebral infarction. The MR CLEAN trial [15] demonstrated that, when compared with a group undergoing only standard drug treatment, patients who received intra-arterial treatment combined with drug therapy had better mRS scores at 90 days, with an adjusted odds ratio of 1.67. Subsequent multicenter randomized controlled trials measuring clinical prognosis in patients with acute cerebral infarction – including the ESCAPE trial [16], the EXTEND-IA test [17], and the SWIFT PRIME trial [2] – confirmed that endovascular intervention treatment combined with standard drug treatment was much better than standard drug treatment alone.

In this study, we hoped to observe the recanalization time and outcome, recovery of neurological function, complications, and long-term clinical prognosis of Solitaire AB stent arterial embolectomy therapy in patients with acute cardiogenic cerebral embolism. We observed significantly better NIHSS scores and GCS scores between admission and discharge for the stent group when compared to the group undergoing drug therapy alone. In addition, long-term clinical outcomes as measured by mRS scores were also significantly better for the group undergoing mechanical thrombectomy ($P<0.05$).

These results corroborate the findings of the previous large cohort studies. When compared with simple venous thrombolytic therapy, arterial embolectomy can significantly improve the recent neurological function and long-term clinical prognosis of patients with acute cardiogenic cerebral embolism, improving the patient's quality of life. There was no significant difference in the incidence of symptomatic intracerebral hemorrhage, high perfusion encephalopathy, or hernia between the

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two groups of patients. There was also no significant difference in mortality between the two groups ($P>0.05$), indicating that arterial embolectomy therapy, either with or without venous thrombolytic therapy, does not increase the incidence of complications or the mortality rate.

Conclusions

Arterial embolectomy using the Solitaire stent is both safe and effective. Short- and long-term functional outcomes of patients undergoing embolectomy, either alone or in conjunction with thrombolytic therapy, are better than in patients who were treated using IV rtPA therapy alone. In addition, there is no significant difference in safety or in patient mortality. The main limitation of our study is its small samples size, and, while adding to the body of literature on this topic, additional large sample multi-center randomized controlled trials are still needed to further corroborate these results.

Conflict of interest

None.

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