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Primary Stenting for Acute Ischemic Stroke Using the Enterprise Intracranial Stent: 2-Year Results of a Phase-I Trial

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Abstract

Background—The preliminary results of a prospective consecutive series of 20 patients who underwent Enterprise-assisted recanalization for acute ischemic stroke were recently reported. Recanalization to thrombolysis in myocardial infarction (TIMI) grade 2 ($n = 6$) or 3 ($n = 12$) flow was achieved in 18 patients (90% revascularization rate). Good outcome (modified Rankin Scale [mRS] score of ≤2) was obtained in 10 patients (50%) at 30 days. Here, we report the 2-year clinical follow-up data for patients enrolled in that prospective study.

Methods—Study patients were scheduled for examinations 2 years postprocedure at which time mRS and Barthel indices were obtained.

Results—Among 12 survivors at 2 years, 11 of the 20 (55%) study patients improved to mRS score ≤2 and 1 (5%) patient was disabled with an mRS 4. Of the 11 patients with mRS 0–2 scores, 10 patients had a Barthel index of 100, and the 11th had a Barthel index of 95. One patient improved from mRS 3 to 2 during the interval between the 6- and 12-month postintervention evaluations after intervention. Eight of 13 (62%) survivors underwent follow-up imaging at 6 months without evidence of instent stenosis or thrombosis.

Conclusion—At 2 years of follow-up, improvement in quality of life after acute stroke intervention was sustained; and 11 of 12 (92%) survivors had an excellent functional outcome. Improvement in functional status can occur even up to 1 year after stroke intervention. These results 2 years after acute stroke intervention demonstrate sustained benefit from acute intervention.

AIS	acute ischemic stroke
CT	computed tomographic
FDA	Food and Drug Administration

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IV	intravenous
MCA	middle cerebral artery
mRS	modified Rankin Scale
NIHSS	National Institutes of Health Stroke Scale Score
SWIFT	Solitaire FR With the Intention For Thrombectomy (SWIFT)
TIMI	thrombolysis in myocardial infarction
tPA	tissue plasminogen activator
TREVO	Thrombectomy REvascularization of large Vessel Occlusions

Keywords

acute ischemic stroke; **E**nterprise; intracranial stent; **l**arge vessel occlusion; prospective study; revascularization; thrombectomy

INTRODUCTION

Stenting for revascularization in the setting of acute ischemic stroke (AIS) has been tested in several phase-I trials approved by the Food and Drug Administration (FDA) with 30–90 day follow-up[1–4]. The midterm (6 months) follow-up results after stent-assisted revascularization using the Wingspan stent (Stryker Neurovascular, Kalamazoo, MI) have been reported [5]. To our knowledge, there are no reports of long-term follow-up (2 years) after stent-assisted revascularization or any other mechanical revascularization strategies for AIS. The goal of this study is to report the 2-year follow-up results for patients enrolled in the FDA-approved phase-I Enterprise-assisted recanalization in acute ischemic stroke (ERAIS) trial [3].

MATERIAL AND METHODS

Study Design

After consultation with the local institutional review board and the FDA, approval for this prospective single-center cohort study was obtained with a planned enrollment of 20 patients. Patients presenting within 8 hours of stroke symptom onset with a contraindication to intravenous (IV) thrombolysis or with no clinical improvement 1 hour after IV thrombolysis were eligible for entry in the ERAIS study if they met the predetermined inclusion and exclusion criteria [3]. Patients were recruited after they underwent a computed tomographic (CT) stroke study. Images were reconstructed on a Vitrea workstation (Toshiba Medical Systems) and reviewed to confirm that patients met the study inclusion and exclusion criteria [3].

Procedural Details

After consenting to participate in the study, patients received a loading dose of aspirin (650 mg) and clopidogrel (600 mg). Stroke interventions were performed in a biplane angiography suite. Conscious sedation was used when possible to allow frequent neurological examination throughout the procedure. Restless or anxious patients who were unable to tolerate conscious sedation were intubated and sedated with propofol. A guide catheter was placed via transfemoral access in a nonocclusive position proximal to the affected vessel. Typically, a 6- or 7-French guide catheter with an occlusive balloon (Stryker Neurovascular, Kalamazoo, MI) was used for the procedure. Heparin was administered with a goal activated coagulation time between 250 and 300 seconds. A microwire was used to cross the lesion; a microcatheter was advanced over the microwire past the lesion, and a combined microcatheter run–guide catheter run was performed to document the occlusion.

The size of the Enterprise stent (Codman, Raynham, MA) was chosen at the discretion of the operator. The device was deployed or used as a thrombectomy device based on operator preference [3]. For deployment cases, the stent was deployed across the occlusion with or without pre- or postballoon angioplasty at the site of vessel occlusion. For thrombectomy cases, the Enterprise stent was partially delivered (50–70% of the total length) into position at the site of the vessel occlusion. The patency of the occluded vessel was tested with angiography from the guide catheter after each partial delivery. The stent was left partially deployed for a period of 3–5 min of “temporary bypass” for the perfu-

sion of the brain and thrombus integration within the stent. The balloon at the distal guide catheter tip was then inflated, and the partially deployed stent and microcatheter were withdrawn as a unit under aspiration through the guide catheter (approximately 20–60 mL) to remove any thrombus debris from the occluded parent vessel and guide catheter. Thereafter, the guide catheter balloon was deflated to restore flow. Angiography was then performed to assess the revascularization effort and assign a thrombolysis in myocardial infarction (TIMI) flow grade. Up to three deployment/thrombectomy attempts were permitted within the parameters of the ERAIS study.

Previously Reported Outcomes

A synopsis of the early results of the study is provided here. Complete details are reported in the study of Dumont et al.[3]. Twenty patients (13 women; average age, 70.1±13.0 years) were enrolled. All patients had intracranial large vessel occlusion (TIMI 0) with an average preoperative National Institutes of Health Stroke Scale (NIHSS) score of 15.5±1.3. Vessel occlusion sites were the middle cerebral artery (MCA) only in 15 patients, intracranial internal carotid artery (ICA) only in 2, basilar artery in 2, and combined carotid terminus/MCA in 1. Six patients had IV tissue plasminogen activator (tPA) without clinical improvement before enrollment. Balloon dilation was used in one patient pretreatment and in nine patients post-treatment. The stent was implanted in 13 patients and used as a thrombectomy device and thus retrieved in seven patients. Three patients had multiple stents used, with two stents implanted among these patients and the remaining stents retrieved.

The time from the start of the procedure to TIMI 2 or 3 recanalization was 43±21 min (mean ± SD) or 40±21 min (median ± SD) respectively, with a range from 16–102 min. Recanalization to TIMI 2 (n = 6) or 3 (n = 12) flow was achieved in 18 patients (90% revascularization rate). Both patients in whom revascularization was not successful survived had received IV tPA prior to attempted revascularization and improved from their baseline NIHSS scores (from 12 to 2 and from 21 to 13, respectively). The first patient recovered to an mRS score of 0 and the second remained with an mRS score of 4 at the 30-day follow-up.

Three major immediate complications were noted (15%) including one myocardial infarction, one symptomatic intracranial hemorrhage, and one ischemic stroke in a distribution other than the qualifying vessel. Seven patients (35%) died within 30 days of revascularization (4 in hospital). Among the 13 survivors, the NIHSS score improved from admission to time of discharge by an average of 11.5±1.8 points. Among the survivors, 10 patients (50%) improved to a favorable mRS score of 0–2 within 30 days after the intervention (mRS scores for this group were as follows: 0, n = 6; 1, n = 2; 2, n = 2).

Two-Year Outcomes

Assessment of mRS scores was performed by certified research nurses or physician investigators at 1-, 3- , and 6-month and at 1 and 2 years postintervention and Barthel indices were assessed at 2 years in accordance with the study protocol. The assessors were not blinded to the procedural information or the historical Rankin scores. Outcomes variables were reported as percentages. Microsoft Excel (version 14; 2011) was used for simple statistical calculations. Six-month angiograms (CT angiography or MR angiography or conventional catheter-based angiography) were necessary as part of the protocol, and the physician investigators reviewed the angiograms to assess any evidence of instent stenosis or thrombosis.

RESULTS

Table 1 shows detailed follow-up results for the 20 patients.

Twelve of 13 (92%) patients who were alive at 1 month were alive at the end of 2 years. The mRS scores were as follows: 0, 6 patients; 1, 4 patients; 2, 1 patients; 4, 1 patient. Eleven of the 20 (55%) study patients improved to an mRS score of ≤2. One (5%) patient was disabled with an mRS score of 4. Of the 13 survivors at 1 month, 2 patients improved from mRS 2 to 1 at 90 days; one patient improved from mRS 3 to 2 between 6 months and 1 year; and another patient who had an mRS score of 4 died between 6 months and 1 year after the stroke intervention. The remaining 9 survivors had the same mRS scores at 2 years as they had at 30 days. Of the 11 patients with mRS scores of 0–2 at 2 years, 10 patients had a Barthel index of 100, and the 11th had a Barthel index of 95 at 2 years. The other patient (with mRS 4) had a Barthel index of 70. There were no delayed complications or adverse events after 30 days, except for the aforementioned death in a patient who had an mRS of 4 and was receiving palliative care.

Eight of 13 survivors had follow-up angiograms at 6 months, each of which showed patency of the occluded vessel and/or the stent (if one was implanted).. Another patient had MR angiography at 12 months that showed vessel patency. The remaining four patients refused follow-up imaging.

Table 1. Follow-up results after Enterprise-assisted stroke revascularization*

PtNo.	Pre-NIHSS	TIMI 2/3	mRS					Barthel @ 2 y	6-month angiogram
			1 mo	3 mo	6 mo	1 y	2 y		
1	9	3	0	0	0	0	0	100	refused
2	15	3	4	4	4	6	6	dead	refused
3	16	3	6	6	6	6	6	dead	dead
4	23	3	6	6	6	6	6	dead	dead
5	13	2	6	6	6	6	6	dead	dead
6	21	3	3	3	3	2	2	95	patent, DSA
7	17	3	0	0	0	0	0	100	patent, MRA @12 m
8	28	3	6	6	6	6	6	dead	dead
9	19	3	6	6	6	6	6	dead	dead
10	25	2	0	0	0	0	0	100	patent, DSA
11	12	1	0	0	0	0	0	100	refused
12	21	0	4	4	4	4	4	70	patent, CTA
13	15	3	0	0	0	0	0	100	patent, DSA
14	12	2	6	6	6	6	6	dead	dead
15	9	3	1	1	1	1	1	100	patent, DSA
16	8	3	1	1	1	1	1	100	refused
17	8	2	2	1	1	1	1	100	patent, CTA
18	12	2	2	1	1	1	1	100	patent, DSA
19	11	2	0	0	0	0	0	100	patent, DSA
20	16	6	6	6	6	6	6	dead	dead

Abbreviations: CTA, computed tomographic angiogram; DSA, digital subtraction angiogram; mo, month(s); MRA, magnetic resonance angiogram; mRS, modified Rankin scale; Pre, prestroke intervention; y, year(s).

*Stents were implanted in patients 2–10, 13, 14, 15, and 17.

DISCUSSION

The key prospective endovascular AIS trials have reported only 90-day outcomes [6–13]. We previously reported 30-day and 6-month outcomes associated with Wingspan stent placement for AIS revascularization in an FDA-approved prospective study[4, 5]. At 6 months in that study, 13 of 20 patients were alive and 11 (55%) achieved an mRS score of ≤2. At 6 months in the present study, 13 of 20 patients were alive and 10 (50%) achieved an mRS score of ≤2. It is important to note that one patient's mRS score changed from 3 to 2 between the 6- and 12-month follow-up assessments, which shows that these patients can improve and have functional recovery even 6 months after stroke intervention, albeit in 1 of 12 survivors (8.3%). To our knowledge, this is the first series reporting prospective, long-term (2 year) outcomes after endovascular revascularization for stroke treatment. Improvement in quality of life after AIS intervention was sustained up to 2 years of follow-up, and 11 of 12 (92%) survivors had an excellent functional outcome at 2 years. The results of the ERAIS study could serve as a benchmark for future studies looking at long-term outcomes after AIS revascularization. Most importantly, this study demonstrates that the benefit after AIS intervention is sustained and permanent.

The Enterprise stent is a self-expanding nitinol stent primarily used as a scaffold in the parent vessel during stent-assisted coiling of wide-necked aneurysms to prevent coil prolapse and achieve better healing of the parent vessel. The Enterprise stent differs from the Wingspan stent (which was primarily designed to treat intracranial atherosclerosis) in that it has less radial expansive force that theoretically may decrease the chance of instent stenosis[14–16]. Enterprise was the first nitinol stent that was resheathable after 80% deployment. This innovation led to the concept of temporary endovascular bypass or stent-retrieval technique during stroke intervention [17–19] and ultimately to the usage (originally designed for aneurysm treatment) of the Solitaire AB stent (Covidien, Irvine, CA) for stroke intervention as a stent retriever, which was resheathable after 100% deployment and detachable electrolytically if necessary[20, 21]. The Solitaire AB was modified to a nondeployable device, the Solitaire FR (Covidien), which was the first stent retriever available for AIS intervention in the United States. This led to the concept of stent retrievers for stroke that has become the primary mode for mechanical revascularization in the United States [22]. The ability to deploy is an advantage of the Enterprise stent over current stent retrievers, especially for situations in which an underlying atherosclerotic plaque becomes unstable and causes vessel thrombosis.

Study Limitations

Self-reporting of variables represents a potential source of bias but was necessary due to limitations in funding. Only 8 of 13 (62%) patients had follow-up angiograms (only 6 were digital subtraction angiograms) as scheduled at 6 months, and all of them had patent stents and/or parent vessels with no evidence of instent stenosis at 6 months. Despite these limitations, ERAIS is the first prospective study to report long-term outcomes after endovascular therapy of stroke.

CONCLUSION

Improvement in quality of life after AIS intervention with the Enterprise stent was sustained up to 2 years of follow-up and 11 of 12 (92%) survivors had an excellent functional outcome at 2 years follow-up. Improvement in mRS scores can occur even up to 6 months to 1 year after endovascular stroke intervention. Sixty-two percent of patients had follow-up imaging at 6 months, and there was no evidence of instent stenosis or thrombosis in these cases. This is the first study to report prospective long-term (2 year) outcomes after endovascular stroke revascularization, and the results of this study will serve as benchmark for future studies looking at long-term outcomes after stroke revascularization. This study demonstrates that the benefit of AIS intervention is sustained and permanent.

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Contributors

Natarajan and Levy are responsible for concepts and design. All authors contributed intellectually. All authors acquired, analyzed, and interpreted the data. Statistical analysis was performed by Natarajan. Manuscript was prepared by Natarajan. All authors reviewed and made critical revision of the manuscript.

Financial Relationships/Potential Conflicts of Interest

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Ethics approval

The institutional review board at the University at Buffalo, State University of New York, approved this study (project NSG1700110A) and a standard Health Insurance Portability and Accountability Act-compliant protocol was followed.

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