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Retrievable stent thrombectomy in the treatment of acute ischemic stroke: Analysis of a revolutionizing treatment technique

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Abstract

Acute ischemic stroke resulting from intracranial vessel occlusion is associated with high morbidity and mortality. The mainstays of therapy are fibrinolytics and mechanical thrombectomy in properly selected patients. A new Food and Drug Administration-approved technology to perform thrombectomy, retrievable stenting, may provide superior revascularization rates and improved patient outcomes. We analyzed the cumulative human experience reported for the Trevo Pro Retrieval System (Stryker, Kalamazoo, MI, USA) and the Solitaire FR Revascularization Device (ev3, Irvine, CA, USA) as the definitive treatment for acute ischemic stroke. A literature search was undertaken to identify studies using the retrievable stents published up to September 2012. Nineteen studies identified a total of 576 patients treated with either the Trevo (n = 221) or Solitaire (n = 355) devices. Pooled data analysis identified baseline National Institutes of Health Stroke Scale scores of 18.5 ± 0.289 (standard error of the mean) and 17.9 ± 0.610 , and time to recanalization of 53.9 ± 23.6 minutes and 59.0 ± 8.0 minutes for the Trevo and Solitaire groups, respectively. Recanalization was variably defined by individual studies, most commonly achieving at least a thrombolysis in cerebral infarction score of 2a–3 or a thrombolysis in myocardial infarction score of 2–3. Revascularization (83%, 82%), mortality (31%, 14%), hemorrhage (8%, 6%), device complications (5%, 6%), and good patient outcomes (51%, 47%) were found with the Trevo and Solitaire devices, respectively. Preliminary analysis reveals excellent clinical outcomes for retrievable stent technology. This may be attributable to both high rates of revascularization with a relatively short time to perfusion restoration.

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Conflicts of Interest/Disclosures

The authors declare that they have no financial or other conflicts of interest in relation to this research and its publication.

Keywords

Endovascular; Ischemia; Neurosurgery; Solitaire; Stent; Stroke; Trevo

1. Introduction

Acute cerebral ischemia is a major cause of morbidity and mortality worldwide. 1-3 The mainstay of medical therapy is intravenous administration of recombinant tissue plasminogen activator (rt-PA) to establish revascularization (reperfusion).⁴ Despite this, the use of rt-PA is successful in only 46.2% of patients when administered intravenously.^{5,6} For patients that do not qualify for rt-PA, or for whom it is not successful, endovascular therapy can be considered.⁷

In addition to intra-arterial rt-PA⁸, endovascular therapies including mechanical thrombectomy devices have evolved to locally obliterate the occlusive thrombus. In 2004, the Merci Retriever (Concentric Medical, CA, USA) was approved by the US Food and Drug Administration (FDA) for mechanical thrombectomy in stroke patients.⁹ The retriever has a corkscrew-shaped coil capable of extracting clots from occluded vessels and into the microcatheter. Another mechanical device, the Penumbra System (Penumbra, CA, USA) is an alternative approach to mechanical thrombectomy. During treatment with the Penumbra, a separator (microwire controlled by the operator) is used to dislodge the clot, while aspiration is applied through a proximal microcatheter.¹⁰ Though revascularization rates with these devices are excellent^{7,10-12}, clinical outcomes have been discordant.^{13,14} While revascularization rates of 48% can be achieved with the Merci Retriever, a modified Rankin scale (mRS) score of 2 is observed for only 27.7% of patients at 90 days.¹¹ Similarly, the Penumbra yields a revascularization rate of 82%, but only 25% of patients have a mRS 2 at 90 days.¹⁵

A new generation of endovascular stroke therapy is now focused on a revolutionary class of devices known as “stentriever.” Rather than extracting the clot using a corkscrew device (Merci Retriever) or aspirating the clot (Penumbra System), stentriever function by first deploying a stent within the clot itself. After allowing time for sufficient stent integration into the clot, the combination of the two is removed. This results in immediate, partial flow restoration as the stent expands, as compared to previous generation devices that require clot extraction to establish flow restoration. The devices currently approved by the FDA are the Solitaire FR Revascularization Device (Solitaire; ev3, Irvine, CA, USA) and the Trevo Pro Retrieval System (Trevo; Stryker, Kalamazoo, MI, USA). Here, we review the initial experience with these two members of this revolutionizing class of devices used as single modality treatment of acute ischemic stroke.

2. Methods

A PubMed and MEDLINE keyword search was conducted to identify studies reporting treatment of acute ischemic stroke with the Solitaire or Trevo devices, published up to September 2012. Abstracts were reviewed and prioritized; full papers were reviewed, and references were obtained as appropriate. Inclusion criteria also required that studies utilized these devices in human subjects. Exclusion criteria consisted of case studies, studies on non-humans, utilization of multi-modal endovascular treatment, and the use of these devices for extra-cranial vascular occlusion. For each study, the device used, number of patients, study design (prospective or retrospective), and median baseline National Institutes of Health Stroke Scale (NIHSS) scores were recorded. Further data extracted included the revascularization rate, as was defined by the scale used by individual study groups to

indicate success.¹⁶⁻¹⁸ Additionally, the mean or median time from groin puncture to revascularization, symptomatic hemorrhage rate, device-related complication rate, mortality at follow-up, mRS score at follow-up, and use of intra-arterial fibrinolytics was recorded. Total final recanalization rate, mortality rate, hemorrhage rate, and percentage of patients with mRS ≥ 2 for each device were calculated using a weighted average of all available studies.

3. Results

In total, 26 manuscripts were identified that reported the use of the Trevo or Solitaire devices. Of these, nine were excluded: one due to incorporation of study subjects into a more contemporary series, six for the use of multi-modal endovascular treatments, one due to its nature as a case study, and one because of the emphasis on extra-cranial vascular occlusion.

The 19 included studies identified a total of 576 patients treated with either the Trevo Pro Retrieval System (n = 221)¹⁹⁻²² or the Solitaire FR Revascularization Device (n = 355).^{20,23-35} Pooled data analysis identified median baseline NIHSS scores of 18.5 ± 0.289 (standard error of the mean) and 17.9 ± 0.610 , and time to recanalization of 53.9 ± 23.6 minutes and 59.0 ± 8.0 minutes in the Trevo and Solitaire groups, respectively. Recanalization was variably defined as specified by individual studies, most commonly achieving at least a thrombolysis in cerebral infarction (TICI) score of 2a–3 or a thrombolysis in myocardial infarction score of 2–3. Revascularization (83%, 82%), mortality (31%, 14%), hemorrhage (8%, 6%), device complications (5%, 6%), and good patient outcomes (51%, 47%) were found for the Trevo and Solitaire devices, respectively (Table 1, 2).

4. Discussion

Retrievable stents, known as stentriever, are a novel technology to perform a mechanical thrombectomy. Unlike prior devices that required clot extraction to achieve reperfusion, stentriever facilitate the immediate restoration of blood flow via expansion of a stent within the clot. The stent integration into the clot also allows for subsequent clot and stent extraction, without any need for permanent device implantation.

In one of the largest randomized trials, angiographic, safety, and clinical outcomes were better for the Solitaire device compared with the Merci device.³³ Fundamentally, it is advantageous to utilize thrombectomy devices with faster revascularization times, as the old adage “time is brain” is important when maximizing clinical outcomes.³⁶ Other technical aspects of stentriever, such as their unlikelihood to result in distal embolization during treatment, may contribute to the improved clinical outcome. While the results of the study by Saver et al. are promising³³, (along with similar results identified in other studies), cautious optimism must be exercised with any proposed radical change in clinical management. It is increasingly being recognized that any single source, no matter the quality of the study, should not be used to guide clinical management.^{37,38} The “gold standard” for clinical efficacy is really the reproducibility of any comparison between groups. With this in mind, stentriever are on a trajectory to result in a paradigm change in the treatment of stroke.

Currently, two clinical trials are registered at ClinicalTrials.gov for the Trevo device, both of which are complete. The TREVO study (NCT01088672) was completed in September 2012 and the final results are yet to be published. The TREVO2 study (NCT01270867) recently published its results, establishing stentriever as highly effective thrombectomy devices.¹⁹

Multiple clinical trials, encompassing hundreds of patients, are also ongoing or planned for the Solitaire device (NCT01657461, NCT00359424, NCT01692379, NCT01327989, NCT01492725). Stentriever technology is poised to become the preferred mechanical thrombectomy device in most patients pending evaluation by further randomized trials.

4.1 Illustrative patient

An 83-year-old woman with a history of atrial fibrillation, hypertension, and diabetes mellitus presented to an outside hospital emergency department (ED) 2 hours after acute-onset right face, arm, and leg weakness with dysarthria and aphasia. Her NIHSS score on arrival was 15. Intravenous rt-PA was administered at 0.9 mg/kg over 1 hour beginning 2 hours and 18 minutes after her symptom onset. The patient was subsequently transferred to our institution's ED, where her NIHSS score was 16.

MRI demonstrated restricted diffusion in the left corona radiata (Fig. 1A, B) with an infarct volume of less than 20 cc. There was no evidence of hemorrhage. Magnetic resonance angiography showed complete occlusion of the mid-M1 segment of the left middle cerebral artery (MCA; Fig. 1C). The patient was emergently transferred to the neuroendovascular suite, where intra-arterial therapy commenced 5 hours and 25 minutes after symptom onset. Catheter-based angiography confirmed complete left mid-M1 segment occlusion (arterial occlusive lesion [AOL] = 0, TICI = 0; Fig. 2A). A 4 mm × 20 mm Solitaire device was deployed (Fig. 2B) across the occlusive lesion at 6 hours and 20 minutes following symptom onset. Following a single pass of the Solitaire device, angiography confirmed virtually complete recanalization of the left MCA (AOL = III, TICI = 3; Fig. 2C). The stent/clot combination was extracted. Gross analysis of the Solitaire device demonstrated clot fragments within the stent retrieval system (Fig. 3).

Post-procedurally, the patient was admitted to the neurosciences intensive care unit for further monitoring. After CT scanning of the head demonstrated no hemorrhage 24 hours after rt-PA administration, the patient was started on systemic anti-coagulation given her history of atrial fibrillation for secondary stroke prevention. She was discharged to a rehabilitation center on hospital day 6 with a NIHSS score of 5 (mild word-finding difficulty; mild right face, arm, and leg weakness; mild dysarthria).

5. Conclusions

High recanalization rates and good clinical outcome rates are found in patients treated with stentriever. Ongoing and planned clinical trials for the Trevo and Solitaire devices will further define and confirm their efficacy.

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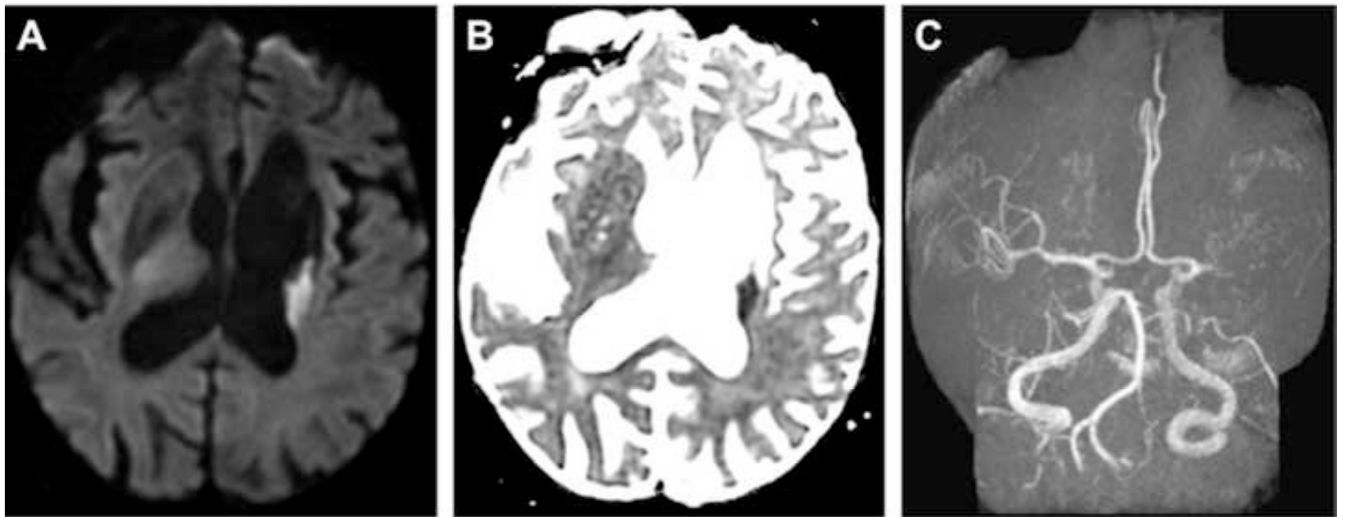


Fig. 1. Axial MRI showing restricted diffusion on (A) diffusion weighted imaging and (B) apparent diffusion coefficient imaging in the left corona radiata with an infarct volume of less than 20 cc. There was no evidence of hemorrhage. (C) Magnetic resonance angiography showed complete occlusion of the mid-M1 segment of the left middle cerebral artery.

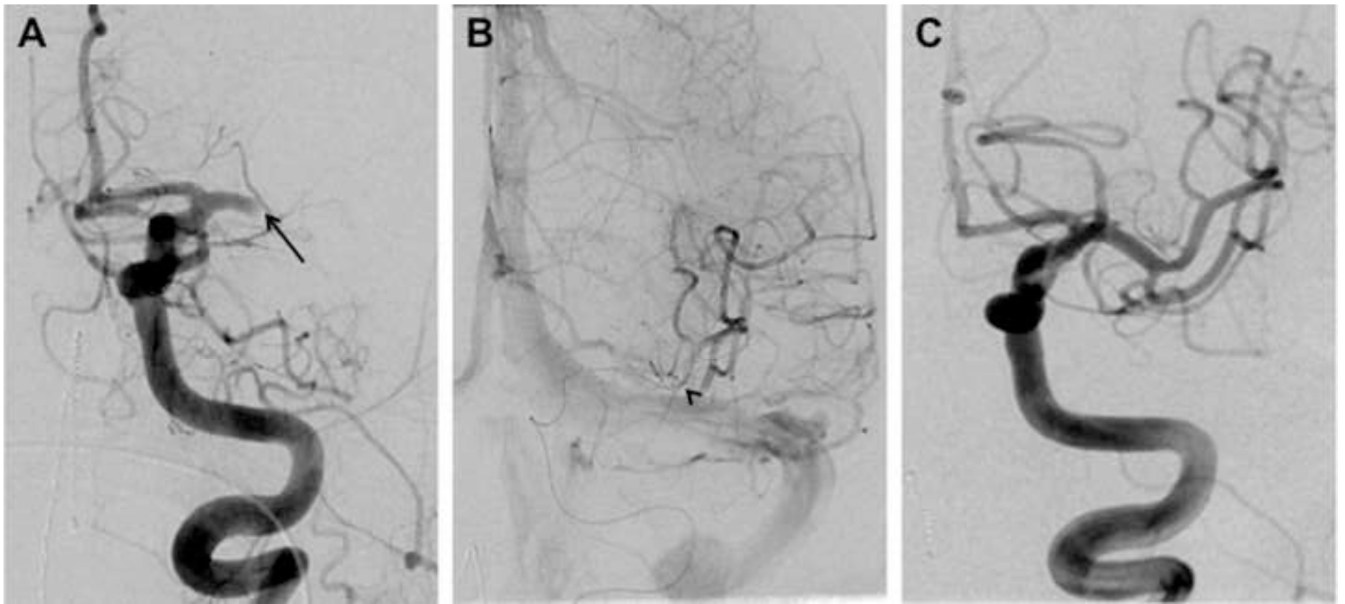


Fig. 2. (A) Catheter-based angiography showing complete left mid-M1 segment occlusion (Arterial Occlusive Lesion [AOL] = 0, Thrombolysis in Cerebral Infarction [TICI] = 0). (B) A 4 mm × 20 mm Solitaire FR Revascularization Device (ev3, Irvine, CA, USA) was deployed across the occlusive lesion at 6 hours and 20 minutes following symptom onset. (C) Following a single pass of the Solitaire device, angiography confirmed virtually complete recanalization of the left middle cerebral artery (AOL = III, TICI = 3).

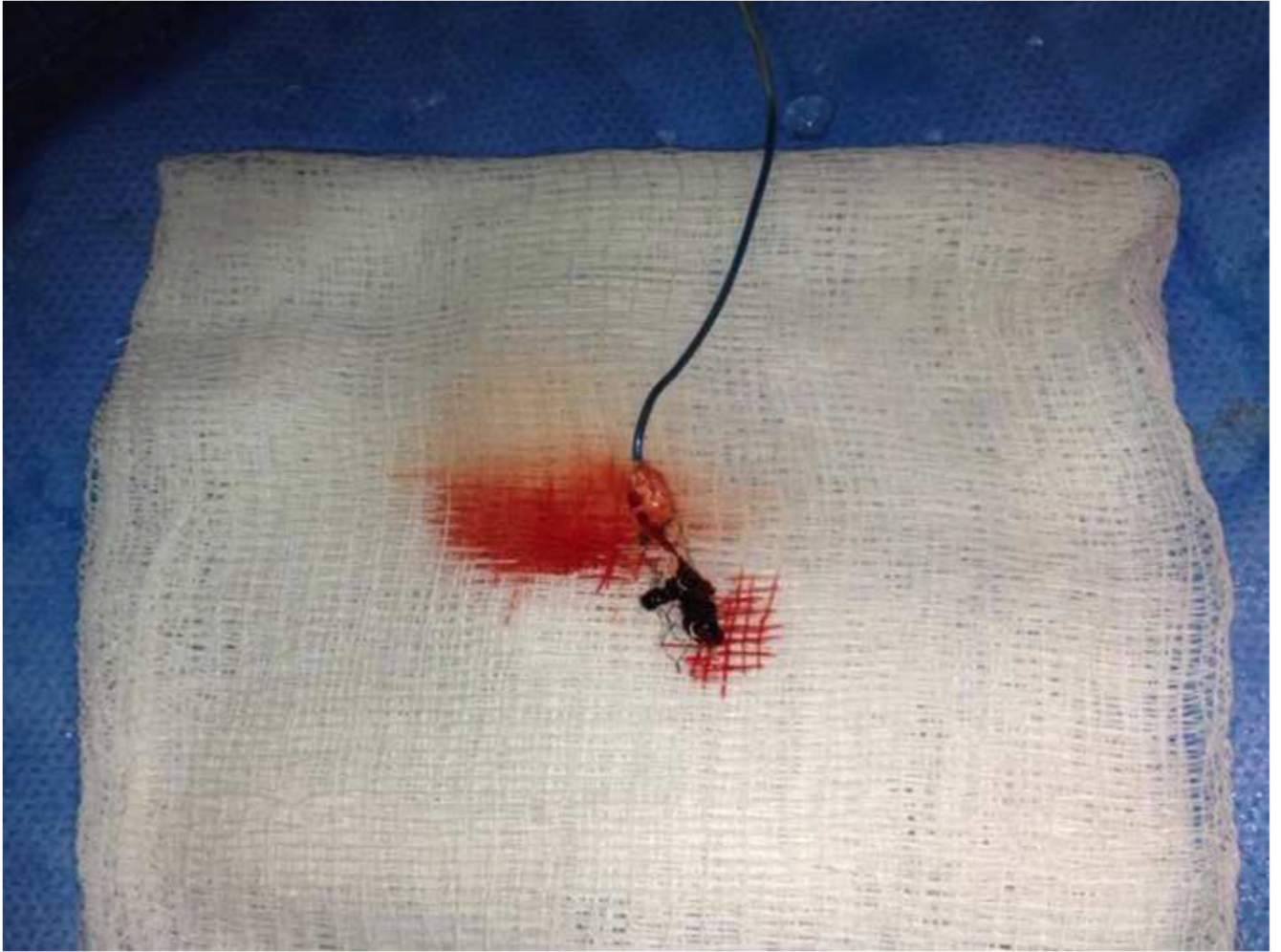


Fig. 3.
Photograph of gross analysis of the Solitaire device (ev3, Irvine, CA, USA) showing clot fragments within the stent retrieval system.

Table 1

Results using the Solitaire FR Revascularization Device[†] reported in the literature.

Author	Year	SD	n	NIHSS	RT	CT	IQR	RC	RC Definition	SH	Complications	Mortality	mRS	Follow-up (days)
Mendonça ²⁰	2012	P	20	17	97	46.7	60%	TICI 2a-3	15%	0%	0%	25%	40%	90
Kim ²⁵	2012	R	10	19.5	80.5	24	70%	TICI 2a-3	20%	0%	0%	30%	40%	90
Saver ³³	2012	P	58	18	36	65	69%	TIMI 2-3	2%	9%	9%	17%	58%	90
Saver ³³	2012	P	31	18	36	65	63%	TIMI 2-3	0%	13%	13%	16%	63%	90
Möhlenbruch ²⁸	2011	R	25	14	54	54	88%	Mori grade 3-4	12%	0%	0%	8%	60%	90
Wehrschoetz ³⁵	2011	R	11	16	94	53	100%	TICI 2a-3	0%	9%	9%	9%	30%	90
Stampfl ³⁴	2011	R	18	21	48.3	29	89%	TICI 2a-3	17%	0%	0%	28%	33%	At discharge
Park ³¹	2011	R	8	20	41.5	15.1	100%	TICI 2b or 3	0%	0%	0%	0%	50%	90
Mpotsaris ²⁹	2010	P	26	16	16	16	88%	TIMI 2-3	0%	0%	0%	15%	38%	19
Nayak ³⁰	2010	R	7	20	84.3	30.5	100%	TIMI 2-3	14%	14%	14%	0%	57%	30
Roth ³²	2010	R	22	18.5	18.5	18.5	91%	TICI 2a-3	9%	0%	0%	18%	50%	90
Castano ²³	2010	P	20	19	50	50	90%	TICI 2a-3	10%	0%	0%	20%	45%	90
Cohen ²⁴	2012	P	17	22	45.2	14.8	100%	TIMI 3	12%	24%	24%	6%	88%	30
Machi ²⁶	2011	R	56	16	37	37	89%	TICI 2b-3	2%	9%	9%	7%	46%	At discharge
Miteiff ²⁷	2011	R	16	22	75.3	24.6	24.6	TIMI 2-3	0%	6%	6%	0%	44%	At discharge
Summary			355	17.9	59.0	59.0	82%		6%	6%	6%	14%	51%	

Mean or median revascularization time is reported in minutes along with the standard deviation for mean values and interquartile range for median values. Complications reported are device-related, not including symptomatic hemorrhage. Average NIHSS score is weighted mean of NIHSS score values.

C = complications, IQR = interquartile range, mRS = modified Rankin scale, NIHSS = National Institutes of Health Stroke Scale, P = prospective, R = retrospective, RC = recanalization, RT = revascularization time, SD = study design, SH = symptomatic hemorrhage rate, = standard deviation, - = not reported.

[†] ev3, Irvine, CA, USA.

Table 2

Results using the Trevo Pro Retrieval System^f reported in the literature.

Author	Year	SD	n	NIHSS	RT	IQR	RC	RC Definition	SH	Complications	Mortality	mRS 2	Follow-up (days)
Nogueira ¹⁹	2012	P	88	19	47.8	-	86%	TICI 2a-3	7%	9%	33%	40%	90
Mendonça ²⁰	2012	P	13	19	95	31	77%	TICI 2a-3	0%	0%	30%	38%	90
San Roman ²¹	2012	P	60	18	80	45-114	73%	TICI 2a-3	12%	0%	28%	45%	90
Liebeskind ²²	2012	P	60	18			90%	TICI 2b-3				60%	
Summary			221	18.5	53.9		83%		8%	5%	31%	47%	

Mean or median revascularization time is reported in minutes along with the standard deviation (o) for mean values and interquartile range (IQR) for median values. A mark of “-” in the IQR column identifies the revascularization time as mean or median but indicates no IQR was reported. Complications reported are device-related. Core lab measures are reported over site measures, where applicable. A average National Institutes of Health Stroke Scale (NIHSS) score is weighted mean of NIHSS score values.

C = complications, IQR = interquartile range, mRS = modified Rankin scale, NIHSS = National Institutes of Health Stroke Scale, P = prospective, RC = recanalization, RT = revascularization time, SD = study design, SH = symptomatic hemorrhage rate, = standard deviation, - = not reported.

^fStryker, Kalamazoo, MI, USA.