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Review

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 median 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.

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-PA,[8] endovascular therapies including mechanical thrombectomy devices have evolved to locally obliterate the occlusive thrombus. In 2004, the Merci Retriever (Concentric Medical, Mountain View, 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, Alameda, 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 $\leqslant 2$ 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 score of $\leqslant 2$ at 90 days.[15]

A new generation of endovascular stroke therapy is now focused on a revolutionary class of devices known as "stentrievers". Rather than extracting the clot using a corkscrew device (Merci Retriever) or aspirating the clot (Penumbra System), stentrievers function by first deploying a stent within the clot itself. After allow-

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ing 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 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 were recorded. Total final recanalization rate, mortality rate, hemorrhage rate, and percentage of patients with a mRS score of $\leqslant 2$ 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 (n = 221)[19–22] or the Solitaire (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).

Table 1
Results using the Solitaire FR Revascularization Device† reported in the literature

Author	Year	SD	n	NIHSS	RT	σ	IQR	RC (%)	RC definition	SH (%)	C (%)	Mortality (%)	mRS ⩽2 (%)	Follow-up (days)
Mendonça[20]	2012	P	20	17	97	46.7		60	TICI 2a–3	15	0	25	40	90
Kim[25]	2012	R	10	19.5	80.5	24		70	TICI 2a–3	20	0	30	40	90
Saver[33]	2012	P	58	18	36		18–65	69	TIMI 2–3	2	9	17	58	90
Saver[33]	2012	P	31	18	36		18–65	63	TIMI 2–3	0	13	16	63	90
Möhlenbruch[28]	2011	R	25	14	54		–	88	Mori grade 3–4	12	0	8	60	90
Wehrschuetz[35]	2011	R	11	16	94	53		100	TICI 2a–3	0	9	9	30	90
Stampfl[34]	2011	R	18	21	48.3	29		89	TICI 2a–3	17	0	28	33	At discharge
Park[31]	2011	R	8	20	41.5	15.1		100	TICI 2b or 3	0	0	0	50	90
Mpotsaris[29]	2010	P	26	16				88	TIMI 2–3	0	0	15	38	19
Nayak[30]	2010	R	7	20	84.3	30.5		100	TIMI 2–3	14	14	0	57	30
Roth[32]	2010	R	22	18.5				91	TICI 2a–3	9	0	18	50	90
Castaño[23]	2010	P	20	19	50		38–71	90	TICI 2a–3	10	0	20	45	90
Cohen[24]	2012	P	17	22	45.2	14.8		100	TIMI 3	12	24	6	88	30
Machi[26]	2011	R	56	16	37	–		89	TICI 2b–3	2	9	7	46	At discharge
Miteff[27]	2011	R	16	22	75.3	24.6			TIMI 2–3	0	6	0	44	At discharge
Summary			355	17.9	59.0			82		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, σ = standard deviation, – = not reported.
† ev3, Irvine, CA, USA.

Table 2
Results using the Trevo Pro Retrieval System† reported in the literature

Author	Year	SD	n	NIHSS	RT	σ	IQR	RC (%)	RC definition	SH (%)	C (%)	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 Román[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 (σ) for mean values and interquartile range (IQR) for median values. A mark of "–" in the σ or IQR column identifies the revascularization time as mean or median but indicates no σ or IQR was reported. Complications reported are device-related. Core lab measures are reported over site measures, where applicable. 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, σ = standard deviation, – = not reported.
† Stryker, Kalamazoo, MI, USA.