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CLINICAL INVESTIGATION

Safety of the Solitaire 4 × 40 mm Stent Retriever in the Treatment of Ischemic Stroke

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Abstract
Purpose Stent retrievers apply mechanical force to the intracranial vasculature. Our aim was to evaluate the safety and efficacy of the long Solitaire 4 × 40 mm stent retriever for large vessel occlusion in stroke patients.
Methods We conducted a retrospective analysis of all patients treated for acute ischemic large vessel occlusion stroke with the Solitaire 2 FR 4 × 40 device between May and October 2016 at our institution. Patient-specific data at baseline and at discharge were documented. Reperfusion was graded with the thrombolysis in cerebral infarction (TICI) classification. Postinterventional angiograms and follow-up cross-sectional imaging were used to evaluate complications.
Results TICI 2b/3 recanalization was achieved in 20 of 23 patients (87.0%), in 17 patients with the first retriever pass. NIHSS improved from a mean score at presentation of 16 (range 4–36) to 11 (range 0–41) at discharge. Mean mRS score at discharge was 3 (range 0–6) and 3 (range 0–6) at 90 days post-treatment. No infarcts in other territories were observed. One patient showed a (reversible) vasospasm in the postinterventional angiogram and another a small contrast extravasation in follow-up imaging.
Conclusion The Solitaire 2 FR 4 × 40 stent retriever is a safe and efficient device for large vessel occlusion acute ischemic stroke with a high recanalization rate and a low peri- and postinterventional complication rate together with a good clinical outcome. Despite potentially higher friction and shearing forces, no increased incidence of visible damage to the vessel wall was observed.

Keywords Mechanical forces · Reports of complications · Friction force · Straightening of vessel course

Introduction

The clinical effectiveness of mechanical thrombectomy (MT) with stent retrievers in acute ischemic stroke (AIS) due to large vessel occlusion (LVO) and the superiority of MT compared to systemic thrombolysis alone have been proven by a series of large-scale randomized trials [1–6]. MT is the standard treatment for LVO strokes, and the number of MT procedures performed has risen rapidly. Recent randomized controlled trials have illustrated a favorable safety profile for stent retrievers—mostly using a diameter of 4 mm and a length of 20 mm. Novel stent retriever designs are constantly being introduced into clinical use. Such devices are tailored to overcome particular challenges in MT such as a tortuous vessel anatomy and thrombus size [7–9]. Increasing the length and changing the radial force or diameter, however, alter the mechanical forces applied to the intracranial vasculature, not necessarily consistent with previous trial results. With a length of 40 mm, the Solitaire 2 FR 4 × 40 device (Covidien, Irvine CA, USA) was recently introduced as a potentially good stent retriever for longer clots and for overcoming anatomical challenges such as a tortuous vessel anatomy leading to procedural difficulties like inadequate clot coverage [10]. The device has recently been

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demonstrated to have effectiveness and complication rates equal to those of preexisting devices in a pig model and an in vitro evaluation [11]. However, longer stent retrievers with more vessel wall contact have higher friction and shearing forces. They may therefore be more prone to cause damage to the vessel wall or perforators may shear off. The purpose of the present study was to evaluate the safety and efficacy results in the first 23 patients treated with this stent retriever at our institution.

Methods

Device Description

The Solitaire 2 FR 4 × 40 (Covidien, Irvine CA, USA) is a laser-cut, closed-cell, nitinol stent retriever specifically designed to retrieve clots in patients with large vessel AIS. Its usable length, at 40 mm, is twice as long as that of its 4 × 20 counterpart. This potentially makes it ideal for covering larger clots and negotiating tortuous anatomies where it can be challenging to achieve an exact retriever placement in order to cover the clot (Figs. 1, 2). Different approaches were used in our patients depending on the individual anatomic characteristics: In 13 cases an 8 or 9 French (Fr) balloon catheter, in 6 cases a distal access catheter, and in 4 cases a guiding catheter alone was used (6 and 7 Fr for vertebral and 8 Fr for internal carotid artery). In most patients, a 21 microcatheter (Prowler Select Plus, Johnson & Johnson, New Brunswick NJ, USA) was used for placement of the retriever (Table 1).

Study Design

This retrospective analysis was approved by the local ethics committee. Patients with acute LVO stroke either in the anterior or posterior cerebral circulation, who were treated using the Solitaire 2 FR 4 × 40 device between May and October 2016, were included in the study. Device selection was at the discretion of the interventionalist depending on occlusion pattern and anatomy of the target vessels. Clots longer than 10 mm located in curvy elongated vessels were considered ideal for the longer retriever. Thrombus length was evaluated in SWI if applicable or native CT. In all patients, the Solitaire 2 FR 4 × 40 was used fully deployed for thrombectomy except for the additional A2-occlusion where it was used partially deployed. Patient-specific data on age, sex, and neurological examination at entry and discharge using the NIH Stroke Scale (NIHSS) score and the modified Rankin scale (mRS) score were recorded. The mRS score was again recorded 90 days post-treatment (Table 1). Furthermore, time from symptom onset to groin puncture (if not known exactly, the time the patient was last seen asymptomatic was considered as symptom onset) and duration of the procedure were recorded. Reperfusion results were assessed using the thrombolysis in cerebral infarction (TICI) score [12].

Procedural complications were evaluated both from the immediate postinterventional angiogram and later follow-up cross-sectional imaging, such as magnetic resonance imaging (MRI) or computed tomography (CT) performed within 24 h postinterventionally. The angiographically recorded procedural complications were: new occlusions in vessels other than the target vessel, vasospasm in the treated vessel greater than 50% of the original vessel lumen, and visible dissection or vessel perforation. Follow-up MRI with susceptibility-weighted imaging (SWI) and/or CT was evaluated for subarachnoid hemorrhage or parenchymal hemorrhage. Intracerebral hemorrhage was graded according to the ECASS II trial [13]; subarachnoid hemorrhage (SAH) was graded as asymptomatic or symptomatic SAH. "Other infarct" was defined as an infarction in a vascular territory not involved in the initial occlusion pattern.

Results

A total of 23 out of 121 patients treated with stent retrievers between May and October 2016 were treated using the Solitaire 2 FR 4 × 40 device. Vascular risk factors were: arterial hypertension (65.2%), dyslipidemia (39.1%), diabetes (17.4%), smoking or history of smoking (30.4%), and atrial fibrillation (21.7%). Eighteen patients (78.3%) had an occlusion located in the anterior cerebral circulation and 5 patients (21.7%) in the posterior cerebral circulation. The individual occlusion pattern was: M1 segment, 13; M2 segment, 1; carotid terminus, 3; basilar, 5; and combined M1 and A2, 1. Nine patients received a combination of intravenous tissue plasminogen activator and endovascular treatment, whereas 14 patients received endovascular treatment alone. Patients with an in-house-diagnosed LVO stroke who could be transferred in the angio suite immediately did not receive intravenous tissue plasminogen activator. No intra-arterial thrombolysis was used. Pre-interventional imaging was performed with MRI (including SWI) in 13 patients and with CT in 10 patients. Postinterventionally, 7 patients underwent MRI and 17 CT. The average time from symptom onset to groin puncture was 264.3 min (standard deviation ± 141.6; range 72–604). TICI 2b or better recanalization was achieved in 22 patients (95.7%), and, in 17 (73.9%) of them, this result was achieved with the first retriever pass. TICI 3 recanalization was achieved in 13 patients. The mean duration of the procedure from groin puncture to recanalization was

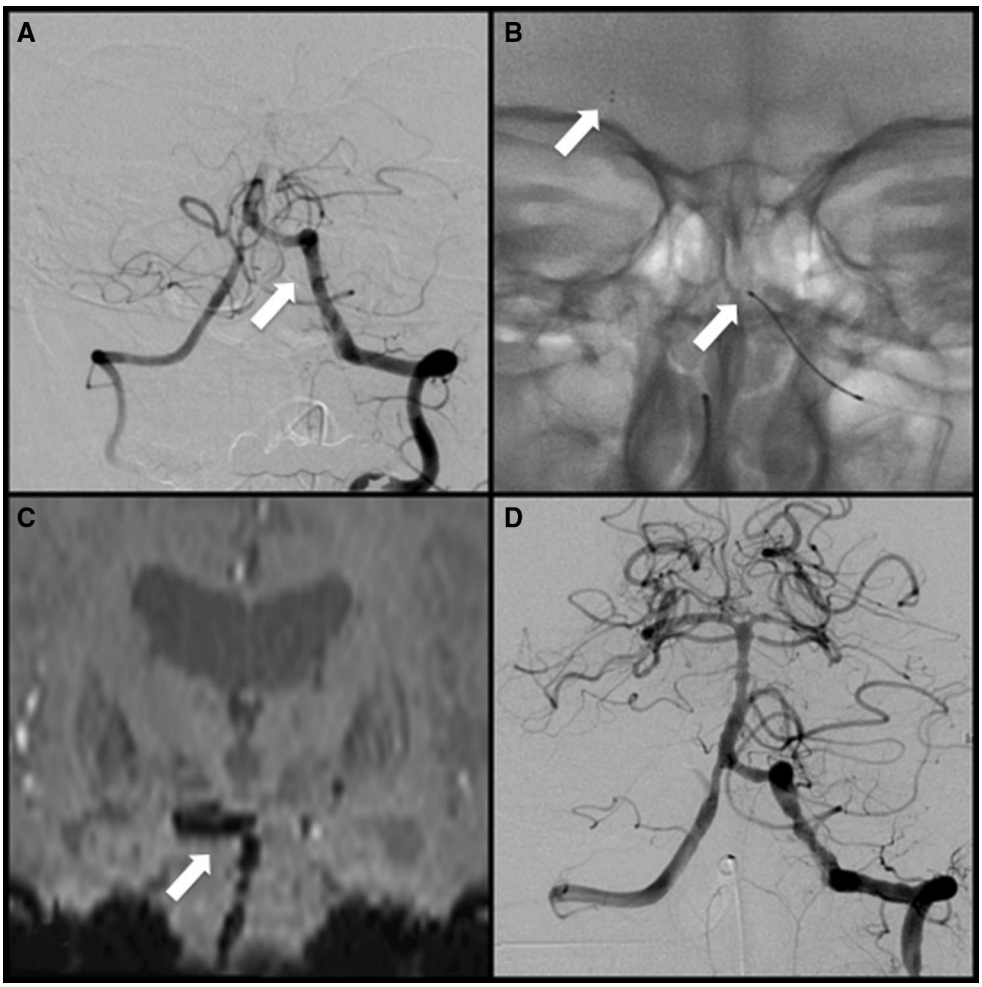

Fig. 1 Patient with an acute basilar artery occlusion. Initial angiogram with site of occlusion in the mid-basilar artery (*arrow*) (**A**); native image showing the proximal and distal markers of the stent retriever (arrows pointing to proximal and distal markers) (**B**); pre-interventional MRI (SWI) showing a long thrombus originating in the mid-basilar artery and reaching to the right P2 segment (*arrow*) (**C**) correlating well to the coverage of the stent retriever (**B**); postinterventional angiogram showing complete recanalization (TICI 3) (**D**)

59.3 min (standard deviation ± 37.7; range 20–160). In 5 patients, 1 or 2 additional thrombectomies were necessary: 3 of these were also performed with the Solitaire 2 FR 4 × 40 device, 1 was performed with the Solitaire 4 × 20 device, and 1 with the Solitaire 6 × 30 device. TICI 2b or better recanalization was achieved in 20 patients (87.0%) with the Solitaire 2 FR 4 × 40 only. In one patient, the intervention was terminated after 1 unsuccessful thrombectomy due to an already visible large infarct volume. No embolization in previously unaffected vascular territory was recorded. Significant vasospasm after thrombectomy was observed in one patient with an M1 occlusion immediately after thrombectomy in the proximal M1 segment. The vasospasm was fully reversible with local intra-arterial infusion of 2 mg nimodipine. No vessel perforation, dissection, or other hemorrhage was observed peri-interventionally. In 5 patients, tandem occlusions were present and necessitated stenting of the proximal occluded vessel (3 proximal vertebral stents and 2 proximal internal carotid artery stents). On follow-up imaging, one patient with an M1 occlusion showed a minor asymptomatic SAH in the insular cistern (MRI) and 2 patients with a middle cerebral artery infarction showed petechial hemorrhage at the infarct margins (HI 1) (CT/MRI) (Table 1).

In one patient with a shorter thrombus and a tortuous anatomy of the common and internal carotid artery, it was therefore necessary to switch to a 4 × 20 stent retriever to enable its comfortable placement. In all the other patients, the correct stent retriever placement could easily be achieved.

In one patient with a carotid terminus occlusion, the initial thrombectomy with the Solitaire 2 FR 4 × 40 resulted in a residual proximal M1 occlusion, revealing a larger vessel caliber than initially anticipated. This required

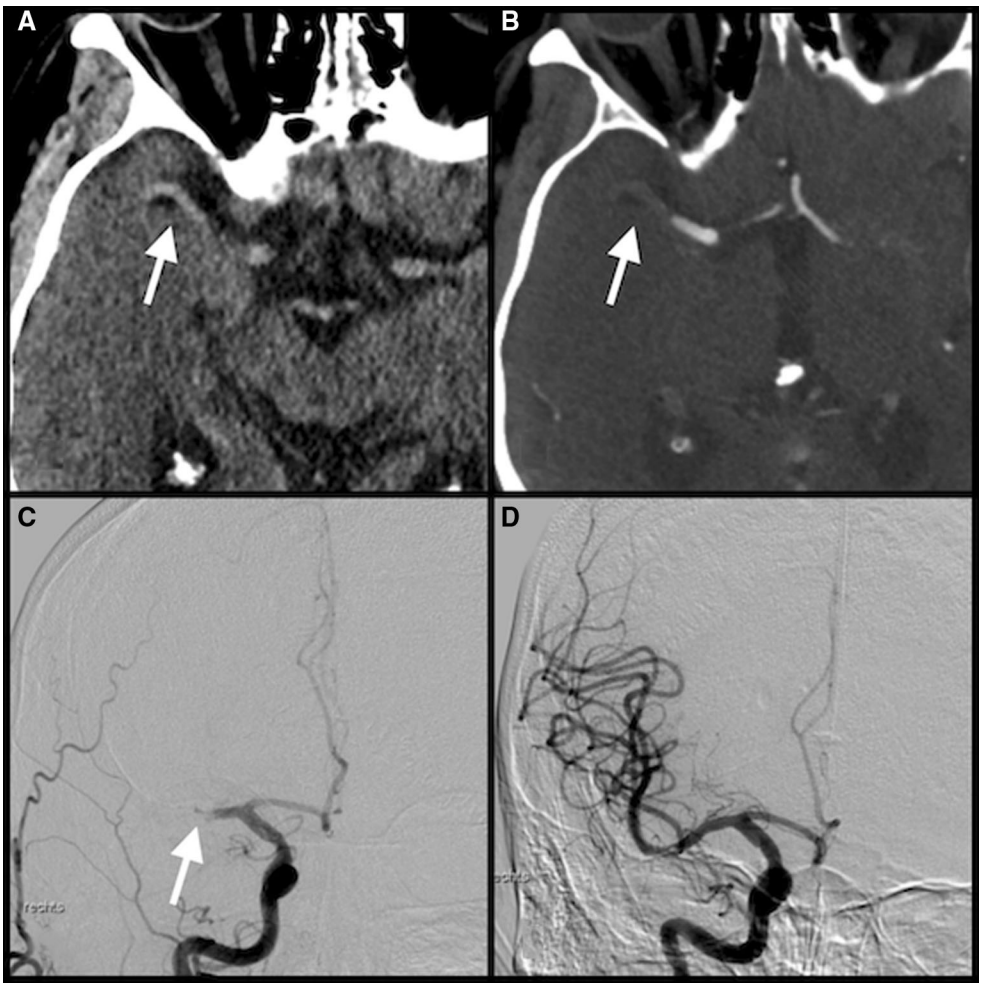

Fig. 2 Patient with an MCA occlusion (proximal M1 segment). Initial non-contrast CT with a large hyperdense clot (*arrow*) (**A**); CT angiogram showing the occlusion with contrast sparing on the clot location (*arrow*) (**B**); pre-interventional DSA, the arrow pointing to the occlusion site (**C**); postinterventional angiogram showing complete recanalization (TICI 3) (**D**)

a change to a Solitaire 6 × 30 stent retriever, resulting in a good recanalization (TICI 2b).

Two patients with basilar occlusion died the day after successful thrombectomy due to massive infarcts in the vertebrobasilar territory and were counted as NIHSS 41 at discharge. During the 90-day follow-up interval, 7 patients (30.4%) including the 2 above-mentioned patients died due to stroke or stroke-related complications. In these patients, a longer time interval from symptom onset to groin puncture of 5.5 versus 3.9 h in the surviving patients and a relatively high number of basilar occlusions (3/7 of the patients who died) was observed.

Mean NIHSS score at presentation was 16 (range 4–36) and 11 (range 0–41) at discharge. Nineteen patients (82.6%) showed an improved NIHSS at discharge (range 0–19) with a mean improvement of 8 points. An improvement of 10 NIHSS points between presentation and discharge was observed in 7 patients (30.4%), and an improvement to an NIHSS score of 0 was seen in one patient at discharge. Mean mRS score at presentation was 1 (range 0–4), at discharge, 3 (range 0–6) and 3 (range 0–6) at 90 days post-treatment. An mRS score of greater than 2 was observed in 6 patients at presentation (26.1%). An mRS score of 2 or less was seen in 6 patients at discharge (26.1%) and in 12 patients at 90 days post-treatment (52.2%) (Table 2).

Discussion

Following the recent randomized controlled trials illustrating high recanalization and low complication rates using stent retrievers, this device group became the gold standard for MT. However, these trials evaluated a narrow selection of stent retrievers. Changing the design and mechanical properties of the devices alters the mechanical forces applied to the intracranial vasculature in ways that are not necessarily consistent with previous trial results.

Table 1 Procedure-specific data

Patient no.	Baseline occlusion	IV tpa	Guide catheter	Reperfusion after first thrombectomy	Residual occlusion	Re-treatment	Reperfusion result	Follow-up imaging	Other
1	M1	Yes	1	0	M1	2 × S4 × 20	2b	NOI	S ICA
2	M1	Yes	2	3			3	NOI	
3	M1	No	1	3			3	NOI	
4	M1	No	3	3			3	NOI	
5	B	No	3	2b			2b	NOI	S VA
6	M1	No	1	3			3	NOI	V
7	B	no	2	3			3	NOI	S VA
8	M1	Yes	1	1	M1	2 × S4 × 40	2b; 1	NOI	
	A2			1					
9	B	No	3	3			3	NOI	
10	M1	No	1	3			3	NOI	
11	M1	No	2	3			3	NOI	
12	Car T	No	1	2b			2b	NOI	
13	M1	Yes	3	3			3	NOI	S ICA
14	M1	Yes	1	3			3	NOI	
15	M1	No	1	0	M1	1 × S4 × 40	2b	HT	
16	M1	No	1	2b			2b	NOI	
17	B	No	2	1	B	2 × S4 × 40	2b	NOI	D
18	Car T	no	1	1	M1	1 × S6 × 30	2b	NOI	
19	Car T	No	2	0			0	CE	NFI
20	M2	Yes	1	3			3	NOI	
21	B	Yes	2	3			3	NOI	D SVA
22	M1	Yes	1	2b			2b	HT	
23	M1	Yes	1	3			3	NOI	

IV tpa, intravenous tissue-type plasminogen activator; NOI, no other infarct; CE, contrast extravasation; HT, hemorrhagic transformation of stroke; S ICA, stenting of proximal internal carotid artery; S VA, stenting of proximal vertebral artery; V, vasospasm in postinterventional angiogram (not visible at follow-up); NFI, no further intervention due to visible large infarct volume; D, patient died (both on the day following intervention). Guide catheter: 1 = Merci; 2 = DAC; 3 = guide alone

Table 2 Clinical data

Clinical examination	At presentation	At discharge	90 days post-treatment
NIHSS	16	11	n.a.
mRS	1	3	3
mRS 0–2	17	6	12
mRS 6	n.a.	2	5

NIHSS, National Institutes of Health Stroke Scale (mean); mRS, modified Rankin scale (mean)

The results of this study indicate that the Solitaire 2 FR 4 × 40 is a safe and efficient device for intracranial thrombectomy in patients with acute LVO stroke. With an overall recanalization rate of TICI 2b or better of 87.0% compared to the rate of 58.7–88.0% reported in recent studies using stent retrievers [2, 3], the Solitaire 2 FR 4 × 40 has comparable rates of recanalization.

As illustrated in Figs. 1 and 2, compared to its 4 × 20 counterpart, the longer stent design potentially increases the probability of covering the thrombus, especially if the thrombus is long and located within a tortuous vessel. Given the same radial force as its 4 × 20 counterpart, in proportion to its length the Solitaire 2 FR 4 × 40 has more friction, which could result in more trauma to the vessel wall and more vessel straightening during retrieval of the device [14]. This assumption has been tested in previous studies showing that larger stent retrievers may cause more trauma to the vessel wall, especially if oversized [15–17].

In our study, we did observe more friction while placing the Solitaire 2 FR 4 × 40 via a 21 microcatheter, although this has not been objectively measured.

The overall complication rate related to the use of the device peri- and postinterventionally in our 23 patients was reasonably low, indicating no more trauma to the vessel wall than was experienced using the 4 × 20 stent retriever. However, at 7/23 (30.4%), the mortality rate was relatively high. This can be explained by a small number effect, a longer time interval from symptom onset to groin puncture of 5.5 h in the patients who died versus 3.9 h in the surviving patients and a relatively high number of basilar occlusions (3/7 of the patients who died). Recent large trials using stent retrievers have reported overall rates for complications such as symptomatic parenchymal hemorrhage of 4.4%, parenchymal hematoma of 5.1%, and a mortality rate of 15.3% [4]. The results of the present study do not indicate an increased complication rate associated with use of the Solitaire 2 FR 4 × 40 stent retriever.

Conclusion

With high recanalization rates and improved clinical outcome, the Solitaire 2 FR 4 × 40 appeared to be an efficient thrombectomy device in the first 23 patients treated for acute LVO stroke at our institution. Despite potentially higher friction and shearing forces, no increased incidence of damage to the vessel wall was observed compared to that seen with preexisting devices. Further studies with larger sample sizes are necessary to evaluate the full potential of this new device.

Compliance with Ethical Standards

Conflict of interest Jan Gralla: Global PI of STAR Study and Global PI of the SWIFT Direct trial, Consultant for Medtronic.

Ethical Approval Statement For this type of study, formal consent is not required.

Informed Consent Statement Informed consent was obtained from all individual participants included in the study.

References

1. Kidwell CS, Jahan R, Gornbein J, Alger JR, Nenov V, Ajani Z, et al. A trial of imaging selection and endovascular treatment for ischemic stroke. N Engl J Med. 2013;368:914–23.
2. Berkhemer OA. A randomized trial of intraarterial treatment for acute ischemic stroke. N Engl J Med. 2015;318:1565.
3. Saver JL, Goyal M, Bonafe A, Diener H-C, Levy EI, Pereira VM, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. N Engl J Med. 2015;372:2285–95.
4. Goyal M, Menon BK, van Zwam WH, Dippel DW, Mitchell PJ, Demchuk AM, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet. 2016;387:1723–31.
5. Akins PT, Amar AP, Pakbaz RS, Fields JD. Complications of endovascular treatment for acute stroke in the SWIFT trial with Solitaire and Merci devices. Am J Neuroradiol. 2014;35:524–8.
6. Campbell BCV, Mitchell PJ, Kleinig TJ, Dewey HM, Churilov L, Yassi N, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. N Engl J Med. 2015;372:1009–18.
7. Kühn AL, Wakhloo AK, Lozano JD, Massari F, De Macedo Rodrigues K, Marosfoi MG, et al. Two-year single-center experience with the "Baby Trevo" stent retriever for mechanical thrombectomy in acute ischemic stroke. J Neurointerv Surg. 2016; neurintsurg-2016-012454.
8. Riedel CH, Zimmermann P, Jensen-Kondering U, Stingele R, Deuschl G, Jansen O. The importance of size: successful recanalization by intravenous thrombolysis in acute anterior stroke depends on thrombus length. Stroke. 2011;42:1775–7.
9. Mordasini P, Brekenfeld C, Byrne JV, Fischer U, Arnold M, Heldner MR, et al. Technical feasibility and application of mechanical thrombectomy with the Solitaire FR revascularization device in acute basilar artery occlusion. Am J Neuroradiol. 2013;34:159–63.
10. Thierfelder KM, Sommer WH, Ertl-Wagner B, Beyer SE, Meinel FG, Kunz WG, et al. Prediction of stent-retriever thrombectomy outcomes by dynamic multidetector ct angiography in patients with acute carotid t or mca occlusions. Am J Neuroradiol. 2016;37:1296–302.
11. Wainwright JM, Jahan R. Solitaire FR revascularization device 4 × 40: safety study and effectiveness in preclinical models. J Neurointerv Surg. 2016;8:710–3.
12. Zaidat OO, Yoo AJ, Khatri P, et al. Recommendations on angiographic revascularization grading standards for acute ischemic stroke. Stroke. 2013;44:2650–63.
13. Larrue V, von Kummer RR, Müller ABE. Risk factors for severe hemorrhagic transformation in ischemic stroke patients treated with recombinant tissue plasminogen activator: a secondary analysis of the European-Australasian Acute Stroke Study (ECASS II). Stroke. 2001;32:438–41.
14. Machi P, Jourdan F, Ambard D, Reynaud C, Lobotesis K, Sanchez M, et al. Experimental evaluation of stent retrievers' mechanical properties and effectiveness. J Neurointerv Surg. 2017;9(3):257–63.
15. Abraham P, Cheung VJ, Lee R, Pannell JS, Gupta M, Rennert R, et al. 302 Vessel wall enhancement on magnetic resonance imaging after stent-retriever thrombectomy. Neurosurgery. 2016;63(Suppl 1):186.
16. Li Y, Turan TN, Chaudry I, Spiotta AM, Turk AS, Turner RD, et al. High-resolution magnetic resonance imaging evidence for intracranial vessel wall inflammation following endovascular thrombectomy. J Stroke Cerebrovasc Dis. 2017;26:e96–8.
17. Hsieh K, Verma RK, Schroth G, Gratz PP, Kellner-Weldon F, Gralla J, et al. Multimodal 3 Tesla MRI confirms intact arterial wall in acute stroke patients after stent-retriever thrombectomy. Stroke. 2014;45:3430–2.