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## Rapid learning curve for Solitaire FR stent retriever therapy: evidence from roll-in and randomised patients in the SWIFT trial

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### Abstract

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**Contributors** SAS, JLS, and RJ made substantial contributions to the conception and design of the work as well as the drafting and revision of the work for important intellectual content and final approval of the version to be published. EIL, TGJ, BB, RGN, WC, RB, and OOO participated in the design of the study, interpretation of the data, and gave final approval of the version to be published. SAS wrote the report, which was revised after review by all coauthors, all of whom provided critical review of the paper. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The statistical analysis was performed by Jill Schafer.

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**Data sharing statement** The data from this study are taken from the SWIFT trial. These data can be accessed if a request is sent to the publication committee of the SWIFT trial.

**Competing interests** The University of California (The Regents) receive funding for JLS's services as a scientific consultant for the trial design and conduct from Covidien/ev3, BrainsGate, CoAxia, Grifols/Talecris, Ferrer, Mitsubishi, Genervon, Benechill, Asubio, and Sygnis. JLS served as an investigator in the NIH FAST-MAG, MR RESCUE, ICES, CUFFS, CLEAR-ER, and IMS 3 multicenter clinical trials for which the UC Regents received payments based on clinical trial performance. JLS has also served as an unpaid site investigator in multicenter trials run by Covidien/ev3, Genervon, Lundbeck, and Mitsubishi for which the UC Regents received payments based on the clinical trial contracts for the number of participants enrolled. JLS and RJ are employees of the University of California, which holds a patent on retriever devices for stroke. The University of California Regents receive funding for RJ's services as a scientific consultant for the trial design and conduct from Covidien/ev3 and Chestnut Medical. EIL is a scientific consultant for Covidien/ev3, Codman and Shurtleff Inc, and TheraSyn Sensors Inc; and receives fees for carotid stent training from Covidien/ev3 and Abbott Vascular. TGJ has served as a scientific consultant to Covidien/ev3, CoAxia, Concentric Medical, and Micrus. RGN has served as a scientific consultant to Covidien/ev3, CoAxia, and Concentric Medical. WC and RB have served as scientific consultants to Covidien/ev3. OOO serves as a scientific consultant to Talecris Biotherapeutics, Stryker, Codman, and MicroVention.

**Background**—In light of recent positive trial data for endovascular therapy in acute ischemic stroke (AIS), stent retriever use by practitioners without prior experience with these devices may become more common.

**Objective**—To assess the safety and efficacy of thrombectomy for AIS using Solitaire for patients treated in the roll-in period of the Solitaire With the Intention For Thrombectomy (SWIFT) trial, which represented the first clinical use of the device for these interventionalists.

**Methods**—Prospectively collected demographic, clinical, and angiographic data on patients treated in the initial roll-in and subsequent randomized phases of the SWIFT study were collected and analyzed. Key statistical analyses were validated by an independent external statistician.

**Results**—Patients in the roll-in period achieved equivalently high rates of reperfusion (55%) compared with those treated with the device in the randomized phase (61%). Rates of adverse events were comparable (13% vs 9%). Rates of good neurological outcome were equivalent between the roll-in and randomized patients treated with Solitaire (63% vs 58%). Including the roll-in patients strengthened the conclusions of the study, that reperfusion rates without symptomatic hemorrhage with Solitaire were greater than with Merci (59% vs 24%,  $p < 0.001$ ).

**Conclusions**—Thrombectomy in AIS using the Solitaire stent retriever device can be performed safely and effectively when used by experienced neurointerventionalists without previous experience with the device.

**Trial registration number**—The SWIFT study is registered with ClinicalTrials.gov, number NCT 01054560.

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## INTRODUCTION

Long-awaited positive trial data are establishing neurothrombectomy as the first new treatment in 20 years with proven benefit for patients with acute ischemic stroke (AIS). Optimism for the technique has sprung from the recent publication of the MR CLEAN trial as well as the expected positive results from other halted studies.<sup>1–4</sup> A key driver of this success is the development and use of stent retriever devices.<sup>5–8</sup> Initial trials of endovascular recanalization therapy using first-generation technologies failed to show any benefit over medical treatment.<sup>9–11</sup> But concurrently, head-to-head trials of stent retrievers against earlier-generation approaches showed that the new devices achieved much higher rates of recanalization, with less hemorrhagic transformation and improved functional outcome.<sup>6,7</sup> Stent retrievers went on to become the preponderant neurothrombectomy device in the subsequent trials of endovascular therapy.

For all new endovascular procedures, a key aspect is how steep the learning curve is for operators and whether the benefits of treatment accrue early or only later after a center begins to deploy the new technique. For stent retriever therapy, this subject can be examined by analysis of the earliest registration trials, which capture the first experience with device therapy overseen by device regulatory authorities. The Solitaire With the Intention For Thrombectomy (SWIFT) trial was the first to demonstrate improved recanalization rates using a stent retriever device compared with the technology existing at that time.<sup>6</sup> In its randomized phase, this trial showed that compared with Merci coil retrievers, thrombectomy

with the Solitaire stent retriever yielded much higher rates of reperfusion, required fewer device passes, had less symptomatic intracranial hemorrhage, improved disability outcomes, and reduced mortality. At the initiation of SWIFT, the Solitaire device was new to investigators in the USA, and as a result US operators in the study had no prior experience of using it in clinical settings. SWIFT therefore included a roll-in phase, in which enrolling sites were required to use the device in two cases before entering patients into the randomized phase.

In this study, we analyze the safety and efficacy of thrombectomy for AIS using Solitaire for the cohort of patients treated in this initial roll-in period. By examining the results of this group in relation to those treated in the subsequent randomized phase, we quantitatively assess the ease of use of the device, and determine whether inclusion of these early patients would have altered the results of the trial. In light of recent data demonstrating the superiority of stent retriever therapy over medical treatment alone, and the likelihood of increased frequency of stent retriever usage for AIS, these findings have implications for the effectiveness in dissemination of these treatments, particularly when performed by practitioners without substantial prior stent retriever experience.

## METHODS

### Study design and participants

SWIFT was a multicenter, roll-in and randomized phase, prospective trial with ascertainment of a blinded primary endpoint. Details of the study design are available elsewhere.<sup>6</sup> Briefly, patients were eligible if they had AIS with moderate to severe neurological deficits, harbored angiographically confirmed occlusions of proximal cerebral arteries, and were treatable by thrombectomy within 8 h of stroke symptom onset. Key inclusion criteria included age (22–85 years), National Institutes of Health Stroke Scale (NIHSS) score (≥ 8 and ≤ 30), and ineligibility for, or failure to respond to, intravenous recombinant tissue plasminogen activator (rt-PA).

### Study site criteria

The following criteria were used in the selection of study sites and principal investigators:

- Previous experience with clinical research and mechanical thrombectomy procedures
- Currently treating subjects who meet the inclusion/exclusion criteria
- Ability to enroll an adequate number of subjects
- Ability to perform required clinical testing, including: angiography, CT, and MRI
- Ability and willingness to provide the sponsor's representatives access to the hospital records, study files, and subject files as they pertain to the study
- Willingness to participate, including compliance with all aspects of the study

- Adequate staffing to conduct the study.

As mentioned in the publication detailing the methods of the study, all participating sites already had experience with the Merci retriever before the study launch, with minimum criteria of having participated in the Merci or Multi-Merci clinical trials or having Merci devices on shelf and an annual volume of 30 endovascular interventions for AIS.<sup>12</sup>

### Roll-in period

To assure neurointerventionalist familiarity with the study device, physicians were trained in the use of the device on a bench vascular model before any procedures were done, and participating sites were required to use the device on two roll-in patients before randomization of patients. Roll-in patients received the Solitaire device as the only initial neurothrombectomy intervention and were analyzed separately from the patients who were randomly allocated to treatment. Note that the roll-in requirement of two clinical implementations of the study device before randomization was for each enrolling site and not for each neurointerventionalist.

### Procedures

Once a patient was assigned to either Solitaire or Merci, the neurointerventionalist selected the proper study device size according to the device-specific instructions for use. A minimum of one deployment of the assigned study device was required within 8 h of symptom onset. The neurointerventionalist then continued recanalization attempts using the assigned device type, continuing until successful recanalization was achieved or until three passes of the study group device through any vessel had been done. The primary endpoint outcome angiogram was then obtained.

After the primary endpoint outcome angiogram was completed, rescue treatment was permitted in patients in whom adequate recanalization had not been achieved. All cases requiring rescue treatment were regarded as device treatment failures. Permitted rescue treatment interventions were as follows: a regulatory-agency-cleared neurovascular thrombectomy device, intra-arterial fibrinolysis according to US guidelines, or both. If any rescue treatment had been carried out, an additional, final, diagnostic angiogram (after all procedures had been done) was obtained.

The primary efficacy endpoint of the study was successful recanalization with the assigned study device (no use of rescue treatment) with no symptomatic intracranial hemorrhage. Successful recanalization was defined as the achievement of Thrombolysis In Myocardial Ischemia (TIMI) scale 2 or 3 flow in all treatable vessels. The stringent cerebral version of the TIMI scale was used as the recanalization metric in this study for consistency of results with prior comparable studies—namely, the Merci trials.<sup>13,14</sup> Successful recanalization of the middle cerebral artery required reperfusion through all M1 and M2 segments. Successful recanalization of internal carotid artery terminus lesions required reperfusion through the internal carotid artery and all M1 and M2 branches. Successful recanalization of a vertebral artery required reperfusion through both the target vertebral artery and the basilar artery. Symptomatic intracranial hemorrhage was defined as any parenchymal hematoma,

subarachnoid hemorrhage, or intraventricular hemorrhage associated with a worsening of the NIHSS score by  $\geq 4$  within 24 h.

Secondary efficacy outcomes included the following: time to achieve initial recanalization, defined as the time from baseline guide catheter run to visualization of TIMI 2 or 3 flow in all treatable vessels; good neurological outcome at 90 days, defined as a modified Rankin scale (mRS) score of  $\leq 2$ , or equal to the pre-stroke mRS if the pre-stroke mRS was  $>2$ , or NIHSS score improvement of  $\geq 10$  points; and neurological condition at 90 days, including NIHSS, Barthel Index, and mRS. The primary safety endpoint was the incidence of device-related and procedure-related serious adverse events. Additional safety endpoints included mortality and symptomatic intracranial hemorrhage.

### Statistical analysis

Key statistical analyses, including the primary endpoint analysis, were validated by an independent external statistician (J Schafer, MS, NAMS, Minneapolis, Minnesota, USA). Analyses of continuous variables were calculated by t test (when mean is reported) or Wilcoxon test (when median is reported). Analyses of discrete variables were conducted using Fisher's exact test and  $\chi^2$  test. Non-inferiority analyses were performed using Wald's method with a delta of 10%, and superiority by Fisher's exact test.

### Role of the funding source

An academic principal investigator (JLS), academic lead interventional investigator (RJ), and academic steering committee supervised the trial design and operations. A publications committee (principal investigator, lead interventional investigator, steering committee, and academic principal investigators of the sites that enrolled most patients) interpreted the results and wrote the report. The sponsor of the study was responsible for site management, data management, and safety reporting. The corresponding author had full access to all the data in this study and had final responsibility for the decision to submit for publication.

## RESULTS

Between February 2010 and February 2011, 18 sites (17 in the USA and one in France) consented and enrolled 144 patients, including 31 roll-in patients who received Solitaire and 113 patients who were randomly allocated to one of the two treatment groups (58 to Solitaire and 55 to Merci). Because the study results showed that the treatment effect for the primary effectiveness endpoint was not significantly different by site ( $p=0.3853$ , Breslow–Day test of homogeneity), the data across sites were pooled. The total number of subjects enrolled and the number of subjects enrolled by randomization assignment at each investigation site is presented in online supplementary table S1. Note that site number assignment for the study was at the sponsor's discretion, not in temporal order of activation nor with contiguous numbering. As shown in table 1, baseline demographic and clinical characteristics of the Solitaire roll-in, Solitaire randomized, and Merci randomized treatment groups were generally similar, including age and presenting stroke severity (NIHSS). Three group differences were noted. An increased prevalence of atrial fibrillation was seen in the Merci group compared with the combined Solitaire arms (roll-in and randomized). There

was no difference in prevalence of atrial fibrillation in the roll-in Solitaire versus randomized Solitaire arms. Also, more patients in the roll-in Solitaire group received IV t-PA compared with the randomized Solitaire group. In addition, more patients in the randomized Solitaire group presented with pre-stroke mRS of 1 and fewer with mRS of 3–5 compared with those in the roll-in period.

Primary trial endpoint results were attained with similar frequencies in the roll-in Solitaire patients and those who were randomized to the device after the roll-in period (table 2). Combining the Solitaire roll-in and randomized patients for comparison with the Merci group resulted in similar point estimates and lower p values than the randomized comparison alone. As shown in table 2, treatment with the Solitaire device in any arm resulted in an increase from 24% to 59% in the rates of successful recanalization without symptomatic ICH, as well as decreased use of rescue treatment.

Similarly, there were no differences in these clinical outcomes in the roll-in phase versus randomized phase patients treated with the Solitaire device (table 3). Combining patients treated with the Solitaire device during the roll-in and randomized periods did not affect the point estimates for rates of final clinical outcomes compared with patients treated with the Merci device, and further lowered p values, indicating device differences. There was no significant difference between the rates of good neurological outcome (mRS  $\leq$  2 at 90 days, NIHSS improvement  $\geq$  10, or return to pre-stroke mRS) between the roll-in and randomized phase patients treated with the study device. As mentioned above, more patients with mRS=0 were enrolled in the roll-in phase compared with the randomized phase.

There was no difference in adverse events between the initial roll-in period patients and those in the randomized phase. There were no incidents of air embolism or vessel perforation in these two groups. There were slightly higher nominal rates of difficulty in device delivery and distal emboli that did not achieve statistical significance (table 4).

As shown in figure 1, mortality over time was comparable for patients in the roll-in and randomized phases who received the Solitaire device. Combining the roll-in patients with the randomized patients further lowered the p value for reduction in mortality in the Kaplan–Meier analysis of Solitaire versus Merci device. Day 90 mRS values for the Solitaire groups and Merci group are shown in figure 2. Final mRS at 90 days in the combined Solitaire group were lower than those in the Merci treatment group ( $p < 0.05$ ,  $\chi^2$  test).

## DISCUSSION

In this study, we found that experienced neurointerventionalists using the Solitaire device for thrombectomy in AIS achieved high levels of safety and efficacy without prior experience of using the device in patients. Patients who received treatment with the device during the study roll-in period achieved equivalently high rates of core-lab assessed reperfusion with the study device alone (63%) compared with those treated with the device in the randomized phase (69%), during which time all sites had experience with using the device in clinical settings. Rates of adverse events were comparable. The final clinical outcome was also similar. Including the patients in the roll-in phase of the trial with those treated in the

randomized phase strengthened the conclusions of the study, that reperfusion rates are greatly improved with the Solitaire device compared with Merci.

Our finding that patients treated in the roll-in phase, during which time US neurointerventionalists would have had no experience with the device, demonstrates the ease of use of the study stent retriever device. As 17 of 18 sites that ultimately randomized patients in SWIFT were US sites, this comprises most patients in the study. It should also be pointed out that as the Solitaire AB is not available in the USA, use of this device in ischemic stroke was the first exposure of US investigators to Solitaire. Recanalization rates were extremely high in this initial period and remained high in the randomized part of the study, suggesting that operators of the device were highly adept with it from their initial usage. Equally as important, the number of adverse events was very low and consistent over time. Single-center, retrospective studies on initial experiences with the Solitaire stent retriever for thrombectomy in stroke have found similar results. One smaller study with 20 patients reported reperfusion rates of nearly 90%, with procedure related complications of about 10%.<sup>15</sup> Two other larger studies from France reported almost identical findings.<sup>16,17</sup>

Widespread dissemination of stent retriever therapy in clinical practice may be expected based on the recent positive results for neurothrombectomy. The pivotal trial demonstrating the benefit of endovascular therapy is primarily stent retriever-based, and contains inclusion criteria that more accurately mimic clinical practice, such as the requirement for intracranial occlusion on non-invasive imaging.<sup>1</sup> Our findings in this analysis of roll-in patients in the SWIFT study suggest that diffusion of stent retriever therapy may lead rapidly to effectiveness in clinical practice, without a steep learning curve, by demonstrating the relative ease of use, safety, and efficacy of the Solitaire device.

This study has limitations. The 18 sites enrolling in the SWIFT study were high-volume stroke centers, and as such although the neurointerventionalists at the 17 US sites had no prior experience using the study device, all were highly experienced in thrombectomy approaches for AIS, as detailed previously in the 'Methods' section. Thus, our finding of safety and efficacy of the patients in the roll-in phase of the SWIFT study cannot be extrapolated to practitioners without prior experience in endovascular therapy for AIS. Further, it should be noted that the entire experience of the SWIFT trial may be considered an 'early' experience, and it is possible that the learning curve for stent-retriever usage in stroke has a continuing upward trajectory beyond the experience captured in this study. In addition, study site assessments of reperfusion allowed for the possibility of bias on the part of the interventionalists during the procedure. However, the final study assessment of reperfusion was performed by a blinded core laboratory protected from bias by removal of all angiographic images that might have identified the type of device used before adjudication.

We conclude that examination of patients treated with the Solitaire device during the roll-in period of the SWIFT study, which was the initial experience using the device in AIS for the participating neurointerventionalists, indicates equivalently high rates of recanalization, with equally low rates of adverse events as those found in the randomized phase. Clinical outcomes were also comparable in the two phases. Thrombectomy in AIS using the Solitaire



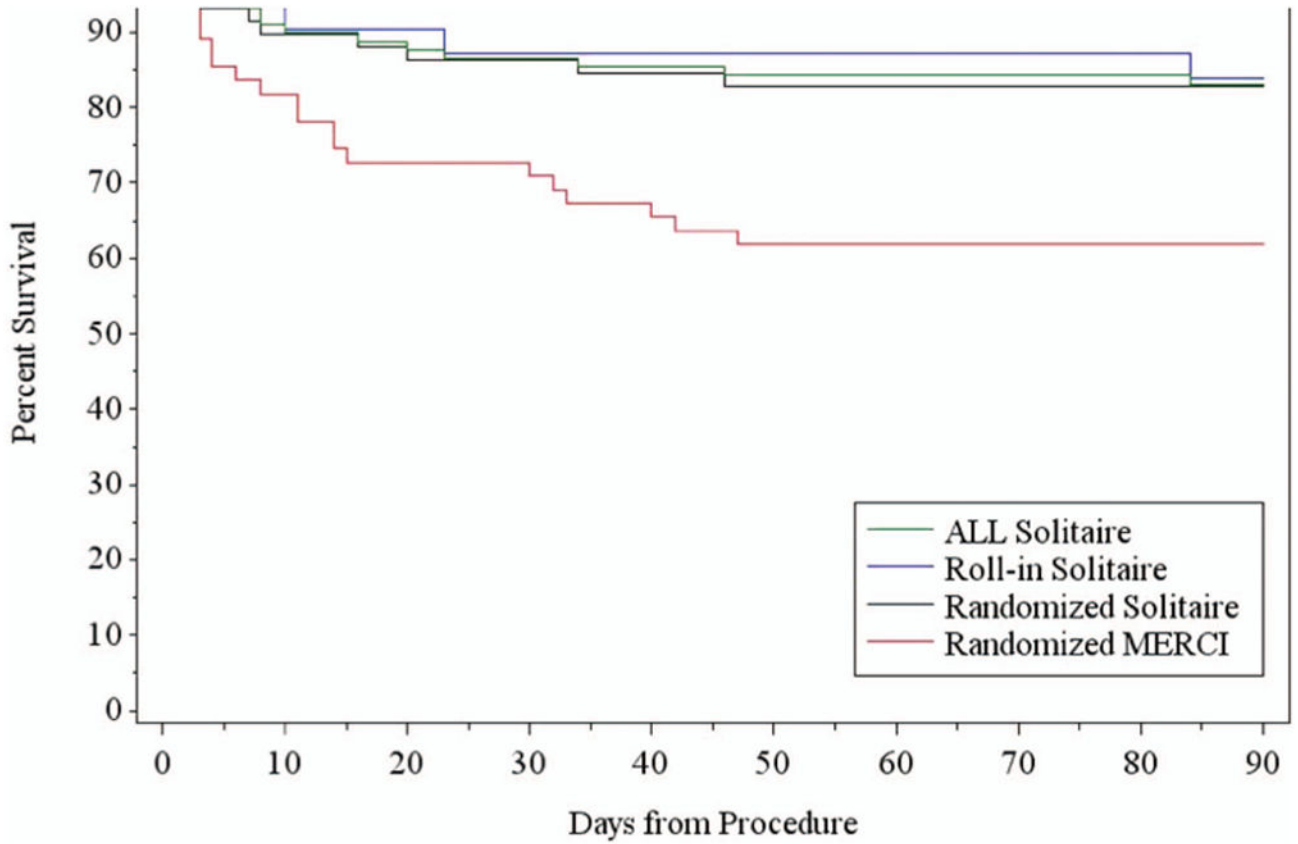
stent retriever device can be performed safely and effectively when used by experienced neurointerventionalists without previous experience of the device.

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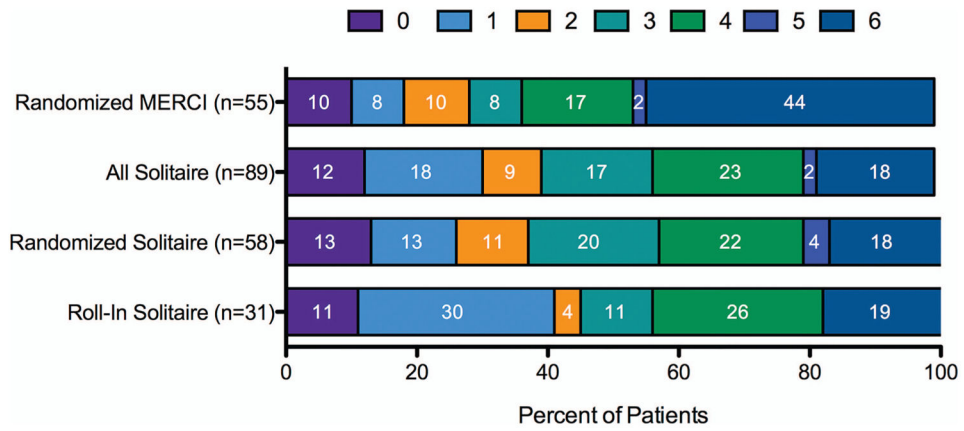
The authors thank Jill Schafer for assistance with performing and independently verifying the statistical analysis in this manuscript.

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**Figure 1.** Kaplan–Meier curves for patients in the roll-in and randomized phases of the SWIFT trial. Curves show time to the endpoint of mortality for patients enrolled in the roll-in phase, randomized phase (Merci and Solitaire arms) and for all Solitaire-treated patients (roll-in and randomized phases). The survival curves for all patients treated with Solitaire is significantly different from those treated with Merci ( $p=0.003$ , log-rank test). There is no significant difference between the survival curves of the patients treated with Solitaire in the roll-in versus randomized phases ( $p=0.86$ , log-rank test).



**Figure 2.** Ordinal 90-day Rankin outcomes for patients in the roll-in and randomized phases of the SWIFT trial. Modified Rankin outcomes are shown for all four groups of patients: randomized phase Merci treated, all Solitaire treated (roll-in and randomized phases), randomized phase Solitaire treated, and roll-in phase Solitaire treated. The final modified Rankin scale at 90 days in the combined Solitaire group was lower than for those in the Merci treatment group ( $p < 0.05$ ,  $\chi^2$  test). There is no difference in Rankin outcomes between those treated with Solitaire in the roll-in versus randomized phases ( $p = 0.25$ ,  $\chi^2$  test).

**Table 1**  
Univariate baseline characteristics of patients in the roll-in and randomized phases of the SWIFT trial

Characteristics	Roll-in Solitaire (N=31)	Randomized Solitaire (N=58)	All Solitaire (N=89)	Randomized Merci (N=55)	p Value* (Roll-in vs Randomized Solitaire)	p Value* (All Solitaire vs Merci)
Age, mean (SD)	65 (14)	67 (12)	66 (13)	67 (11)	0.556	0.777
Female (%)	58	52	54	49	0.657	0.609
NIHSS, mean (SD)	18 (5)	17 (5)	17 (5)	18 (5)	0.866	0.881
NIHSS, median (IQR)	18 (14–20)	18 (14–19)	18 (14–20)	18 (13–22)	0.736	0.728
NIHSS, categorical (%)					0.926	0.928
8–12	16	22	20	22		
13–17	29	26	27	25		
18–22	39	38	38	35		
23–42	16	14	15	18		
Medical history						
Atrial fibrillation (%)	39	45	43	67	0.656	0.006
Hypertension (%)	55	72	66	69	0.106	0.855
Coronary artery disease/ myocardial disease (%)	39	36	37	40	0.822	0.728
Diabetes (%)	32	24	27	31	0.458	0.704
Hyperlipidemia (%)	52	53	53	56	1.000	0.732
Peripheral artery disease (%)	10	2	4	7	0.120	0.481
Smoking (%)	16	22	20	13	0.586	0.269
Prior stroke/TIA (%)	29	21	24	25	0.436	0.843
Pre-stroke modified Rankin scale, mean (SD)	0.5 (1.2)	0.5 (0.8)	0.5 (1.0)	0.5 (1.0)	0.861	0.903
Pre-stroke modified Rankin scale, categorical					0.006	0.750
0 (%)	84	66	72	75		
1 (%)	0	25	16	14		
2 (%)	0	5	3	6		
3 (%)	12	5	7	4		
4 (%)	4	0	1	0		

Characteristics	Roll-in Solitaire (N=31)	Randomized Solitaire (N=58)	All Solitaire (N=89)	Randomized Merci (N=55)	p Value* (Roll-in Solitaire vs Randomized Solitaire)	p Value* (All Solitaire vs Merci)
5 (%)	0	0	0	2		
BMI, mean (SD)	30 (9)	29 (7)	29 (8)	29 (6)	0.720	0.947
Target occlusion location (%)					0.944	0.329
Carotid T	17	20	19	20		
ICA	3	2	2	6		
M1	66	68	67	54		
M2	14	11	12	20		
Baseline ASPECTS score, mean (SD)	9.0 (2.2)	9.5 (1.2)	9.3 (1.6)	9.5 (1.4)	0.176	0.420
Receipt of IV t-PA (%)	68	34	46	47	0.004	1.000
Baseline serum glucose, mean (SD)	139 (60)	139 (72)	139 (68)	139 (49)	0.963	0.992
Number of device passes, mean (SD)	1.9 (0.9)	1.7 (0.9)	1.8 (0.9)	2.2 (0.9)	0.294	0.005
Time from onset to hospital arrival, median (IQR)	242 (190–300)	230 (175–300)	230 (184–300)	240 (205–340)	0.615	0.279
Time from hospital arrival to groin puncture, median (IQR)	57 (51–77)	58 (47–74)	57 (49–76)	63 (50–84)	0.893	0.224
Time from onset to groin puncture, median (IQR)	295 (258–360)	274 (239–362)	284 (246–361)	315 (273–390)	0.484	0.054
Time from onset to reperfusion, median (IQR)	346 (297–416)	336 (274–408)	336 (276–408)	367 (323–450)	0.540	0.046
Time from onset to reperfusion, mean (SD)	355 (87)	342 (84)	347 (85)	379 (90)	0.528	0.049

\* p Values for continuous variables calculated by t test (when mean is reported) or Wilcoxon test (when median is reported); p values for discrete variables calculated by Fisher's exact test.

ASPECTS, Alberta Stroke Program Early CT Scores; BMI, body mass index; ICA, internal carotid artery; NIHSS, National Institutes of Health Stroke Scale; SWIFT, Solitaire With the Intention For Thrombectomy; t-PA, tissue plasminogen activator.

Trial technical efficacy endpoints

Table 2

Endpoints	Roll-in Solitaire (N=31)	Randomized Solitaire (N=58)	All Solitaire (N=89)	Randomized Merci (N=55)	p Value for non-inferiority (all Solitaire vs Merci)	p Value for superiority (all Solitaire vs Merci)	p Value for superiority (roll-in vs randomized Solitaire)
Successful recanalization without symptomatic ICH (core laboratory), % (n/N)*	55 (16/29)	61 (34/56)	59 (50/85)	24 (13/54)	<0.001	<0.001	0.649
Successful recanalization with study device (core laboratory), % (n/N)	63 (17/27)	69 (37/54)	67 (54/81)	30 (16/53)	<0.001	<0.001	0.626
Successful recanalization with the study device (site assessed), % (n/N)	77 (24/31)	83 (45/54)	81 (69/85)	48 (26/54)	<0.001	<0.001	0.569
Use of rescue therapy, % (n/N)	23 (7/31)	21 (12/58)	21 (19/89)	44 (24/55)	<0.001	0.008	1.000
End of procedure successful recanalization (site assessed), % (n/N)	94 (29/31)	89 (49/55)	91 (78/86)	69 (37/54)	<0.001	0.001	0.705
End of procedure successful recanalization (core laboratory), % (n/N)	79 (22/28)	77 (43/56)	77 (65/84)	59 (32/54)	<0.001	0.035	1.000

\* Prespecified trial primary endpoint.

ICH, intracranial hemorrhage.

Table 3

## Clinical efficacy endpoints

Endpoints	Roll-in Solitaire (N=31)	Randomized Solitaire (N=58)	All Solitaire (N=89)	Randomized Merci (N=55)	p Value for non-inferiority (all Solitaire vs Merci)	p Value for superiority (all Solitaire vs Merci)	p Value for superiority (roll-in vs randomized Solitaire)
Good neurological outcome % (n/N) *	63 (17/27)	58 (32/55)	60 (49/82)	33 (16/48)	<0.001	0.006	0.812
Mortality at 90 days, % (n/N)	16 (5/31)	17 (10/58)	17 (15/89)	38 (21/55)	<0.001	0.006	1.000

\* Good neurological outcome was defined as mRS 2 at 90 days, NIHSS improvement 10, or return to pre-stroke Rankin. mRS, modified Rankin scale; NIHSS, National Institutes of Health Stroke Scale.

Serious adverse events (SAEs)

**Table 4**

Adverse events	Roll-in Solitaire (N=31)	Randomized Solitaire (N=58)	All Solitaire (N=89)	Randomized Merci (N=55)	p Value (all Solitaire vs Merci)	p Value (roll-in vs randomized Solitaire)
All study device-related SAEs, % (n/N)	13 (4/31)	9 (5/58)	10 (9/89)	16 (9/55)	0.306	0.714
All procedure-related SAEs, % (n/N)	19 (6/31)	14 (8/58)	16 (14/89)	16 (9/55)	1.000	0.548
Selected adverse events and procedural and technical events						
Air embolism, % (n/N)	0 (0/31)	0 (0/58)	0 (0/89)	2 (1/55)	0.382	N/A
Device fracture, % (n/N)	0 (0/31)	2 (1/58)	1 (1/89)	0 (0/55)	1.000	1.000
Vasospasm, % (n/N)	10 (3/31)	5 (3/58)	7 (6/89)	5 (3/55)	1.000	0.416
Vessel perforation, % (n/N)	0 (0/31)	0 (0/58)	0 (0/89)	4 (2/55)	0.144	N/A
Difficulty in device delivery, % (n/N)	6.5 (2/31)	3.4 (2/58)	4.5 (4/89)	3.6 (2/55)	1.00	0.61
Distal emboli, % (n/N)	6.5 (2/31)	3.4 (2/58)	4.5 (4/89)	5.5 (3/55)	1.00	0.61