Stent-assisted coiling with LVIS Evo and HydroCoil embolic system: 1-year results of the SEALANT study

Jonathan Downer, Omer F. Eker, Roberto Riva, Ansgar Berlis, Antonio Pitrone, Paul Stracke, Illario Tancredi, Charbel Mounayer, Chrysanthi Papagiannaki, Arun Chandran, Jean Christophe Gentric, Herve Brunel, Michel Piotin, Naga Kandasamy, Sebastian Fischer, Levansri Makalanda, Daniele G. Romano, Florence Tahon, Mariangela Piano, Edoardo Boccardi, René Chapot

Angaben zur Veröffentlichung / Publication details:

Downer, Jonathan, Omer F. Eker, Roberto Riva, Ansgar Berlis, Antonio Pitrone, Paul Stracke, Illario Tancredi, et al. 2026. "Stent-assisted coiling with LVIS Evo and HydroCoil embolic system: 1-year results of the SEALANT study." *Journal of NeuroInterventional Surgery*. https://doi.org/10.1136/jnis-2026-025179.

OPEN ACCESS

Original research

Stent-assisted coiling with LVIS Evo and HydroCoil embolic system: 1-year results of the SEALANT study

Jonathan Downer ,[1] Omer F Eker,[2] Roberto Riva ,[2] Ansgar Berlis,[3] Antonio Pitrone,[4] Paul Stracke,[5] Illario Tancredi,[6] Charbel Mounayer,[7] Chrysanthi Papagiannaki ,[8] Arun Chandran,[9] Jean Christophe Gentric,[10] Herve Brunel,[11] Michel Piotin,[12] Naga Kandasamy,[13] Sebastian Fischer,[14] Levansri Makalanda ,[15] Daniele G Romano,[16] Florence Tahon,[17] Mariangela Piano,[18] Edoardo Boccardi,[18] René Chapot [19]

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/jnis-2026-025179).

For numbered affiliations see end of article.

Correspondence to
Dr Jonathan Downer; jonathan.downer@ed.ac.uk

Received 18 February 2026
Accepted 19 May 2026

To cite: Downer J, Eker OF, Riva R, *et al*. *J NeuroIntervent Surg* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/jnis-2026-025179

ABSTRACT

Background More high-quality evidence for stent-assisted coiling (SAC) of cerebral aneurysms is needed. Randomized controlled trials have shown lower recurrence with the HydroCoil Embolic System (HES) compared with bare platinum coils, and self-adjudicated LVIS Evo SAC studies have demonstrated favorable safety and technical success. The objective of the SEALANT study is to investigate the safety and effectiveness of this device combination.

Methods SEALANT is an open-label, prospective, single-arm, multicenter study including patients with aneurysms up to a maximum size of 12 mm. The primary effectiveness endpoint was complete occlusion on digital subtraction angiography (DSA), and the primary safety endpoint was major ipsilateral stroke or neurological death. Adverse events and imaging were independently adjudicated.

Results 206 patients were enrolled; 193 had follow-up imaging for outcome assessment; and 164 satisfied all criteria, were treated with both study devices (including ≥90% HES), and had DSA follow-up. The participants' mean age was 56.8±11.6 years; 65% were female. Of 212 aneurysms, 86.3% were bifurcation and 13.2% sidewall; 25.0% were previously treated and 17.9% previously ruptured; 89.6% were anterior circulation, 34.0% at the anterior communicating artery, and 30.7% at the middle cerebral artery; and 84.9% were wide-necked (neck ≥4 mm or dome/neck ratio <2). The primary effectiveness endpoint of complete occlusion was achieved in 82.1% (95% CI 76.4% to 87.9%) of aneurysms. 2.4% (95% CI 0.3% to 4.5%) of patients met the primary safety endpoint of major ipsilateral stroke or neurological death. The primary safety endpoint was significantly associated with baseline modified Rankin Scale and history of previous stroke.

Conclusion 1-year SEALANT results confirm the safety and effectiveness of SAC using LVIS Evo and HES.

Trial registration number NCT04999423.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Stent-assisted coiling (SAC) is widely used, but high-quality prospective evidence remains relatively limited. Randomized controlled trials (RCTs) have shown reduced recurrence with the HydroCoil Embolic System (HES), and retrospective studies suggest favorable safety and technical performance of the LVIS Evo stent.

WHAT THIS STUDY ADDS

⇒ SEALANT is the first prospective, multicenter study with independent core lab and clinical event adjudication to assess SAC using LVIS Evo in combination with HES coils. At 1 year, 82.1% of aneurysms were completely occluded and 2.4% of patients had experienced major ipsilateral stroke or neurological death. Baseline disability and prior ischemic stroke were significantly associated with the primary safety outcome.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ SEALANT provides robust prospective evidence supporting the safety and effectiveness of SAC using LVIS Evo and HES coils, in a population of predominantly wide-necked aneurysms. The results can be used to inform clinical decision-making and as a benchmark against alternative endovascular strategies. They also provide a foundation for the design of future RCTs comparing SAC with other treatments.

INTRODUCTION

Background/rationale

Stent-assisted coiling (SAC) is a standard method of treating patients with unruptured intracranial aneurysms (UIAs) in day-to-day use around the world, typically for wide-necked bifurcation aneurysms. However, there is still a recognized need for more high-quality evidence—for example, from well-designed post-market studies evaluating device safety and effectiveness.[1]

Stents provide neck coverage to trap coils in an aneurysm, but they may also promote a healing response in the parent vessel, acting as a scaffold for endothelial growth across the neck while providing some degree of flow diversion.[2 3] The fully visible, recapturable, low-profile braided design of the

LVIS Evo stent (Low-profile Visualized Intraluminal Support) allows an operator to optimize deployment and neck coverage. Combined with smaller cell size compared with laser-cut stent designs, this could enhance coil packing and flow-diverting effect.[4 5] Published early clinical experience using LVIS Evo, including a meta-analysis of seven self-adjudicated retrospective studies, has demonstrated favorable safety and technical success.[6–11]

On the other hand, three randomized controlled trials (RCTs) have shown benefit from Hydrogel coils compared with bare platinum.[12–14] The most recent of these, HEAT (Hydrogel Endovascular Aneurysm Treatment Trial), showed significantly lower rates of aneurysm recurrence in patients randomized to treatment using second-generation HydroCoil Embolic System (HES) coils compared with bare platinum coils (BPC) (4.4% HES vs 15.4% BPC, P=0.002) without increased harm.[14]

So, when used together, LVIS Evo and HES coils have the promise to be highly effective, with low rates of recurrence, while maintaining procedural safety. SEALANT is the first prospective clinical study examining this device combination.

Objective

The objective of this study is to investigate the safety and effectiveness of cerebral aneurysm treatment using LVIS Evo and HES coils.

METHODS

Study design

SEALANT (Safety and Effectiveness Analysis of stent-assisted coiling with LVIS Evo and HydroCoil Embolic System in ANeurysm Treatment) is an open-label, prospective, single-arm, multicenter clinical study. It was registered in the United States National Library of Medicine ClinicalTrials.gov database before enrolling participants. All required local and national ethics and regulatory approvals were obtained for participating sites. Ethics committee details are supplied in the online supplemental material. All participants gave written informed consent, and the study was run in accordance with Good Clinical Practice standards.

Setting

The study is being conducted at 17 neurointervention centers in Europe, located in Germany, France, Italy, Belgium, and the UK. Two hundred and six patients were enrolled between January 2022 and August 2023. This paper presents outcome data at 1 year after aneurysm treatment. The study will continue to follow-up enrolled patients for up to 3 years.

Participants

Participants were adults with an unruptured or previously ruptured intracranial aneurysm (>30 days since occurrence) up to a maximum size of 12 mm, judged suitable for endovascular treatment using LVIS Evo and HES by the investigator. Patients with intracranial hemorrhage <30 days before treatment, partially thrombosed or fusiform aneurysms, and those whose target aneurysm had been previously treated with a stent were excluded. A complete list of inclusion and exclusion criteria is provided in the online supplemental material. Based on the intervention protocol of the HEAT RCT, patients were required to receive treatment with at least 90% HES of the total coil length used. The study protocol did not mandate a standardized antiplatelet therapy regimen.

Variables

The primary effectiveness endpoint is the proportion of aneurysms with complete occlusion based on Raymond-Roy occlusion classification (RROC) evaluated using digital subtraction angiograms (DSA). The primary safety endpoint is the proportion of patients with major ipsilateral stroke or neurological death. Major stroke was defined as an ischemic or hemorrhagic stroke persisting for more than 24 hours and resulting in a ≥4 point increase in the National Institutes of Health Stroke Scale (NIHSS) score compared with baseline or any subsequent lower score.

Data sources/measurement

Data were captured in an electronic case report form and independently monitored by a contract research organization (CRO). Adverse events were adjudicated by an independent clinical events adjudicator (CEA). Imaging was evaluated by an independent core laboratory (core lab). Statistical analysis was performed by a CRO statistician. The principal investigators had full access to all data in the study and take responsibility for its integrity and the data analysis.

Bias

The study protocol stipulated that consecutive eligible patients should be recruited to minimize selection bias. Independent adjudication of imaging and adverse events reduces the risk of investigator-related reporting bias. Presenting data for both intention-to-treat (ITT) and per protocol (PP) populations enhances transparency of reporting and helps reduce bias when interpreting results. Study reporting in this paper conforms to STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines.[15]

Study size

The expected proportion of aneurysms with complete occlusion (RROC class I) at 1 year was estimated at 80% based on the pivotal US first-generation LVIS trial[16] and Atlas IDE trial (Investigational Device Exemption).[17] Calculating precision using the formula $e=1.96\times\sqrt{p}\times(1\,p)/n$, a sample size of 200 patients was necessary to allow estimation of the proportion of aneurysms with complete occlusion ranging from 65% to 90% with precision from ±4.2% to ±6.6%. With 10% loss to follow-up this sample size maintained precision of ±4.4% to ±7% for effectiveness parameters.

Quantitative variables

Functional independence was defined as a modified Rankin Scale (mRS) score of 0 to 2. Aneurysms with neck ≥4 mm or dome-to-neck ratio <2 were categorized as wide-necked aneurysms.[18]

Statistical methods

Quantitative data are summarized using descriptive statistics. Continuous variables are summarized by mean, SD, and number of observed and missing values, and categorical variables by using absolute and relative frequencies (percentages). Endpoint results are reported as the number of occurrences, their relative proportions (percentages), and 95% confidence intervals (95% CI). Missing data were not imputed, as the mechanism was considered missing not at random, and too complex in the uncontrolled study environment for reliable modeling without risk of bias. Subgroup comparisons were performed using inferential methods. Comparisons for nominal variables were conducted using the χ^2 test, Fisher's exact test, or the

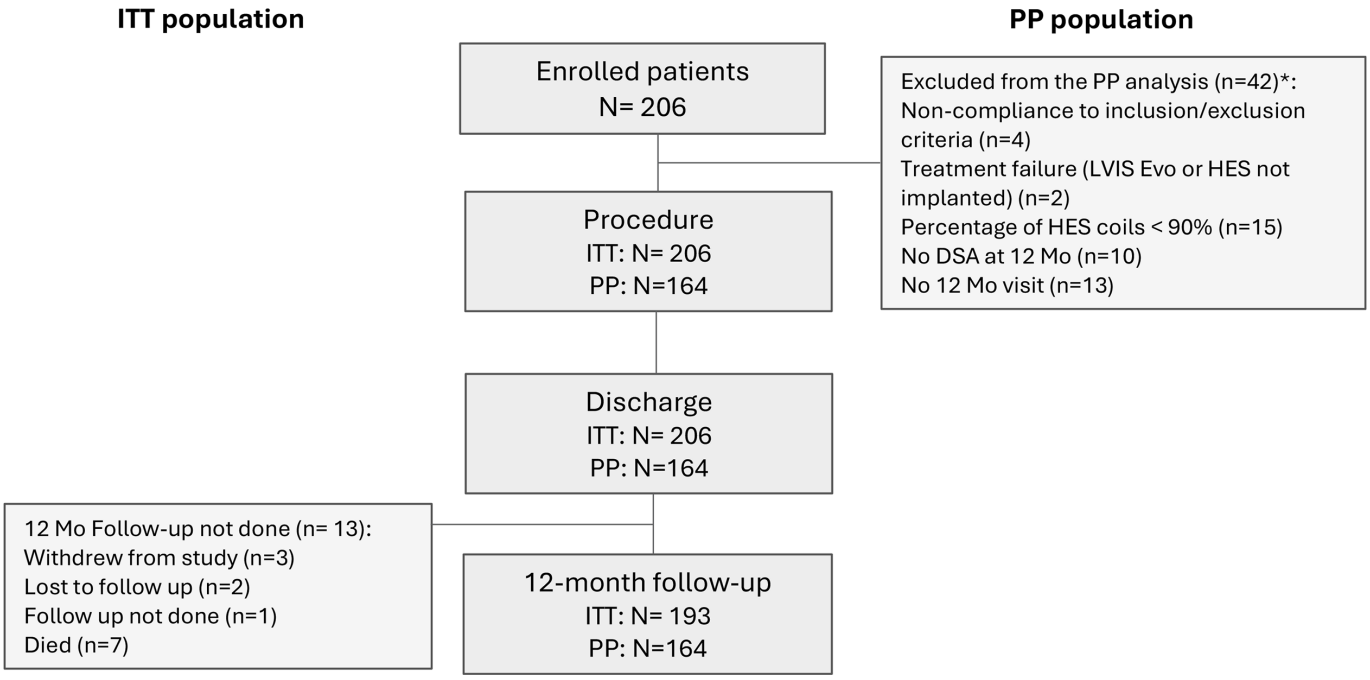

Figure 1 CONSORT flow diagram. *Two patients have two reasons for PP exclusion. CONSORT, CONsolidated Standards Of Reporting Trials; DSA, digital subtraction angiography; HES, HydroCoil Embolic System; LVIS, Low-profile Visualized Intraluminal Support; PP, per protocol.

Fisher-Freeman-Halton test for more than two categories, and continuous variables using the Student's t-test. Statistical significance was defined as $P<0.05$. SAS software version 9.4 for Windows was used, in accordance with ISO 1455 and ICH E9 guidelines.

RESULTS

Participants

The ITT population included all patients who were enrolled in the study and had at least one study device inserted into a microcatheter during their treatment procedure (206 patients). The 1-year effectiveness ITT population included all patients who had successful placement of at least one study device at the target aneurysm, and core lab RROC assessment at 12±6 months using all imaging modalities (193 patients), but DSA was required for the primary effectiveness endpoint. The PP population included all patients who satisfied all inclusion and exclusion criteria, had successful placement of both study devices at the target aneurysm (including HES coils of at least 90% of the total coil length used) and DSA follow-up at 12±6 months (164 patients). Information on the analyzed populations is summarized in a CONSORT (CONsolidated Standards Of Reporting Trials) flow diagram (figure 1).

Descriptive data

Baseline patient characteristics

The mean age of the ITT population was 56.8±11.6 years, and 65% were female; 46.6% had a smoking history, 57.8% a history of hypertension, and 9.7% had a family history of cerebral aneurysms; 26.2% had previous hemorrhagic stroke, 3.9% prior ischemic stroke, and 5.8% transient ischemic attack; and 98.1% were functionally independent at baseline. Baseline patient data for ITT and PP populations is presented in table 1. There were no statistically significant differences between ITT and PP populations.

Aneurysm characteristics

Of the 206 patients in the ITT population, 200 had a single target aneurysm treated in the study, while six patients had two aneurysms treated using the study devices, making a total of 212 aneurysms treated in the ITT population. Of these, 86.3% were bifurcation aneurysms and 13.2% sidewall. There was one fusiform aneurysm (0.5%); 25.0% of aneurysms had been previously treated, of which 84.9% had been coiled; 17.9% of aneurysms were previously ruptured; 34.0% were located at the anterior communicating artery and 30.7% at the middle cerebral artery; and 89.6% were anterior circulation aneurysms. The aneurysm mean height was 5.3±2.4 mm and width 5.2±2.1 mm, with a mean neck of 3.7±1.5 mm; 84.9% were wide-necked aneurysms. The mean distal parent artery diameter was 2.3±0.7 mm and proximal 2.8±0.7 mm. A breakdown of target aneurysm characteristics for ITT and PP populations is provided in table 1. There were no statistically significant differences between ITT and PP populations. Further baseline patient and aneurysm data are provided in the online supplemental material.

Procedural data

LVIS Evo

All but one patient in the ITT population (99.5%) had successful implantation of LVIS Evo. In this case, a partially deployed stent was accidentally withdrawn with its delivery microcatheter, and the aneurysm was treated with coiling alone. Five ITT and four PP patients (2.4%) were treated with two LVIS Evo stents (two ITT/one PP with T-stenting, two H-stenting and one with telescoped stents). Three ITT/two PP implanted stents had balloon inflation following deployment to address incomplete opening (1.4% ITT/1.2% PP).

≥90% HES

All but one aneurysm in the ITT population was treated with at least one HES coil. In this case, the jailed coiling microcatheter position was lost, no coils were placed, and the aneurysm was

Table 1 Baseline patient data and target aneurysm characteristics

Patients	ITT n=206	PP n=164
Female gender	134 (65.0%)	107 (65.2%)
Age (mean±SD)	56.8±11.6	55.8±11.5
Functional independence (mRS 0–2)	202 (98.1%)	160 (97.6%)
Systemic hypertension	119 (57.8%)	91 (55.5%)
Smoking	96 (46.6%)	73 (44.5%)
Family history of aneurysms	20 (9.7%)	14 (8.5%)
History of hemorrhagic stroke	54 (26.2%)	44 (26.8%)
History of ischemic stroke	8 (3.9%)	6 (3.7%)
Transient ischemic attack	12 (5.8%)	8 (4.9%)
Aneurysms	**ITT n=212**	**PP n=169**
Anterior circulation	190 (89.6%)	151 (89.3%)
Posterior circulation	22 (10.4%)	18 (10.7%)
Bifurcation	183 (86.3%)	148 (87.6%)
Sidewall	28 (13.2%)	21 (12.4%)
Fusiform	1 (0.5%)	N/A
Previously treated	53 (25.0%)	44 (26.0%)
Previously ruptured (validated)	38 (17.9%)	32 (18.9%)
Aneurysm size in mm (mean±SD)		
Height	5.3±2.4	5.0±2.1
Width	5.2±2.1	5.0±2.0
Neck	3.7±1.5	3.6±1.4
Dome-to-neck ratio		
<2	174 (82.1%)	142 (84.0%)
≥2	38 (17.9%)	27 (16.0%)
Wide necked aneurysm (neck ≥4 mm or D/N ratio <2)	180 (84.9%)	143 (84.6%)
Parent artery size in mm (mean±SD)		
Distal diameter	2.3±0.7	2.3±0.7
Proximal diameter	2.8±0.7	2.8±0.7

D/N, dome-to-neck; ITT, intention-to-treat; mRS, modified Rankin Scale; PP, per protocol.

treated with LVIS Evo alone (with core lab adjudicated complete occlusion at 1 year). Of the remaining 211 aneurysms, 91.5% had at least 90% HES of the total coil length used.

Treatment procedure

A jailing technique was used to treat 53.8% of the aneurysms in the ITT population (49.7% PP), and a stent through balloon technique (coiling with balloon remodeling before stenting using a dual lumen balloon catheter) in 17.0% (17.8% PP); 85.4% of ITT patients were treated using femoral access and 13.6% radial (86.6%/12.8% PP). Mean procedure time was 106.4±40.2 min and fluoroscopy time 38.5±19.0 min. Further procedural data are provided in the online supplemental material.

Antiplatelet therapy

A total of 91.7% of the ITT population received pre-procedure antiplatelet loading (92.7% PP) and 71.4% had antiplatelet function testing (70.1% PP). Clopidogrel resistance was identified in 22.4% of these (19.1% PP), and in all but one case, the antiplatelet medication was changed as a result (in all cases in PP population); 15.0% were hyper-responders (16.5% PP), but no changes were made to their antiplatelet regimen. Overall, the most used P2Y12 inhibitor was clopidogrel; 93.2% of ITT patients were on dual antiplatelet therapy (DAPT) at discharge (94.5% PP), with most receiving aspirin and clopidogrel, while 5.8% (4.9% PP) were on single antiplatelet therapy (SAPT). Two ITT patients were on no antiplatelets at discharge, in one case because no stent was implanted, and in the other DAPT was prescribed but the patient was non-compliant (one patient in PP population). At a follow-up of mean 11.8±3.6 months for ITT patients, 58.0% were on SAPT (57.9% PP), 30.1% were on no antiplatelets (30.5% PP), and 11.9% were on DAPT (11.6% PP). Where they had been stopped, the mean duration of post-procedure P2Y12 inhibitors in ITT patients was 3.9±2.8 months for clopidogrel, 4.0±2.1 months for ticagrelor, and 5.3±2.7 months for prasugrel. Further antiplatelet therapy data are provided in the online supplemental material.

Outcome data

Effectiveness data

Follow-up imaging was at a mean of 11.6±3.7 months for ITT patients and 11.5±3.7 months for PP. Effectiveness outcomes for both the ITT and PP populations are presented in table 2. Where the core lab was unable to assess the imaging, data were treated as missing.

Primary effectiveness endpoint

A total of 82.1% (95% CI 76.4% to 87.9%) of aneurysms in the PP population met the primary effectiveness endpoint of core lab adjudicated complete occlusion (RROC class I) (ITT 80.7%, 95% CI 75.1% to 86.4%).

Secondary effectiveness endpoints

8.9% of PP aneurysms had RROC class II occlusion (ITT 10.1%), 48.8% had improved occlusion compared with final intraprocedural results, and 44.0% were unchanged. No patient in the study had been retreated.

Safety data

Clinical follow-up for safety outcome data was at a mean of 11.8±3.6 months. Safety reporting included all 206 patients in the ITT population. For six patients (three withdrew, two lost to follow-up, and one no follow-up), data are up to the latest time point available. Safety results are summarized in table 3.

Primary safety endpoint

In total, 2.4% (95% CI 0.3% to 4.5%) of patients met the primary safety endpoint of CEA adjudicated major ipsilateral stroke or neurological death.

Secondary safety endpoints

Just 1.0% (95% CI 0% to 2.3%) of patients had major ipsilateral stroke or neurological death adjudicated to be related to the study devices or treatment procedure. All-cause mortality was 3.4%. Of the seven deaths, four were neurological (one related to ipsilateral ischemic stroke at day 4 post-procedure, one contralateral ischemic stroke at 8 months, one ischemic stroke following complications of treatment of another aneurysm after the study procedure at 3.5 months, and one traumatic acute subdural hematoma at day 15). Two deaths were not neurological (one cancer related at 2 years, one abdominal infection at 6 months). One death was of unknown cause at 4 months. In total, 96.5% of patients were functionally independent at

Table 2 Effectiveness outcomes at mean 11.6±3.7 months ITT, and 11.5±3.7 months PP

Imaging assessment by core lab using DSA	ITT n=183 patients/189 aneurysms	PP n=164 patients/169 aneurysms
Complete occlusion (RROC I) (95% CI)	151/187 80.7% (75.1% to 86.4%)	138/168 82.1% (76.4% to 87.9%)
Residual neck (RROC II) (95% CI)	19/187 10.2% (5.8% to 14.5%)	15/168 8.9% (4.6% to 13.2%)
Missing data*	2	1
Imaging assessment by core lab	**ITT (all modalities) n=193 patients/199 aneurysms**	**PP (DSA) n=164 patients/169 aneurysms**
Modified Raymond-Roy score (per aneurysm)		
Class I: Obliteration	153/189 (81.0%)	138/168 (82.1%)
Class II: Residual neck	19/189 (10.1%)	15/168 (8.9%)
Class IIIa: Residual aneurysm with contrast within coil interstices	10/189 (5.3%)	9/168 (5.4%)
Class IIIb: Residual aneurysm along aneurysm wall	7/189 (3.7%)	6/168 (3.6%)
Missing data*	10	1
Change in aneurysm occlusion (per aneurysm)		
Improved	92/189 (48.7%)	82/168 (48.8%)
Same	83/189 (43.9%)	74/168 (44.0%)
Worsened	14/189 (7.4%)	12/168 (7.1%)
Missing data*	10	1
In stent stenosis (per patient)		
No stenosis	156/181 (86.2%)	140/163 (85.9%)
Stenosis <50%	20/181 (11.0%)	18/163 (11.0%)
Stenosis ≥50%	5/181 (2.8%)	5/163 (3.1%)
Missing data*	12	1

*Images not assessable by core lab.
DSA, digital subtraction angiography; ITT, intention-to-treat; PP, per protocol; RROC, Raymond-Roy occlusion classification.

12±6 months follow-up (98.1% functionally independent at baseline). Major stroke occurred in 2.4%, and minor stroke in 3.9%. Three patients (1.5%) experienced intraprocedural subarachnoid hemorrhage, two of which were asymptomatic, and the other had only transient mild clinical impact; 3.4% of patients had device-related serious adverse events, and 2% stent-related thromboembolic events.

Main results

One-year results of the SEALANT study showed 82.1% (95% CI 76.4% to 87.9%) of PP aneurysms were completely occluded, and 2.4% (95% CI 0.3% to 4.5%) of patients had experienced major ipsilateral stroke or neurological death.

Other analyses

Subgroup analysis for safety and effectiveness endpoints

Subgroup analysis for the primary safety endpoint showed a statistically significant association with baseline mRS (mRS 4: 100% vs mRS 1: 7.7%, vs mRS 0: 1.2%, P=0.011) and history of prior ischemic stroke (25.0% vs 1.5%, P=0.012). No other statistically significant differences in safety outcomes were observed across subgroups. There were no statistically significant differences in effectiveness outcomes across subgroups defined by aneurysm type, location or percentage HES implanted. Subgroup analysis data are provided in the online supplemental material.

Table 3 Safety outcomes at mean 11.8±3.6 months

	n=206	95% CI
Major ipsilateral stroke or neurological death	5 (2.4%)	0.3% to 4.5%
Major ipsilateral stroke or neurological death related to study devices or procedure	2 (1.0%)	0% to 2.3%
Ischemic stroke		
Minor	7 (3.4%)	0.9% to 5.9%
Major	4 (1.9%)	0.1% to 3.8%
Hemorrhagic stroke		
Minor	1 (0.5%)	0% to 1.4%
Major	1 (0.5%)	0% to 1.4%
Intra procedural subarachnoid hemorrhage	3 (1.5%)	0% to 3.1%
Due to aneurysm rupture	2 (1.0%)	0% to 2.3%
Due to parent or branch artery perforation	1 (0.5%)	0% to 1.4%
Thromboembolic complication		
In stent	3 (1.5%)	0% to 3.1%
Distal or proximal to stent	1 (0.5%)	0% to 1.4%
Device related SAE	7 (3.4%)	0.9% to 5.9%
Procedure related SAE	8 (3.9%)	1.2% to 6.5%

Major stroke defined as ischemic or hemorrhagic stroke that persists for >24 hours and results in a ≥4-point increase in the National Institutes of Health Stroke Scale score compared with baseline or any subsequent lower score.
SAE, serious adverse event.

DISCUSSION

Key results

SEALANT is the largest and only prospective, independently adjudicated multicenter study both of LVIS Evo and its use with HES coils, for treating cerebral aneurysms. Device engineering characteristics and existing evidence suggest that this combination should be highly effective, without compromising safety and technical feasibility.[6 14] The 1-year results of the study confirm the safety and effectiveness of SAC using LVIS Evo and HES coils.

Limitations

Despite the strengths of the study protocol, including measures to reduce bias, there are limitations inherent in its open-label, single arm design. The study does not include a control group, and investigators are not blinded to treatment allocation. So, relative to an RCT, a single arm study cannot directly quantify treatment effect size, and interpretation of results requires knowledge outside the study—for example, from external comparators.[19] The protocol stipulated consecutive enrollment, but some risk of selection bias remains as inclusion was subject to investigator interpretation of cases suitable for treatment with study devices. The observational design of the study did not predefine benchmarks for safety and effectiveness.[20]

Interpretation

Feasibility

Results of the SEALANT study show high levels of technical feasibility. LVIS Evo was successfully placed in 99.5% of the ITT

population, consistent with meta-analysis of self-reported LVIS Evo SAC studies[6] (99.3%, 95% CI 98.5% to 100% technical success). In the SEALANT ITT population, the mean percentage HES coil by length implanted was 97.6% (SD 7.5%), compared with the GREAT RCT of aneurysm treatment using ≥50% HES coil by length versus BPC, where the mean percentage HES coil by length implanted was 83.2% (SD 21.4%).[13]

Effectiveness

One-year effectiveness results are good (82.1%, 95% CI 76.4% to 87.9% complete occlusion), and can be compared with outcomes reported in similar studies of SAC, the pivotal US first generation LVIS trial[16] (79.1% complete occlusion) and Atlas IDE trial[17] (88.2%, 95% CI 82.0% to 92.9% complete occlusion), as well as meta-analysis of self-reported LVIS Evo SAC studies[6] (86.8%, 95% CI 80.4% to 93.2% complete occlusion). Effectiveness is in line with meta-analysis of published studies of intracranial aneurysm treatment for concluding positive results (median 78.8%, IQR 68.4–88.0% complete occlusion at final follow-up), recognizing that this paper identified methodological flaws in the analyzed literature.[20] The STAT RCT (Stenting in the Treatment of Aneurysm Trial)[21] showed lower rates of core lab adjudicated 1-year complete occlusion with SAC at 44.7%, which may at least in part reflect differences in study design and inclusion criteria.

Safety

One-year primary safety outcome results are also good, with a 2.4% (95% CI 0.3% to 4.5%) rate of major ipsilateral stroke or neurological death, which can be compared with the pivotal US first generation LVIS trial[16] (5.2% major stroke or death within 30 days or major ipsilateral stroke or neurological death within 12 months) and Atlas IDE trial[17] (4.4%, 95% CI 1.9% to 8.5% major ipsilateral stroke and neurological death at 1 year), as well as meta-analysis of self-reported LVIS Evo SAC studies[6] (3.0% morbidity plus mortality). Safety is also comparable with meta-analysis of published studies of intracranial aneurysm treatment for concluding positive results (median 3.8%, IQR 0–21.0% major complications), again accepting the paper identified methodological flaws in the analyzed literature.[20] The STAT RCT[21] showed higher rates of major complications from SAC, with as-treated 1-year mortality and morbidity (mRS >2) at 9.6%, although this outcome measure included all-cause mortality or dependency, and study design differed. SEALANT demonstrates a significant association of the primary safety endpoint with baseline disability and a history of prior ischemic stroke, which adds to the published literature linking baseline frailty and cerebral ischemic comorbidity with postoperative complications after elective UIA treatment.[22–25]

How do results compare with intrasaccular treatment benchmarks?

While external comparison with studies of coiling and WEB (Woven EndoBridge) must be treated with caution scientifically, it provides an interesting context for SEALANT results. The coiling RCT HEAT[14] estimated complete occlusion at 3 to 12 months of 64.9% for HES and 49.0% for BPC, and found all-cause mortality and morbidity (mRS >2) of 7.6% for HES and 7.9% for BPC. But HEAT had a significantly different design and included both ruptured and unruptured intracranial aneurysms. For WEB, 1-year results of the WEB-IT pivotal study[26] showed 53.8% complete occlusion, and 0.7% primary safety events (any non-accidental death or major stroke within 30 days, or major ipsilateral stroke or neurological death within 12 months). One-year results of the CLEVER study of WEB-17, including both ruptured and unruptured intracranial aneurysms, reported 73.1% complete occlusion and 1.8% primary safety events (any non-accidental death or major stroke within 30 days, or major ipsilateral stroke or neurological death within 12 months).[27 28] With caveats, this signals that SAC with LVIS Evo and HES may achieve higher rates of complete occlusion than coiling or WEB, with a question about comparative safety, as the 95% CI for the primary safety endpoint in SEALANT overlaps the lower results for WEB in WEB-IT and CLEVER.

Implications for future research

There is a wide and seemingly ever-expanding range of endovascular UIA treatment options. Many physicians crave RCT data to inform their daily decision-making in clinics and angio-labs. A previous attempt at an RCT of UIA treatment (the TEAM trial), which failed due to poor recruitment, provides evidence of the practical challenges and potential solutions for RCTs in this area.[29] SEALANT adds to the scientific base for designing a successful RCT comparing SAC with other endovascular treatment approaches. Following patients in SEALANT out to 3 years will be valuable, as longer-term treatment outcomes matter to patients, and similar studies typically close when only short-term results are known. Iterative device innovation, improvements in technique, and research to define optimal antiplatelet therapy regimens have the potential to further enhance the safety and effectiveness of SAC beyond where we stand today.

Generalizability

The open inclusion criteria and pragmatic non-interventional study design, reflecting real-world practice, strengthen the external validity of SEALANT study results. The diversity of participating sites, with 17 centers in five countries, and treatment heterogeneity—for example, in antiplatelet therapy regimens—are also positive attributes for generalizability.

Author affiliations
[1]Royal Infirmary of Edinburgh, Edinburgh, UK
[2]Hospices Civils de Lyon, Lyon, France
[3]University Hospital Augsburg, Augsburg, Germany
[4]G Martino University Hospital of Messina, Messina, Italy
[5]University Hospital Münster, Münster, Germany
[6]Interventional Radiology Department, University Hospital of Charleroi - Marie Curie Hospital, Charleroi, Belgium
[7]Centre Hospitalier Universitaire de Limoges, Limoges, France
[8]Centre Hospitalier Universitaire de Rouen, Rouen, France
[9]The Walton Centre NHS Foundation Trust, Liverpool, UK
[10]Centre Hospitalier Universitaire de Brest, Brest, France
[11]Hôpital de la Timone, Marseille, France
[12]Hôpital Fondation Rothschild, Paris, France
[13]King's College Hospital NHS Foundation Trust, London, UK
[14]University Hospital Knappschaftskrankenhaus Bochum, Bochum, Germany
[15]Barts Health NHS Trust, London, UK
[16]University Hospital 'San Giovanni di Dio e Ruggi d'Aragona', Salerno, Italy
[17]Hopital Prive Clairval, Marseille, France
[18]Niguarda Hospital, Milan, Italy
[19]Alfried Krupp Krankenhaus Rüttenscheid, Essen, Germany

Contributors All authors have read and approved the manuscript. The corresponding author is the guarantor.

Funding The SEALANT study (Safety and Effectiveness Analysis of stent assisted coiling with LVIS® Evo™ and HydroCoil® Embolic System in ANeurysm Treatment) was funded by Terumo Neuro.

Competing interests JD reports fees from Terumo Neuro related to the conduct of the study; institutional grants or contracts from Medtronic Neurovascular, Terumo Neuro, Oxford Heartbeat, Stryker Neurovascular and Phenox; honoraria from Terumo Neuro and Medtronic Neurovascular; travel support from Europa Group; and advisory committee activities for Terumo Neuro. OE reports grants or contracts from Phenox

Wallaby; consulting fees, honoraria or travel support from Terumo Neuro, Penumbra, Balt, Stryker and Phenox Wallaby; a patent (BE1024922B1); and participation in the WAVE Study (Terumo Neuro). AP reports institutional support, grants, consulting fees, honoraria, expert testimony fees and travel support from MicroVention, Penumbra, Stryker and Medtronic. PS reports consulting fees from Acandis and Balt, and honoraria from Vesalio, Balt and Acandis. CM reports consulting fees from Balt, Medtronic and Terumo Neuro. CP reports consulting fees and honoraria from MicroVention and Stryker and holds stock/options in BCV MedCo. JCG reports consultancy activities for Terumo Neuro; consulting fees from Phenox, Balt, Stryker and Medtronic; a leadership role and stock/options in Intradys. MPiotin reports travel support from Balt International and holds stock/options in BCV, Synchron, Intradys, GeoAlsics, Radical Catheter Technologies, Vastrax andSerenity. NK reports conference and travel support from Europa. LM reports consulting fees from Terumo, Johnson & Johnson, Penumbra, MicroVention, Stryker, Perfuze and Sela Medical; honoraria from Terumo, Johnson & Johnson, Penumbra, Balt and Stryker; and travel support from Terumo, Johnson & Johnson, Penumbra and Stryker. FT reports consultancy and advisory activities related to adverse event classification. RC reports consulting fees from Asahi; honoraria from Siemens, Balt, Medtronic and MicroVention; patent-related interests with Siemens; and stock/options in Bendit. RR, AB, IT, AC, HB, SF, DR, MPiano and EB report no competing interests.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the following national ethics committees. Germany: Approval was granted by the principal Ethics Committee of the North Rhine Medical Association on 11 October 2021, and by local ethics committees where applicable. UK: Approval was obtained from the West of Scotland REC 5 Ethics Committee on 19 November 2021. Italy: Approvals were received from the Inter-Agency Ethics Committee of Messina on 18 January 2022, the Catania Ethics Committee 1 on 16 May 2022, and the Inter-Agency Ethics Committee of Campania Sud on 20 Apri 2022. Belgium: Approval was granted by the central Ethics Committee of ERASME (Brussels) on 29 April 2022, and by the local Ethics Committee ISPPC on 23 March 2022. France: The study was submitted and published on the Health Data Hub, as required for RNIPH studies. Data processing was conducted in accordance with the Reference Methodology MR-004. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. De-identified data may be shared upon reasonable request and subject to GDPR and applicable privacy laws, study site agreements, and participant informed consent forms.

ORCID iDs
Jonathan Downer https://orcid.org/0000-0002-8272-092X
Roberto Riva https://orcid.org/0000-0002-1520-2057
Chrysanthi Papagiannaki https://orcid.org/0000-0002-9473-9644
Levansri Makalanda https://orcid.org/0000-0001-6637-9293
René Chapot https://orcid.org/0000-0002-9245-0636

REFERENCES

1 Tjoumakaris SI, Hanel R, Mocco J, *et al*. ARISE I Consensus Review on the Management of Intracranial Aneurysms. *Stroke* 2024;55:1428–37.
2 Tateshima S, Tanishita K, Hakata Y, *et al*. Alteration of intraaneurysmal hemodynamics by placement of a self-expandable stent. Laboratory investigation. *J Neurosurg* 2009;111:22–7.
3 Wanke I, Forsting M. Stents for intracranial wide-necked aneurysms: more than mechanical protection. *Neuroradiology* 2008;50:991–8.
4 Wang C, Tian Z, Liu J, *et al*. Flow diverter effect of LVIS stent on cerebral aneurysm hemodynamics: a comparison with Enterprise stents and the Pipeline device. *J Transl Med* 2016;14:199.
5 Çay F, Arat A. Appraisal of the Flow Diversion Effect Provided by Braided Intracranial Stents. *J Clin Med* 2024;13:3409.
6 Cortez GM, Gutierrez-Aguirre SF, de Toledo OF, *et al*. Technical Success and Clinical Outcomes of the Low-Profile Visualized Intraluminal Support EVO (LVIS EVO) Stent in the Treatment of Intracranial Aneurysms: A Systematic Review and Meta-Analysis. *Neurosurgery* 2026;98:23–32.
7 Vollherbst DF, Berlis A, Maurer C, *et al*. Periprocedural Safety and Feasibility of the New LVIS EVO Device for Stent-Assisted Coiling of Intracranial Aneurysms: An Observational Multicenter Study. *AJNR Am J Neuroradiol* 2021;42:319–26.
8 Kayan Y, Delgado Almandoz JE, Copelan A, *et al*. Multicenter early United States feasibility study and periprocedural safety of LVIS EVO for the treatment of unruptured intracranial aneurysms. *J Neurointerv Surg* 2025;17:405–9.
9 Mosimann PJ, Yamac E, Wallocha M, *et al*. LVIS EVO stent-through-balloon after hydrocoil embolization of intracranial aneurysms: one-year results. *Interv Neuroradiol* 2024;30:649–56.
10 Aydin K, Puthuran M, Onal Y, *et al*. The Angiographic and Clinical Follow-up Outcomes of the Wide-Necked and Complex Intracranial Aneurysms Treated With LVIS EVO-Assisted Coiling. *Neurosurgery* 2023;92:827–36.
11 Maurer CJ, Berlis A, Maus V, *et al*. Treatment of broad-based intracranial aneurysms with the LVIS EVO stent: a retrospective observational study at two centers with short- and medium-term follow-up. *Sci Rep* 2023;13:7232.
12 White PM, Lewis SC, Gholkar A, *et al*. Hydrogel-coated coils versus bare platinum coils for the endovascular treatment of intracranial aneurysms (HELPS): a randomised controlled trial. *Lancet* 2011;377:1655–62.
13 Taschner CA, Chapot R, Costalat V, *et al*. GREAT-a randomized controlled trial comparing HydroSoft/HydroFrame and bare platinum coils for endovascular aneurysm treatment: procedural safety and core-lab-assessed angiographic results. *Neuroradiology* 2016;58:777–86.
14 Bendok BR, Abi-Aad KR, Ward JD, *et al*. The Hydrogel Endovascular Aneurysm Treatment Trial (HEAT): A Randomized Controlled Trial of the Second-Generation Hydrogel Coil. *Neurosurgery* 2020;86:615–24.
15 Vandenbroucke JP, von Elm E, Altman DG, *et al*. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. *Int J Surg* 2014;12:1500–24.
16 Fiorella D, Boulos A, Turk AS, *et al*. The safety and effectiveness of the LVIS stent system for the treatment of wide-necked cerebral aneurysms: final results of the pivotal US LVIS trial. *J Neurointerv Surg* 2019;11:357–61.
17 Jankowitz BT, Hanel R, Jadhav AP, *et al*. Neuroform Atlas Stent System for the treatment of intracranial aneurysm: primary results of the Atlas Humanitarian Device Exemption cohort. *J Neurointerv Surg* 2019;11:801–6.
18 Hendricks BK, Yoon JS, Yaeger K, *et al*. Wide-neck aneurysms: systematic review of the neurosurgical literature with a focus on definition and clinical implications. *J Neurosurg* 2020;133:159–65.
19 European Medicines Agency. Reflection paper on establishing efficacy based on single- arm trials submitted as pivotal evidence in a marketing authorisation application EMA/CHMP/458061/2024. 2024.
20 Volovici V, Verploegh IS, Satoer D, *et al*. Outcomes Associated With Intracranial Aneurysm Treatments Reported as Safe, Effective, or Durable: A Systematic Review and Meta-Analysis. *JAMA Netw Open* 2023;6:e2331798.
21 Boisseau W, Darsaut TE, Fahed R, *et al*. Stent-Assisted Coiling in the Treatment of Unruptured Intracranial Aneurysms: A Randomized Clinical Trial. *AJNR Am J Neuroradiol* 2023;44:381–9.
22 Rangwala SD, Han JS, Lamorie-Foote K, *et al*. Frailty is a Predictor of Increased Readmissions and Increased Postoperative Complications After Elective Treatment of Unruptured Aneurysms. *World Neurosurg* 2024;181:e882–96.
23 Kandregula S, Savardekar AR, Terrell D, *et al*. Microsurgical clipping and endovascular management of unruptured anterior circulation aneurysms: how age, frailty, and comorbidity indexes influence outcomes. *J Neurosurg* 2023;138:922–32.
24 Ji W, Liu A, Lv X, *et al*. Risk Score for Neurological Complications After Endovascular Treatment of Unruptured Intracranial Aneurysms. *Stroke* 2016;47:971–8.
25 Ji W, Xu L, Wang P, *et al*. Risk Factors to Predict Neurologic Complications After Endovascular Treatment of Unruptured Paraclinoid Aneurysms. *World Neurosurg* 2017;104:89–94.
26 Arthur AS, Molyneux A, Coon AL, *et al*. The safety and effectiveness of the Woven EndoBridge (WEB) system for the treatment of wide-necked bifurcation aneurysms: final 12-month results of the pivotal WEB Intrasaccular Therapy (WEB-IT) Study. *J Neurointerv Surg* 2019;11:924–30.
27 Spelle L, Costalat V, Caroff J, *et al*. CLinical EValuation of WEB 17 device in intracranial aneuRysms (CLEVER): procedural, 30-day and 1-year safety results for ruptured and unruptured aneurysms. *J Neurointerv Surg* 2024;16:1299–306.
28 Spelle L, Costalat V, Caroff J, *et al*. CLinical EValuation of WEB 17 device in intracranial aneuRysms (CLEVER): 1-year effectiveness results for ruptured and unruptured aneurysms. *J Neurointerv Surg* 2025;17:878–82.
29 Raymond J, Darsaut TE, Molyneux AJ, *et al*. A trial on unruptured intracranial aneurysms (the TEAM trial): results, lessons from a failure and the necessity for clinical care trials. *Trials* 2011;12:64.