Safety and efficacy of aneurysm treatment with WEB in the cumulative population of three prospective, multicenter series


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ORIGINAL RESEARCH

Safety and efficacy of aneurysm treatment with WEB in the cumulative population of three prospective, multicenter series

Laurent Pierot, Jacques Moret, Xavier Barreau, Istvan Szikora, Denis Herbreteau, Francis Turjman, Markus Holtmannspötter, Anne-Christine Janel, Vincent Costalat, Jens Fiehler, Joachim Klisch, Jean-Yves Gauvrit, Werner Weber, Hubert Desal, Stéphane Velasco, Thomas Liebig, Luc Stockx, Joachim Berkefeld, Andrew Molyneux, James Byrne, Laurent Spelle

ABSTRACT
Background Flow disruption with the WEB is an innovative endovascular approach for treatment of wide-neck bifurcation aneurysms. Initial studies have shown a low complication rate with good efficacy.

Purpose To report clinical and anatomical results of the WEB treatment in the cumulative population of three Good Clinical Practice (GCP) studies: WEBCAST (WEB Clinical Assessment of Intrasaccular Aneurysm), French Observatory, and WEBCAST-2.

Methods WEBCAST, French Observatory, and WEBCAST-2 are single-arm, prospective, multicenter, GCP studies dedicated to the evaluation of WEB treatment. Clinical data were independently evaluated. Postoperative and 1-year aneurysm occlusion was independently evaluated using the 3-grade scale: complete occlusion, neck remnant, and aneurysm remnant.

Results The cumulative population comprised 168 patients with 169 aneurysms, including 112 female subjects (66.7%). The patients’ ages ranged between 27 and 77 years (mean 55.5±10.2 years). Aneurysm locations were middle cerebral artery in 86/169 aneurysms (50.9%), anterior communicating artery in 36/169 (21.3%), basilar artery in 30/169 (17.8%), and internal carotid artery terminus in 17/169 (10.1%). The aneurysm was ruptured in 14/169 (8.3%). There was no mortality at 1 month and procedure/device-related morbidity was 1.2% (2/168). At 1 year, complete aneurysm occlusion was observed in 81/153 aneurysms (52.9%), neck remnant in 40/153 aneurysms (26.1%), and aneurysm remnant in 32/153 aneurysms (20.9%). Re-treatment was carried out in 6.9%.

Conclusions This series is at the moment the largest prospective, multicenter, GCP series of patients with aneurysms treated with WEB. It shows the high safety and good mid-term efficacy of this treatment.

Clinical trial registration French Observatory: Unique identifier (NCT18069); WEBCAST and WEBCAST-2; Unique identifier (NCT01778322).

INTRODUCTION
As wide-neck aneurysms are sometimes untreatable or difficult to treat with standard coiling, alternative techniques have been developed, including flow disruption.1–4 Flow disruption involves the placement of an intrasaccular cage that will disrupt the blood flow at the level of the neck and induce aneurysmal thrombosis. Two devices are currently available (Artisse: Medtronic, Minneapolis, Minnesota, USA, and WEB: Sequent Medical, Aliso Viejo, California, USA). Clinical evaluation data for the Artisse device are limited, but the WEB device has been evaluated in several retrospective and prospective series.5–10 Moreover Good Clinical Practice studies, including two European (WEBCAST (WEB Clinical Assessment of Intrasaccular Aneurysm), WEBCAST-2), 1 US (WEB-IT), and 1 French (French Observatory), have been conducted since the introduction of this new device in Europe in 2010.11–13

This paper reports the clinical and anatomical results, including mid-term (1-year) follow-up, of WEB aneurysm treatment in the accumulated population of the WEBCAST, French Observatory, and WEBCAST-2 series, which, to date, is the largest prospective and multicenter group of patients treated with WEB.

MATERIALS AND METHODS
The WEBCAST, WEBCAST-2, and French Observatory, are single-arm, prospective, consecutive, multicenter studies dedicated to the evaluation of WEB treatment for bifurcation aneurysms, conducted in Europe and France, respectively.

The three studies received national regulatory authorization, including in France CCTIRS (Consultative Committee of Information Processing in Healthcare Research programme) approval, Reims Institutional Review Board approval, and CNIL (National Commission for Data Processing and Freedom) approval. For WEBCAST and WEBCAST-2 centers outside France, national or institutional approval was obtained according to each country’s regulations. Written informed consent was obtained from all patients.

WEB devices
The WEB is a self-expanding, retrievable, electrothermally detachable, nitinol braided device, which
Trial design and procedural modalities

Trial design and procedural modalities have been described in previous publications. Inclusion and exclusion criteria are presented in (Table 1). Inclusion criteria for the three studies were ruptured (Hunt and Hess grade I, II, or III) and unreptured aneurysms located in the basilar artery (BA), middle cerebral artery (MCA), or anterior cerebral artery (ACAt). Anterior communicating artery (AcomA/ACAt) bifurcation, internal carotid artery terminus (ICAt), or the microcatheter outside the limit of the aneurysm sac and/ or extravasion of contrast media. Morbidity was defined as mRS score >2 when preoperative mRS was ≤2 (or in the case of a ruptured aneurysm) and as an increase of 1 point when the preoperative mRS score was >2.

In the three studies, an expert interventional neuroradiologist (IB) independently evaluated aneurysm location on the initial angiogram, and aneurysm occlusion at the last angiographic follow-up, using the previously validated three-grade scale: complete occlusion, neck remnant, and aneurysm remnant. According to a previous publication, opacification of the proximal recess of the WEB device was considered as complete occlusion. Evolution of aneurysm occlusion between postoperative DSA and mid-term follow-up was also evaluated by the core laboratory using a three-grade scale: improved, stable, worse.

Statistical analysis

Continuous variables were described as mean±SD. Categorical data were described numerically as a categorical total and as a percentage of the analyzed population. Binomial data were described as a ratio of the true value and the analyzed population

Table 1 Inclusion and exclusion criteria for French Observatory, WEBCAST, and WEBCAST-2.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>French Observatory</th>
<th>WEBCAST/WEBCAST2</th>
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<tbody>
<tr>
<td>Inclusion</td>
<td>Similar criteria</td>
<td></td>
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<tr>
<td>► Age ≥18 years</td>
<td></td>
<td></td>
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<tr>
<td>► Ruptured/unruptured aneurysms</td>
<td></td>
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<tr>
<td>► Location: BA, MCA, ICAt, AcomA/ACAt</td>
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<tr>
<td>► Diameter suitable for WEB use</td>
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<tr>
<td>► DN ratio ≥1</td>
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<tr>
<td>► Ruptured aneurysm: H&amp;H &gt;III</td>
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<tr>
<td>Inclusion</td>
<td>Distinctive criteria</td>
<td></td>
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<tr>
<td>► Recanalized aneurysms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>► Neck size &gt;4 mm</td>
<td></td>
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<tr>
<td>► No additional implant</td>
<td></td>
<td></td>
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<tr>
<td>Exclusion</td>
<td>Similar criteria</td>
<td></td>
</tr>
<tr>
<td>► Age &gt;75 years</td>
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<tr>
<td>► More than one aneurysm to be treated within 30 days</td>
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<td></td>
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<tr>
<td>► Microcatheter could not reach target aneurysm</td>
<td></td>
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<tr>
<td>► Tumor or AVM</td>
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<tr>
<td>Exclusion</td>
<td>Distinctive criteria</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
<td></td>
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<tr>
<td>► Unruptured aneurysm: SAH/ICH within 3 months prior treatment</td>
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ACA, anterior cerebral artery; AcomA, anterior communicating artery; AVA, arteriovenous malformation; BA, basilar artery; DN, Dome-to-Neck; ICAt, intracranial hemorrhage; H&H, Hunt and Hess grade; ICAt, internal carotid artery terminus; MCA, middle cerebral artery; SAH, subarachnoid hemorrhage.
RESULTS

Patient and aneurysm population

The cumulative population comprised 168 patients (WEBCAST: 51; French Observatory: 62; WEBCAST2: 55), including 112 female subjects (66.7%). The patients' ages ranged between 27 and 77 years (mean 55.5±10.2 years). All but one patient had one aneurysm, leading to a total number of aneurysms of 169. Aneurysm status was ruptured in 14/169 (8.3%), unruptured in 150/169 (88.8%), and recanalized in 5/169 (3.0%). In the five recanalized aneurysms, the initial aneurysm treatment was coiling. Aneurysm locations according to core laboratory analysis were MCA in 86/169 aneurysms (50.9%), AcomA in 36/169 (21.3%), BA in 30/169 (17.8%), and internal carotid artery terminus in 17/169 (10.1%).

Aneurysm size was between 2.4 and 17.0 mm (mean 7.6±2.5 mm).

Aneurysm neck size was between 2.4 and 13.8 mm (mean 5.2±1.6 mm). The neck was wide (≥4 mm) in 144/169 aneurysms (85.2%).

Antiplatelet treatment before and during the procedure is reported in (table 2). Antiplatelet activity testing was not performed in all participating centers and was not analyzed.

Treatment feasibility, adjunctive treatments, and adverse events

Treatment was successfully performed in 163/169 aneurysms (96.4%). Causes of failure were protrusion and subsequent retrieval of the device in two aneurysms, lack of appropriate device sizing in three aneurysms, and inability to deploy the WEB in one aneurysm.

Among aneurysms treated with WEB devices, adjunctive devices were used in 12/163 aneurysms treated with WEB (7.4%); coils alone in seven aneurysms (4.3%) and stents or flow diverters in five aneurysms (3.1%). A WEB DL was implanted in 78/163 aneurysms (47.9%) and WEB SL/SLS in 85/163 aneurysms (52.1%).

Adverse events are reported in (table 3). Intraoperative rupture (2/167 patient, 1.2%) and intracranial hemorrhage (related to antiplatelet treatment, 1/167 patients, 0.6%) were asymptomatic.

Mortality/morbidity at 1 month

Mortality and morbidity at 1 month are shown in (figure 1). Intraoperative rupture (2/167 patient, 1.2%) and intracranial hemorrhage (related to antiplatelet treatment, 1/167 patients, 0.6%) were asymptomatic.

There was no mortality at 1 month. Global morbidity was observed in 5/167 patients (3.0%): related to a thromboembolic event in two patients (mRS score 3) with device protrusion in one patient, to initial aneurysm rupture in two patients (mRS scores 3 and 4), and to worsening of pre-existing aneurysm mass effect in one patient (mRS score 3). Morbidity was related to the device in one patient (0.6%), to the procedure in one patient (0.6%), and to the disease in three patients (1.8%).

Mortality/morbidity at 1 year

At the 12-month follow-up (mean±SD 12.1±1.7 months), 153 of the 168 patients (91.1%) enrolled in the study were clinically evaluated with mRS scoring (figure 1).

Five out of 153 patients (3.3%) died between the 1-month and 1-year follow-up: three unrelated to aneurysm disease or treatment (cancer: two and cirrhosis: one), one from worsening of pre-existing mass effect described previously (this patient had a mRS score of 3 at 1 month), and one as a consequence and...
complication of a retroperitoneal hematoma during the index procedure. At 1 year all-cause, neuro-related, and procedure-related morbidity are respectively, 5/153 (3.3%), 1/153 (0.7%), and 1/153 (0.7%).

Among the five patients who had a mRS score of >2 at 1 month related to the procedure, 1 died between 1 month and 1 year (progressive brainstem compression), three had improved at 1 year (one patient was mRS score 1 and two patients were mRS score 2), and one was unchanged (mRS score 3 due to a thromboembolic event). Another patient had a mRS score 3 due to a thromboembolic event that occurred during re-treatment with a flow diverter (see below). At 1 year all-cause, neuro-related, and procedure-related morbidity are respectively, 2/153 (1.3%), 0/153 (0.0%), and 2/153 (1.3%).

**Anatomical results at mid-term follow-up**

Anatomical results at 1 year (mean±SD 12.1±1.7 months) were evaluated in 152/168 patients (90.5%) with 153/169 aneurysms (90.5%) (figure 1).

For patients re-treated before or at the 1-year follow-up, aneurysm occlusion was evaluated by DSA performed at the beginning of the re-treatment. The vascular imaging technique was DSA in 134/153 (87.6%) aneurysms, CT angiography in 4/153 aneurysms (2.6%), and MR angiography in 15/153 aneurysms (9.8%).

Aneurysm occlusion at mid-term and evolution of occlusion from immediate postoperative DSA to mid-term follow-up imaging is presented in (table 4) for the global population and patients treated with DL and SLS/SL/SLS. At mid-term, complete occlusion (figure 2) was seen in 81/153 aneurysms (52.9%), neck remnant (figure 3) in 40/153 aneurysms (26.1%), and aneurysm remnant (figure 4) in 32/153 aneurysms (20.9%). Adequate occlusion (complete occlusion or neck remnant) was observed in 121/153 aneurysms (79.1%).

Importantly no neck or aneurysm remnant was associated with bleeding/rebleeding during the follow-up period.

**Re-treatment**

The re-treatment rate was evaluated in 160 aneurysms. Excluded from this analysis were the six aneurysms that were not treated with WEB, the aneurysms of the two patients who withdrew their consent, and one aneurysm in a patient lost to follow-up. Eleven aneurysms were re-treated (6.9%): with stent and coils in four aneurysms, flow diverters in four, stent in one patient, WEB and stent in one patient and WEB in one patient. One patient re-treated with a flow diverter 14 months after the initial procedure had a delayed parent artery occlusion with clinical worsening (mRS score 3). Re-treatment of one patient was attempted with a flow diverter, but it was not possible to place the diverter correctly for anatomical reasons (coverage of perforators).

**DISCUSSION**

The cumulative population of the three European and French GCP studies is the largest prospective and multicenter cohort of patients with aneurysms treated with WEB with a completely independent evaluation of clinical and anatomical results.

**Feasibility and safety of WEB aneurysm treatment**

The treatment with WEB was highly feasible (96.4%) knowing that three of six failures were related to the lack of appropriate size availability. Adjunctive devices were used in a relatively limited percentage of cases (7.4%). In 4.3%, coils were used in addition to the WEB device on a planned or unplanned basis. For some aneurysms, their shape or size made it clear that treatment with the WEB alone was potentially difficult and adjunctive use of coils was foreseen at the beginning of the procedure. In other cases, the adjunctive placement of coils was decided after WEB detachment if the device was not properly deployed against the aneurysm wall or was not occluding the neck. This situation was mostly encountered at the beginning of the WEB experience, when the device was not routinely oversized. Stents and flow diverters were added in 3.1% of aneurysms in cases of WEB protrusion or when the neck was so wide that it was not possible to manage it without an intravascular device.

Thromboembolic events, including the asymptomatic appearance of thrombus during the procedure, were seen in 14.4% of patients, but permanent deficit was found in only 3.0% of patients. This rate of thromboembolic events is slightly higher than that reported in a large coiling series (7.1% in ATENA/unruptured aneurysms and 13.3% in CLARI/ruptured aneurysms). Importantly, those series included all kinds of aneurysms, whereas the present series is dealing with wide-neck bifurcation aneurysms, associated with a higher risk of thromboembolic events.

Intraoperative rupture was reported in two patients (1.2%). This rate is lower than that reported in ATENA (2.0%) and CLARI (3.7%). Moreover, both ruptures were asymptomatic. Finally, one delayed (48 hours) intracranial bleeding was observed (0.6%) with no clinical worsening.

Global morbidity and mortality at 1 month were, respectively, 3.0% and 0.0%. Treatment-related morbidity and mortality were, respectively, 1.2% and 0.0% and are comparable or better than the rates reported in coiling series like ATENA (morbidity: 1.7%; mortality: 1.4%) or CLARI (morbidity: 3.7%; mortality: 1.5%). These percentages confirm the high degree of safety of the treatment, considering that the WEB treatment was used in difficult aneurysms and the studied population was partially included at the beginning of the clinical experience with WEB (learning curve).

A comparison of morbidity/mortality with that in surgical series is more difficult. In the largest meta-analysis dealing with unruptured aneurysms treated by clipping, the rate of death after surgery (1.7%) was higher than in the present series (0.0%) and the rate of unfavorable outcomes at 1 year was 6.7% compared with 4.6% in the present series (with procedure-related morbidity and mortality: 1.7%; mortality: 1.4%) or CLARI (morbidity: 3.7%; mortality: 1.5%). These percentages confirm the high degree of safety of the treatment, considering that the WEB treatment was used in difficult aneurysms and the studied population was partially included at the beginning of the clinical experience with WEB (learning curve).
Figure 2  Unruptured left middle cerebral artery aneurysm. (A) DSA, working view and (B) 3D-DSA show the aneurysm (transverse diameter: 6.3 mm; height: 5.3 mm; neck: 5.4 mm). (C) and (D) DSA at the end of the procedure (unsubtracted and subtracted view, respectively) show the detached WEB device (WEB SL 7×3 mm) and residual flow in the aneurysm and the device. (E) and (F) DSA at 6 months (unsubtracted and subtracted views, respectively) show the WEB device and complete aneurysm occlusion. (G) and (H) DSA at 12 months (unsubtracted and subtracted views, respectively) shows the WEB device and stable complete aneurysm occlusion.

Figure 3  Unruptured left middle cerebral artery aneurysm. (A) 3D DSA shows the aneurysm (transverse diameter: 3.8 mm; height: 4.2 mm; neck: 2.4 mm). (B) One-year DSA (unsubtracted view) shows the WEB device. (C) One-year 3D-DSA shows a neck remnant.
Hemorrhagic stroke unfavorable outcomes of 2.0%). Similarly, in the International Study of Unruptured Intracranial Aneurysms (ISUIA), in a very large prospective group of patients treated by surgery, the rate of surgery-related death was 1.8% and morbidity (mRS score 3–5) 3.0%. At 1 year, surgery-related death was 2.7% and morbidity 1.4%. In one single-center series, dealing with ruptured and unruptured MCA aneurysms (the most common indication for WEB in the studied population), surgical mortality was 5.3% and at late follow-up permanent neurological morbidity was 4.6%. In patients with unruptured MCA aneurysms, poor outcomes were seen in 6.1%.

Efficacy of WEB aneurysm treatment Complete aneurysm occlusion was observed in 52.9% of aneurysms with adequate occlusion (complete occlusion or neck remnant) in 79.1% of aneurysms. These results are very similar to results reported in a retrospective European series, with complete and adequate occlusion, respectively, of 69.0% and 89.7%, at mid-term follow-up (median: 13 months), and respectively, of 68.4% and 84.2%, at long-term follow-up (median: 27 months). Anatomical results observed in this cumulative population are difficult to compare with previous series dealing with other endovascular approaches, as WEB treatment is used in a relatively specific group of aneurysms (wide-neck bifurcation aneurysms that are prone to recurrence). In the Matrix and Platinum Science (MAPS) Trial, a subgroup analysis was conducted showing that in unruptured wide-neck aneurysms (not necessarily bifurcation), the rate of complete and adequate occlusion (at 12 months) was, respectively, 27.1% and 57.6% with coils. With stenting and coiling, higher rates of complete and adequate occlusion (respectively, 45.7% and 62.8%) were obtained, although accompanied by a higher rate of complications. Finally, it is very difficult to compare WEB treatment and clipping efficacy as surgical series reporting 1-year or long-term anatomical results evaluated with DSA by an independent core laboratory are lacking.

Re-treatment was performed in a limited percentage of aneurysms treated with the WEB (6.3%). It is difficult to compare re-treatment rates from one study to another, as indications for re-treatment are not well established and vary considerably from one center to another. However, the very low re-treatment rate observed with WEB is comparable to the lowest rate of re-treatment reported in the largest coiling series: HELPS trial, 3.0% with both bare and hydrogel coils; CLARITY study, 3.3% for aneurysms treated with bare coils, but 9.5% in the matrix group; Cerecyte Coil Trial, 3.5% in the bare coils group and 7.7% in the Cerecyte coils group; MAPS wide-neck aneurysm subset, 13.7% for coils alone and 14.1% for stent and coils. Place of the WEB device in the EVT armamentarium In the three GCP series, the WEB device was used in typical indications: wide-neck bifurcation aneurysms. Recent publications suggest that indications for WEB aneurysm treatment may increase in the future. In a recent, single-center series, WEB treatment was used in 49% of aneurysms treated with EVT. In another multicenter series, WEB was used in ‘atypical’ locations.

Limitations This study has two main limitations. First, it is not a randomized study, and comparison with other techniques is difficult. However, it is to date the largest GCP series of patients with aneurysms treated with WEB and demonstrates the good safety and efficacy (at mid-term follow-up) of this treatment. Second, long-term follow-up is needed to precisely evaluate the place

Figure 4  Unruptured anterior communicating artery aneurysm. (A) DSA, working view and (B) 3D-DSA show the aneurysm (transverse diameter: 6.2 mm; height: 4.3 mm; neck: 4.6 mm). (C) and (D) DSA (unsubtracted and subtracted views, respectively) shows the detached WEB device (WEB SL 7×3 mm) and slow flow in the aneurysm and the device. (E) and (F) 3D-DSA at 12 months (with and without device subtraction, respectively) shows a small aneurysm remnant.
of this treatment in the management of intracranial aneurysms. Follow-up at 3 and 5 years is foreseen in French Observatory, WEBCAST and WEBCAST-2.

CONCLUSION
This analysis of the cumulative population of three GCP studies dealing with wide-neck bifurcation aneurysm treatment with the WEB device (WEBCAST, French Observatory, and WEBCAST-2) confirmed the high safety of this treatment with no mortality and low morbidity at 1 month. This treatment is associated with a good efficacy at 1 year with a complete and adequate occlusion rate of 52.9% and 79.1%, respectively.

Author affiliations
1 Hôpital Maison-Blanche, Université Reims-Champagne-Ardenne, Reims, France
2 Hôpital Bièvre, Assistance Publique-Hôpitaux de Paris, Kremlin-Bicêtre, France
3 CHU Bordeaux, Bordeaux, BORDEAUX, France
4 National Institute of Clinical Neurosciences, Budapest, Hungary
5 CHU Tours, Tours, France
6 CHU Lyon, Lyon, France
7 Righospitalet, Copenhagen, Denmark
8 CHU Toulouse, Toulouse, France
9 CHU Montpellier, Montpellier, France
10 Department of Neuroradiology, University Medical Center Hamburg-Eppendorf, Hamburg, Germany
11 Helios General Hospital, Erfurt, Germany
12 CHU Rennes, Rennes, France
13 Universitätsklinikum Knappschaftskrankenhaus Bochum GmbH, Bochum, Germany
14 CHU Nantes, Nantes, France
15 CHU Poitiers, Poitiers, France
16 Universitätsklinikum Köln, Cologne, Germany
17 ZOLZiekenhuis Oost-Limburg, Genk, Genk, Belgium
18 Institut für Neuroradiologie, Klinikum der Johann Wolfgang Goethe-Universitat, Frankfurt, Germany
19 Nuffield Department of Surgical Sciences, Oxford University, Oxford, UK

Contributors All authors have provided a substantial contribution to the conception and design of the studies and/or the acquisition and/or the analysis of the data and/or the interpretation of the data; drafted the work or revised it for significant intellectual content; approved the final version of the manuscript; agree to be accountable for all aspects of the work, including its accuracy and integrity.

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Patient consent Obtained.

Ethics approval Reims institutional review board.

Provenance and peer review Not commissioned; externally peer reviewed.

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