PulseRider

The PulseRider (Cerenovus, Johnson & Johnson Medical Devices, New Brunswick, NJ, USA) is a aneurysm neck reconstruction device that is used for the treatment of unruptured wide-necked bifurcation aneurysms

http://www.pulsarvascular.com/

see Video

The PulseRider Aneurysm Neck Reconstruction Device is intended for use with embolic coils in the treatment of intracranial aneurysms originating on or near a vessel bifurcation.

Since ISAT, there has been a revolution in interventional neuroradiology which includes a shift toward catheter based procedures. Unfortunately, for a variety of reasons there are not always endovascular treatment options available to some patients with intracranial aneurysms, especially if the neck of the aneurysm is wide. Additionally there is a range of concerns relating to patient comorbidities, aneurysm geometry or the location of the lesion. Consequently there are many challenges, even today, when treating patients with such lesions. Hence there has been significant research in this arena to develop adjunctive devices to be used with embolic coils as well as sole therapy devices.

The PulseRider has an open cell frame. The unique frame configuration opens to conform to the vessel walls. The PulseRider is specifically designed to resolve the shortcomings of current endovascular devices by preserving luminal patency and hemodynamic flow through the parent vessel bifurcation, while minimizing exposed metal in order to encourage early endothelialization while securely retaining embolic agents within the aneurysm sac. The PulseRider is delivered through commercially available microcatheters using standard endovascular techniques. The implant is retrievable and may be repositioned by retracting it into the microcatheter at any time during or after deployment (prior to detachment). The implant is designed with an open frame to maintain luminal patency. It is deployed at the parent vessel bifurcation and across the aneurysm neck to provide a support framework, bridging the aneurysm neck while retaining embolic agents within the aneurysm. The PulseRider is electrolytically detached from the delivery wire.

In the early experience with the Pulse Rider device its use was safe and effective as an adjunct in the



treatment of bifurcation aneurysms arising at the basilar apex or carotid terminus ¹⁾.

Case series

A study aimed to compare the six-month outcomes of PulseRider and single stent-assisted embolization for intracranial unruptured Wide-Necked Intracranial Bifurcation Aneurysms (WNBAs) using propensity score adjustment. Between February 2012 and October 2021, 46 unruptured WNBAs (34 basilar and 12 middle cerebral arteries) smaller than 10 mm in diameter were treated with PulseRider-assisted embolization (n = 17) or single stent-assisted embolization (n = 29). The immediate and six-month outcomes were compared using inverse probability of treatment weighting analysis. The immediate adequate occlusion rates for the PulseRider- and single stent-assisted embolization were similar (47.1% vs. 62.1%). At six months, adequate occlusion rates for the two groups were also similar (94.1% vs. 86.2%). However, the complete obliteration rate was significantly high after PulseRider-assisted embolization (88.2% vs. 41.4%, adjusted OR 10.54, 95% CI 1.93-57.63). The angiographical improvement rate was also significantly high after PulseRider-assisted embolization (70.6% vs. 37.9%, adjusted OR 6.06, 95% CI 1.54-23.76). The neurologic thromboembolic complication rate was 0% after PulseRider-assisted embolization and 3.4% after single stent-assisted embolization. PulseRider-assisted embolization of WNBAs smaller than 10 mm in diameter was associated with complete obliteration and angiographical improvement at six months. The unique shape of the PulseRider might contribute to the improved midterm aneurysm occlusion²⁾

The safety and probable benefit of the PulseRider (Pulsar Vascular, Los Gatos, California) for the treatment of broad-necked, bifurcation aneurysms was studied in the context of the prospective, nonrandomized, single arm clinical trial-the Adjunctive Neurovascular Support of Wide-neck aneurysm Embolization and Reconstruction (ANSWER) Trial.

Aneurysms treated with the PulseRider device among sites enrolling in the ANSWER trial were prospectively studied and the results are summarized. Aneurysms arising at either the carotid terminus or basilar apex that were relatively broad necked were considered candidates for inclusion into the ANSWER study.

Thirty-four patients were enrolled (29 female and 5 male) with a mean age of 60.9 years (27 basilar apex and 7 carotid terminus). Mean aneurysm height ranged from 2.4 to 15.9 mm with a mean neck size of 5.2 mm (range 2.3-11.6 mm). In all patients, the device was delivered and deployed. Immediate Raymond I or II occlusion was achieved in 82.4% and progressed to 87.9% at 6-month follow-up. A modified Rankin Score of 2 or less was seen in 94% of patients at 6 months.

The results from the ANSWER trial demonstrate that the PulseRider device is safe and offers probable benefit as for the treatment of bifurcation aneurysms arising at the basilar apex or carotid terminus. As such, it represents a useful addition to the armamentarium of the neuroendovascular specialist ³⁾.

A study was a prospective registry of patients treated with PulseRider at 13 American neurointerventional centers following FDA approval of this device. Data collected included clinical presentation, aneurysm characteristics, treatment details, and perioperative events. Follow-up data included degree of aneurysm occlusion and delayed (> 30 days after the procedure) complications.

A total of 54 aneurysms were treated, with the same number of PulseRider devices, across 13 centers. Fourteen cases were in off-label locations (7 anterior communicating artery, 6 middle cerebral artery, and 1 A1 segment anterior cerebral artery aneurysms). The average dome/neck ratio was 1.2. Technical success was achieved in 52 cases (96.2%). Major complications included the following: 3 procedure-related posterior cerebral artery strokes, a device-related intraoperative aneurysm rupture, and a delayed device thrombosis. Immediately postoperative Raymond-Roy occlusion classification (RROC) class 1 was achieved in 21 cases (40.3%), class 2 in 15 (28.8%), and class 3 in 16 cases (30.7%). Additional devices were used in 3 aneurysms. For those patients with 3-or 6-month angiographic follow-up (28 patients), 18 aneurysms (64.2%) were RROC class 1 and 8 (28.5%) were RROC class 2.

PulseRider is being used in both on- and off-label cases following FDA approval. The clinical and radiographic outcomes are comparable in real-world experience to the outcomes observed in earlier studies. Further experience is needed with the device to determine its role in the neurointerventionalist's armamentarium, especially with regard to its off-label use ⁴⁾.

Case reports

51-year-old male patient with a basilar apex aneurysm who was treated with PulseRider but had postprocedural brainstem infarctions caused by one of the proximal markers covering the origin of a perforator. In such cases, repositioning of the PulseRider should be performed to avoid infarctions ⁵⁾.

Wide-neck aneurysms and the Adjunctive Neurovascular Support of Wide-neck aneurysm Embolization and Reconstruction (ANSWER) Trial showed efficacy in the treatment of unruptured wide-neck aneurysms.

O'Connor et al., demonstrated the use of the PulseRider device in the treatment of ruptured wideneck aneurysms.

The two patients in the series presented with subarachnoid hemorrhage secondary to ruptured basilar apex aneurysms. The patients were taken to the neurointervention suite for embolization of their aneurysms with the PulseRider® and platinum microcoils.

In both cases, a Roy Raymond class III embolization was achieved. The patients recovered from their subarachnoid hemorrhage and were discharged with resolution of their symptoms. The presented cases document the safety and efficacy of treating ruptured aneurysms with the PulseRider device ⁶⁾.

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