Neurovascular Stents Used for Stent-Assisted Coiling of Unruptured Brain Aneurysms: Letter to Health Care Providers

Dear Health Care Provider,

To promote safe and effective use of neurovascular stents used for stent-assisted coiling (SAC) of brain aneurysms, the FDA is providing recommendations regarding patient selection and device use. The FDA has received reports associated with the use of these devices in the treatment of unruptured brain aneurysms that suggest some events of peri-procedural stroke and/or death may have been related to procedural risks or patient selection related factors. These factors include patients who had serious co-morbidities resulting in a reduced life expectancy, or who were intolerant to required anticoagulation or anti-platelet therapy.

Neurovascular stents used for SAC are intended to treat wide-neck, intracranial, saccular aneurysms, arising from various sized parent vessel diameters depending on the manufacturers' intended use (e.g., > 2 millimeters and < 4.5 millimeters). Wide-neck is defined as having a neck width > 4 millimeters or a dome-to-neck ratio < 2. These devices are available from multiple manufacturers and have been approved by FDA through the **Humanitarian Device Exemption (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/HumanitarianDeviceExemption/ucm2007515.htm)** (HDE) regulatory pathway, after demonstrating safety and probable benefit for their intended use.

Neurovascular stents for SAC provide important options for the treatment of wide-neck brain aneurysms, and their technology continues to evolve. However, these procedures are not without risks, and careful patient selection and proper device use are critical to ensure that the benefits to the patient outweigh the risk of treatment. Many patients with unruptured brain aneurysms can be managed conservatively with routine monitoring and follow-up depending on their individual risk factors for aneurysm rupture. There are well-established factors that are known to increase the risk of brain aneurysm rupture and should be considered in selecting appropriate patients for treatment with a neurovascular stent. These risk factors include patient age, presence of patient symptoms (e.g., cranial nerve deficit), a family history of brain aneurysm(s) or subarachnoid hemorrhage (SAH), prior SAH, gender, ethnicity, tobacco use, hypertension, brain aneurysm location, morphology, size, and changes over time of size and morphology. For example, smaller brain aneurysms (e.g., < 5 millimeters) are more common, and have been shown to have a low rupture risk, around 0.7% per year, while large (e.g., 11-25 millimeters) and giant brain aneurysms (e.g., > 25 millimeters) can have rupture rates as high as 6% per year.

RECOMMENDATIONS

When using neurovascular stents for SAC, the FDA recommends that health care providers:

- Consider and discuss with your patients the benefits and risks of neurovascular stent devices and procedures, as well as the availability of any alternative management modalities.
  - For smaller brain aneurysms, or for patients with reduced life expectancy, in the absence of other risk factors, the risks of treatment may outweigh the benefits of treatment. Therefore, the patient should be properly informed of the rates of serious adverse events and the rupture risk as part of the decision making to undergo intervention.
- Be aware that neurovascular stent devices for SAC are approved for the treatment of brain aneurysms of limited characteristics and parent vessel sizes, and the FDA has not evaluated the safety and probable benefit outside those parameters. Consult the specific device manufacturer's product labeling for further information.

- Avoid use of neurovascular stents for SAC in patients who are not candidates for systemic anticoagulation and/or not able to receive anti-platelet medications as use of the devices require peri-procedural anticoagulation and/or anti-platelet therapy. Thrombosis in or around the stent may result in serious harm, including ischemic stroke and death.
- Select a neurovascular stent for SAC of proper length and diameter based on the dimensions of the brain aneurysm and parent vessel. As stent foreshortening may occur after deployment, be sure to follow the manufacturer's guidance on stent size selection.
- Only use delivery microcatheters which have been found compatible for use by the neurovascular stent manufacturer. Consult the specific device manufacturer's instructions for use.
- Carefully observe micro-guidewires and microcatheters when they are manipulated within or passed through the struts of an implanted stent. Be aware that these devices may become entangled with stent struts, change stent position, cause vessel injury, or rupture the brain aneurysm.
- Carefully observe embolization coil(s) when they are manipulated within a brain aneurysm and avoid coil prolapse through stent struts. Ensure that the specific coil models and sizes chosen are indicated for the embolization of brain aneurysms.
- Report any adverse events associated with neurovascular stents for SAC that come to your attention. Please include the following information in your report:
  - The length of time between the procedure and the event;
  - The type of brain aneurysm treated (i.e., ruptured, unruptured);
  - The anatomical location and target vessel dimensions;
  - The size of the brain aneurysm;
  - The size of the device/s used;
  - And any device, patient (e.g., comorbidities such as a history of subarachnoid hemorrhage), and/or procedure related factors.

    Voluntary reports can be submitted through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**. Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** regulations. Health care personnel employed by facilities that are subject to **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

FDA ACTIONS

The FDA will update this communication if significant new information becomes available.

Included below are additional resources related to the issue:

- **B. Gregory Thompson, Robert D. Brown, Sepideh Amin-Hanjani, Joseph P. Broderick, Kevin M. Cockroft, E. Sander Connolly, Gary R. Duckwiler, Catherine C. Harris, Virginia J. Howard, S. Claiborne (Clay) Johnston, Philip M. Meyers, Andrew Molyneux, Christopher S. Ogilvy, Andrew J. Ringer, and James Torner. 2015. "Guidelines for the Management of Patients with Unruptured Intracranial Aneurysms." Stroke 46 (8). (http://stroke.ahajournals.org/content/early/2015/06/18/STR.0000000000000070) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Komotar, Ricardo J., J Mocco, and Robert A. Solomon. 2008. "Guidelines for the Surgical Treatment of Unruptured Intracranial Aneurysms: The First Annual J. Lawrence Pool Memorial Research Symposium—Controversies in the Management of Cerebral Aneurysms." Neurosurgery 62 (1): 183–94. (https://miami.pure.elsevier.com/en/publications/guidelines-for-the-surgical-treatment-of-unruptured-intracranial-) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

- Rinkel, Gabriel J. E., Mamuka Djibuti, Ale Algra, and J. van Gijn. 1998. "Prevalence and Risk of Rupture of Intracranial Aneurysms A Systematic Review." Stroke 29 (1): 251–56. (https://www.ncbi.nlm.nih.gov/pubmed/9445359)
- Wiebers, David O. 1998. "Unruptured Intracranial Aneurysms — Risk of Rupture and Risks of Surgical Intervention." New England Journal of Medicine 339 (24): 1725–33. doi:10.1056/NEJM199812103392401) (http://www.nejm.org/doi/full/10.1056/nejm199812103392401) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

CONTACT US

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041, or 301-796-7100.

Sincerely,

/s/
William Maisel, MD, MPH
Deputy Center Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration

More in Letters to Health Care Providers (/MedicalDevices/Safety/LetterstoHealthCareProviders/default.htm)