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The New England Journal of Medicine: Adjunctive Middle Meningeal Artery Embolization for Subdural Hematoma

- The surgical cohort of the EMBOLISE clinical trial was published in the New England Journal of Medicine on Nov. 20, 2024.
- Among patients with symptomatic subacute or chronic subdural hematoma with an indication for surgical evacuation, middle meningeal artery embolization plus surgery was associated with a lower risk of hematoma recurrence or progression leading to reoperation than surgery alone. Further study is needed to evaluate the safety of middle meningeal artery embolization in the management of subdural hematoma.

Medtronic, a global leader in healthcare technology, announced the publication of the EMBOLISE (Embolization of the Middle Meningeal Artery With Onyx™ Liquid Embolic System (LES) in the Treatment of Subacute and Chronic Subdural Hematoma) trial surgical cohort that was conducted across 39 sites in the U.S.

Late breaking results were presented at the International Stroke Conference (ISC) in Feb. 2024 and were just published in the [New England Journal of Medicine](#).

"We are excited to see the publication of the EMBOLISE trial in the NEJM and the potential treatment opportunity this may present to patients diagnosed with chronic subdural hematoma. We look forward to additional insights of the study in the coming months," said Linnea Burman, senior vice president and president of Neurovascular business, which is part of the Neuroscience Portfolio at Medtronic.

Subacute and chronic subdural hematoma (SDH) can lead to acute symptoms such as headache, dizziness, or limb dysfunction,¹ and can cause further brain injury and serious long-term sequelae,² as well as progression of brain atrophy that can lead to dementia and reduced compliance of brain tissues.³

Overall, current conservative and surgical treatment options for subacute and chronic SDH do not address the underlying cause of the hematoma (does not stop the flow of blood to the hematoma). Given this, hematomas are prone to recur/progress, often necessitating repeated surgical interventions.⁴ Embolization with the Medtronic Onyx™ Liquid Embolic System has been used for almost 20 years for the treatment of neurovascular, presurgical brain arteriovenous malformations in the U.S. This also includes more than 20 years of treatment OUS for embolization of lesions in the peripheral and neurovasculature, including arteriovenous malformations and hypervascular tumors.

EMBOLISE Study Results⁵

The EMBOLISE trial was a prospective, multicenter, randomized, interventional, controlled, open-label, adaptive design trial that enrolled patients requiring surgical evacuation of subacute and chronic SDH as the primary management. The surgical cohort of the trial enrolled 400 patients at 39 sites in the United States.

The publication concluded that “among patients with symptomatic subacute or chronic subdural hematoma with an indication for surgical evacuation, middle meningeal artery embolization plus surgery was associated with a lower risk of hematoma recurrence or progression leading to reoperation than surgery alone. Further study is needed to evaluate the safety of middle meningeal artery embolization in the management of subdural hematoma.”

“The EMBOLISE trial marks an important point in the future opportunities for neurovascular care and we are glad to see these early outcomes with this data,” said Brett Wall, executive vice president and president of the Medtronic Neuroscience portfolio.

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References:

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About the Medtronic Neurovascular business

With the largest neurovascular technology business in the world, Medtronic Neurovascular led evidence-based medicine in neurointervention with five landmark studies published in The New England Journal of Medicine in 2015. Its clinical and regulatory leadership and bold approach shaped the current guidelines for treating strokes.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient

monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow on [LinkedIn](#).

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Contacts:

Kelli Lynch
Public Relations
+1-203-500-3328

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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