

Emerging Technology List

DEVICE FOR TREATMENT OF ISCHEMIC STROKE

CANADIAN COORDINATING
OFFICE FOR HEALTH
TECHNOLOGY ASSESSMENT



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Technology: Device to remove blood clots from the brain (Merci[®] Retriever/Merci[®] Retrieval System)

Manufacturer: Concentric Medical, Inc., Mountain View CA

Purpose: Management of ischemic stroke

Current Regulatory Status: The Merci Retriever is intended to restore blood flow in the neuro-vasculature by removing blood clots in patients experiencing ischemic stroke. Patients who are ineligible for intravenous (IV) tissue plasminogen activator (tPA) or who fail IV tPA therapy are candidates for treatment. Health Canada issued the Merci Retriever a licence for this application in May 2003 (Kathleen Savage, Health Canada: personal communication 15 November 2004). The Merci Retriever received 510(k) marketing approval from the US Food and Drug Administration (FDA) in August 2004. The device had already been approved by the FDA for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neural, peripheral and coronary vasculature.¹

Description: The Merci Retriever System consists of three parts: the Merci Retriever, the Merci Microcatheter and the Merci Balloon Guide Catheter. The Merci Retriever is a nitinol (nickel-titanium) wire with a platinum coil attached to a helical-shaped distal tip. Angiography is used to locate the blood clot. Under x-ray guidance, the balloon guide catheter is inserted through the femoral artery up to the carotid artery. Using the microcatheter, the Merci Retriever is passed through the blood clot and retracted, bringing the clot with it.²

Cost: Based on information from the manufacturer, the prices for the sale of the Merci Retriever System in Canada are: US\$2,150 Merci Retriever, US\$525 for the Merci Balloon Guide Catheter and US\$325 for the Merci Microcatheter.³

Evidence: The US FDA approval was based on the results of a prospective, multicentre (25 sites), cohort study of patients with symptoms suggestive of acute ischemic stroke.^{4,5} The primary endpoint was successful revascularization (measured through angiography) in all treatable vessels, while limiting serious adverse events. Secondary endpoints were patients' neurological status at 30 and 90 days. The study's success was defined as successful revascularization of $\geq 30\%$ of patients, and statistical superiority to the 18% benchmark, as derived from the control arm (placebo) of the Prolyse in Acute Cerebral Thromboembolism (PROACT) II study.⁶ At a Neurological Devices Panel meeting, however, an FDA representative noted that MERCI and PROACT II patients are not truly comparable and that patients from the latter study do not provide a good control group.⁴

The patient population included individuals who presented within three hours of symptom onset, but were not candidates for thrombolytic therapy. It also included patients who presented after three hours, for whom the thrombectomy procedure could be completed within eight hours after the onset of symptoms.

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Of the 144 patients from 25 centres enrolled in the Merci Retriever study, 137 were treated. Complete acute data were available for 121 patients at the time of the manufacturer's submission. In seven of these patients, the retriever was not deployed in the target vessel, leaving 114 in the final analysis. For five of the seven patients, there was an inability to access the occlusion and place the balloon guide or advance the retriever, resulting in a 4% failure-to-treat rate.

Serious adverse events were experienced by 15 of 114 (13%) patients; four of these were device-related and three procedure-related. Overall, the symptomatic intracranial hemorrhage rate within 24 hours of treatment was 8% (9/114), compared with 6% in the PROACT II population. Mortality was 38%, compared with 27% for PROACT II – this is thought to represent the expected mortality in the population treated, as stroke patients treated in the Merci Retriever study had more acute symptoms.

Of 114 patients treated with the Merci Retriever, 54% (n=61) had thrombolysis in myocardial infarction (TIMI) flow grade II or III immediately post-procedure. This is statistically significant compared with the 18% rate for the placebo group in PROACT II ($p < 0.0001$) and significantly greater than the target success rate of 30%. Excluding patients with serious adverse events, the study success rate (revascularization with the Retriever alone) was 47% (57/120).

Of 61 patients who had successful clot retrieval, 25% (15/61) died before follow-up at 90 days after the procedure. In 10 of 17 patients, where the Merci Retriever was unsuccessful in restoring blood flow, there was successful revascularization using another therapy [eight with intra-arterial (IA) thrombolysis and two with other mechanical devices].

With secondary trial endpoints, the analysis of the clinical outcomes of all patients treated with the Merci Retriever did not show a significant improvement compared with the outcome of patients in the PROACT II placebo group.

A recent paper reported results for the first 30 patients in the MERCI 1 trial, who were from seven US centres.⁷ Successful revascularization with mechanical embolectomy was achieved in 12 (43%) patients; and with additional IA thrombolysis in 18 (64%). There was one procedure-related technical complication, with no clinical consequence; and 12 asymptomatic and no symptomatic intracranial hemorrhages. At one month, nine of 18 revascularized patients and none of 10 non-revascularized patients had achieved significant recovery.

Concentric Medical's web site refers to two ongoing studies: the Multi-MERCI trial at sites in the US and Canada; and MR Rescue. The latter is a multicentre randomized controlled trial of 120 ischemic stroke patients with large vessel occlusions in the anterior circulation. These patients will be randomized to receive treatment with the Merci system or medical therapy (Aspirin and heparin).⁸

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Available Alternative Technologies:

IV thrombolysis using tPA has been shown to improve outcomes in ischemic stroke when administered within three hours of the onset of symptoms. IA thrombolysis, which has a longer treatment window of up to six hours after the onset of symptoms, has been used at many centres. It is often used in combination with IV administration of agents such as abciximab, which is a platelet glycoprotein IIb/IIIa antagonist.^{6,9}

Other endovascular treatments for the mechanical removal of emboli include endovascular thrombectomy with suction or snaring devices; clot disruption with mechanical or photo-acoustic devices; and augmented fibrinolysis with mechanical or ultrasonic devices. Most of these devices are undergoing phase I or II trials or are approved for other uses.¹⁰ A recent paper reported that in patients with acute ischemic stroke, continuous transcranial Doppler augments tPA-induced arterial revascularization. There was a non-significant trend toward an increased rate of recovery from stroke, in comparison with placebo.¹¹

Commentary:

The Merci Retrieval System is another step in the development of new approaches for treating ischemic stroke. It provides an additional option when thrombolysis has failed or is inappropriate. Use of the device requires a high skill level. Data on the effectiveness of the device are limited; it is expected that the results of ongoing trials will provide further information.

References:

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This summary was prepared by David Hailey, PhD, CCOHTA.

This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

These summaries have not been externally peer reviewed.

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