

Mechanical Thrombectomy for Acute and Subacute Blocked Arteries and Veins in the Lower Limbs: Recommendation

Final Recommendation

Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding mechanical thrombectomy for lower extremities for adults who are candidates for catheter-directed intervention.

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment¹ and made the above recommendation after considering the clinical, economic, and patient preference and values evidence.

Based on the evidence, for arterial acute limb ischemia, mechanical thrombectomy may improve the complete removal of a blockage and return blood flow to a lower limb artery. For acute deep vein thrombosis (DVT), evidence supports that mechanical thrombectomy likely reduces the duration for catheter-directed thrombolysis (CDT) and may also reduce the proportion of people who experience post-thrombotic syndrome. Mechanical thrombectomy may also reduce the duration of hospital stay for patients having treatment for blocked arteries or veins in the lower limbs. The committee acknowledged the lived experience of patients and the anxiety around the potential health consequences of deep vein thrombosis and preference for timely and quick treatment. The cost effectiveness of mechanical thrombectomy was not evaluated because of the uncertainty in the clinical effects. Publicly funding mechanical thrombectomy for adults with blocked arteries of the lower limbs is estimated to not substantially increase costs for Ontario. However, it was estimated that publicly funding mechanical thrombectomy to treat acute DVT would increase costs to the province by about \$5.5 million over 5 years.

The committee recommended publicly funding mechanical thrombectomy as a treatment for acute DVT because of the likely benefit of reducing the time required for CDT, which is conducted in the intensive care unit (ICU), and thereby reduce the duration of ICU stay and because this aligns with patient preferences and values for care and removal of the blockage as quickly as possible. Additionally, the estimated total 5-year cost to the province for acute DVT treatment seemed reasonable. The committee also supported publicly funding mechanical thrombectomy as a treatment for arterial blockages because of the potential for complete removal of the blockage and restoration of blood flow to the artery, and that the uncertainty of the evidence for these treatment effects must be balanced with the risk of limb loss and the urgent need for intervention. Additionally, the estimated cost to the province is minimal. The committee recognized that, for patients with either arterial or venous blockages, mechanical thrombectomy may reduce the duration of hospital stay, which has benefits to patients and the health care system.

The funding recommendation reflects that the majority of the included clinical evidence evaluated the use of mechanical thrombectomy compared with CDT alone. The committee noted that Ontario Health CorHealth is well positioned to support the implementation of mechanical thrombectomy into the health care system.

Decision Determinants for Mechanical Thrombectomy for Acute and Subacute Blocked Arteries and Veins in the Lower Limbs

Overall Clinical Benefit

Effectiveness

How effective is the health technology/intervention likely to be (taking into account any variability)?

We included 40 studies (3 RCTs, and 37 observational studies) in the clinical evidence review. In arterial acute limb ischemia, mechanical thrombectomy compared to CDT alone may have greater technical success (removal of a blockage) and patency (return of blood flow), and reduced hospital length of stay (GRADE: Very low). In acute deep vein thrombosis, mechanical thrombectomy may reduce thrombolytic medication volume used (GRADE Very low) and the duration of thrombolytic infusion (a determinant of intensive care unit duration) compared to not using mechanical thrombectomy, but it is uncertain if use of MT leads to a meaningful reduction in transfusion time (GRADE: Moderate to Very low). It may also reduce the proportion of people who experience post-thrombotic syndrome and overall hospital length of stay (GRADE: Very low).

Safety

How safe is the health technology/intervention likely to be?

The evidence demonstrated inconsistency in whether mechanical thrombectomy has more or different adverse events than comparators. However, clinical experts and guidelines agree that patient eligibility assessment is pivotal in ensuring safety. Additionally, there are concerns with major bleeding from other treatment options. For instance, CDT carries a risk of major bleeding for patients, which requires ICU monitoring for the duration of the infusion, and specifically with prolonged CDT use, which requires that patients be monitored in the ICU during CDT treatment.

Burden of Illness

What is the likely size of the burden of illness pertaining to this health technology/intervention?

Patients with arterial acute limb ischemia are at great risk for limb loss and have an urgent need for intervention, and patients with acute deep vein thrombosis may experience life-long post-thrombotic syndrome, which can be painful and interfere with walking and other activities of daily living.

Need

How large is the need for this health technology/intervention?

Mechanical thrombectomy is an alternative treatment that may be used in lieu of, or in conjunction with, current treatment options, of which the most common one seen in the included published evidence was CDT. However, CDT, carries a risk of major bleeding for patients that require ICU monitoring for the duration of the infusion, and reducing the duration of CDT required is important for patient safety and for health care utilization. Furthermore, some patients may not be eligible to receive the CDT due to a blood clotting disorder or if there is a high risk of immediate limb loss from the blockage, and the time required to administer CDT (approximately 8–36 hours) is determined to be too risky for saving the limb. We estimated that each year there will be around 350 hospitalized

individuals with arterial acute limb ischemia and around 400 hospitalized individuals with acute DVT who are eligible for mechanical thrombectomy as either the primary or adjunctive treatment.

Patient Preferences and Privacy

Patient Preferences and Values

Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment?

Patients reported having anxiety about potential health consequences of DVT and trust that their physicians would choose the most appropriate treatment option. While most patients were unaware of mechanical thrombectomy, it was generally seen as a positive option, and those with direct experience reported positively on its value as a treatment to quickly remove DVT. None of the people with whom we spoke had direct experience with arterial acute limb ischemia.

Autonomy, Privacy, Confidentiality, and/or Other Relevant Ethical Principles as Applicable

Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment?

We did not identify any concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles.

Equity and Patient Care

Equity of Access or Outcomes

Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?

There are 14 vascular centres in Ontario currently providing mechanical thrombectomy for lower limb occlusions through hospital global budgets. Ensuring appropriate transfers between care centers throughout the province may be part of providing equitable access.

Patient Care

Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?

Mechanical thrombectomy may reduce the need for patients to receive CDT for extended periods of time, which requires ICU observation. It has been proposed that it may alleviate the need for CDT altogether for some patients. Additionally, mechanical thrombectomy may be conducted in an interventional radiology suite in some hospitals, in which case it may support diverting some patients from needing the operating room. Timely access to mechanical thrombectomy includes identifying eligibility of patients with acute (symptoms < 14 days) and subacute (14–28 days) occlusions.

Cost-effectiveness

Economic Evaluation

How efficient is the health technology/intervention likely to be?

We did not conduct a primary economic evaluation due to the uncertainty with the magnitude of the treatment effects.

Feasibility of Adoption Into Health System

Economic Feasibility

How economically feasible is the health technology/intervention?

Public funding mechanical thrombectomy for adults with arterial acute limb ischemia likely would not lead to any substantial cost increase, and public funding for adults with acute DVT would lead to an estimated additional cost of \$5.5 million over the next 5 years.

Organizational Feasibility

How organizationally feasible is it to implement the health technology/intervention?

Provincial structures are in place and Ontario Health–CorHealth is well positioned to support the implementation of mechanical thrombectomy.

Reference

- (1) Ontario Health. Mechanical thrombectomy for acute and subacute blocked arteries and veins in the lower limbs: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2023 Jan;23(1):1–244. Available from: <https://www.hqontario.ca/Evidence-to-Improve-Care/Health-Technology-Assessment/Reviews-And-Recommendations/Mechanical-Thrombectomy-for-Acute-and-Subacute-Blocked-Arteries-and-Veins-in-the-Lower-Limbs>

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ISBN 978-1-4868-6605-2 (PDF)

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Citation

Ontario Health. Mechanical thrombectomy for acute and subacute blocked arteries and veins in the lower limbs: Ontario Health recommendation [Internet]. Toronto (ON): King's Printer for Ontario; 2023 January. 6 pp. Available from: <https://www.hqontario.ca/Evidence-to-Improve-Care/Health-Technology-Assessment/Reviews-And-Recommendations/Mechanical-Thrombectomy-for-Acute-and-Subacute-Blocked-Arteries-and-Veins-in-the-Lower-Limbs>