

EMERGING EVIDENCE IN ENDOVASCULAR MECHANICAL THROMBECTOMY - WHAT DOES IT MEAN FOR MY PRACTICE?

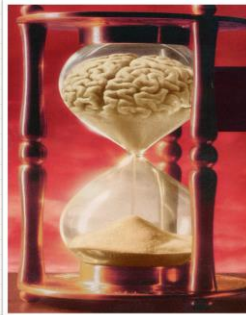
Racing Against the Clock
June 7, 2018

Objectives

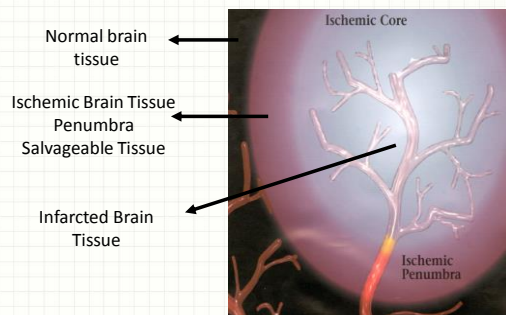
- To review the stroke endovascular mechanical thrombectomy evidence and the Canadian Best Practice Hyperacute Recommendations related to Mechanical Thrombectomy.
- To review the emerging Stroke Mechanical Thrombectomy evidence.
- To review the Stroke Mechanical Thrombectomy Inclusion Criteria, Patient Flow Algorithm and Post Procedural Care and Management.

Hyperacute Ischemic Stroke Management Goals

- To limit irreversible ischemic damage during an acute ischemic stroke caused by an arterial occlusion.
- To restore blood flow to the artery by opening up the artery with either IV tPA or Stroke Mechanical Thrombectomy.
- 1,900,000 brain cells die each minute blood supply is cut off to the brain.
- Each minute that blood supply is cut off to the brain equates to 1 week of healthy life lost.

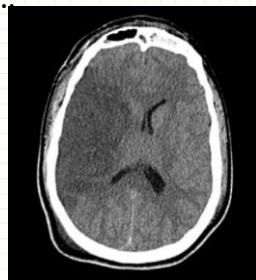


Ischemic Cascade – Process of Ischemic to Infarction



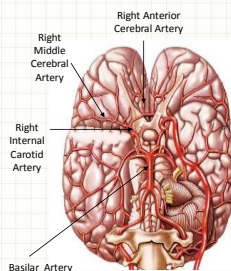
Effect of Ischemia on the Brain Size of the infarction depends on

- Site of occlusion
- Degree of reduction of blood flow
- Presence of collaterals
- Duration of ischemia
- Reperfusion



Proximal Artery Occlusions

- Approximately 20% of all strokes are due to large vessel occlusions
- Large vessel occlusion (LVO):
 - Internal Carotid Arteries
 - Middle Cerebral Arteries
 - Basilar Artery
- Recanalization Rates with IV tPA in LVO overall is 25 – 30% leaving patients with significant stroke deficits
- Size of the Clot is the most significant predictor of recanalization rates
- Clots greater than 8 mm or greater have consistently poor recanalization rates



2015 Endovascular Therapy for Large Vessel Acute Ischemic Strokes

➤ All of the trials have demonstrated statistically significant differences in:

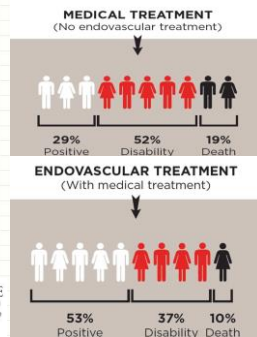
- Rate of functional independence in the endovascular stroke clot retrieval group versus the intravenous thrombolysis.
- NNT ranging from 2.5 – 7.
- Decrease in mortality in the endovascular stroke clot retrieval group versus intravenous thrombolysis.
- No difference in symptomatic intracerebral hemorrhage.

Three additional RCT's have found similar results as these landmark trials.

ESCAPE

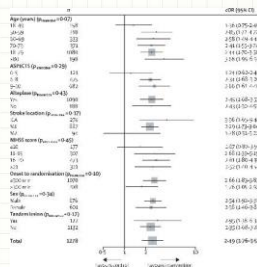
Benefits of EVT

- ARR = 23.7%
- NNT = 4 (to live independently)
- Risk of ICH = 3%



Hermes Collaboration Meta-Analysis of 5 EVT Trials

- Found Benefit for Endovascular Therapy:
 - All ages
 - Whether received IV tPA or not
 - All anterior circulation strokes, even patients with internal carotid artery tandem occlusion
 - All stroke severities
 - Men and women
- NNT was 2.6 for one patient to have reduced disability of at least 1 point on the Modified Rankin Scale
- No difference in Intracerebral hemorrhage or mortality at 90 days versus IV tPA



Goyal et al. Lancet 2016

What is Mechanical Thrombectomy?

- EVT is a highly specialized procedure involving mechanical removal of a clot in the brain
- The procedure:
 - A catheter is inserted into the femoral artery (groin area)
 - Using advanced imaging to guide, the catheter is navigated to the clot in the brain
 - A mesh stent is inserted through the catheter to the clot
 - The catheter is retracted, allowing the stent to expand through the clot. This expansion causes the clot to become trapped within the stent. The stent can then be removed, bringing the clot with it.

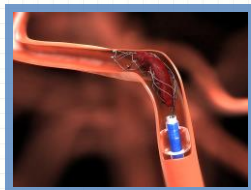


Image credit: medscape.com

<https://www.youtube.com/watch?v=7gn96se6j00>

Canadian Best Practice Recommendations for Stroke Care (July, 2015)

4.3 Endovascular therapy

- Endovascular therapy is indicated in patients **based upon imaging selection with noncontrast CT head and CTA** (including extracranial and intracranial arteries) [Evidence Level A]. See [Appendix S4](#) for Inclusion Criteria for endovascular therapy.
- Eligible patients who can be **treated within six-hours (i.e. whose groin can be punctured within six-hours of symptom onset)** should receive endovascular therapy [Evidence Level A]. Refer to [Appendix S4](#) for Inclusion Criteria for endovascular therapy.
 - Select patients** with disabling stroke **presenting between 6 and 12 h of stroke symptom onset**, including those with **stroke symptoms upon awakening, who meet clinical and imaging criteria**, may be considered for endovascular therapy [Evidence Level B], in accordance with local protocols.

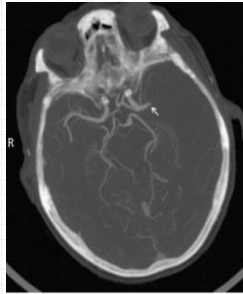
Canadian Best Practice Recommendations for Stroke Care (July, 2015)

4.3 Endovascular therapy

- Endovascular therapy is indicated in patients who have received **intravenous tPA and those who are not eligible for intravenous tPA** [Evidence Level A].
- Patients eligible for intravenous tPA** as well as endovascular therapy **should also be treated with intravenous tPA**, which can be initiated while simultaneously preparing the angiography suite for endovascular therapy [Evidence Level A].
- Device selection: Retrievable stents are recommended as the first-choice endovascular device** [Evidence Level A].
 - Other interventional devices (e.g. thrombus aspiration devices) may be used based on local protocols and expertise [Evidence Level C].

Who is Eligible for EVT Treatment?

- 20% of ischemic stroke patients.
- Those eligible and those ineligible for tPA.
- Disabling Stroke.
- Stroke Symptoms within 6 hours of time last seen normal.
- Large blood vessel blockage with a reachable clot.
- Brain tissue that is still alive (ASPECTS ≥ 6)



Scott's Story

[Voices in the Community](#)

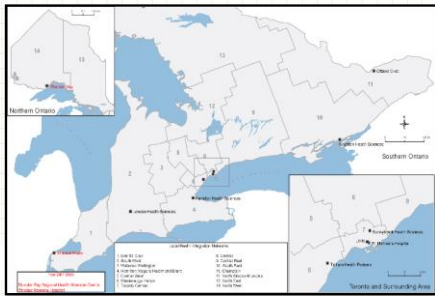


Case 2

- An 85 year old woman was last seen normal by her family at 1000 hours. She was found at 1300 hours with dense left hemiplegia and right gaze preference. Patient known to have atrial fibrillation and on warfarin - INR 3.3.
- She was not a candidate for tPA as she was outside the tPA window and her INR was greater than 1.7. The Stroke team contacted the HGH Neurologist and Neurointerventional MD for consideration for Endovascular Therapy.
- She was transferred to HGH direct to DI for repeat CT and then to the Endovascular Suite and successfully underwent Mechanical Thrombectomy.
- She was repatriated back to Grand River to continue her acute stroke care in 24 hours after the procedure with mild left sided weakness.

PROVINCIAL AND REGIONAL SYSTEMS FOR ACCESSING STROKE ENDOVASCULAR THERAPY

Stroke Endovascular Therapy Centres



Provincial Paramedic Prompt Card

- "Last Seen Normal" window has been increased from 4.5 to 6 hours in regions where Endovascular Therapy (EVT) is regionally available* (full force **March 1 2018**).
- Other recent changes (December 2017)
 - For patients with blood sugar <3 mmol/L should still be transferred if symptoms persist after correction of blood glucose level (full force December 2017)
 - Contraindication changed from CTAS Level 2 to CTAS Level 1 (full force December 2017)

Emergency Health Regulatory and Accountability System
Paramedic Prompt Card for Acute Stroke Bypass Protocol

This prompt card provides a quick reference of the Acute Stroke Bypass Protocol contained in the First Step Report Form (First Step Report Form) and the Acute Stroke Bypass Protocol (ASBP) and is intended to be used by paramedics.

Indications under the Acute Stroke Protocol
Patients are eligible for the Acute Stroke Protocol if they meet the following criteria:

1. Patient meets the criteria for a stroke or TIA (Transient Ischemic Attack) as defined by the paramedic.
2. Patient meets the criteria for a stroke or TIA as defined by the paramedic.
3. Patient meets the criteria for a stroke or TIA as defined by the paramedic.
4. Patient meets the criteria for a stroke or TIA as defined by the paramedic.
5. Patient meets the criteria for a stroke or TIA as defined by the paramedic.
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10. Patient meets the criteria for a stroke or TIA as defined by the paramedic.

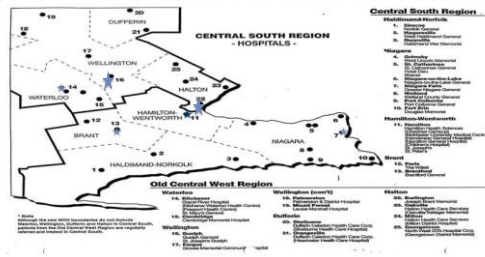
Contraindications under the Acute Stroke Protocol
Patients are not eligible for the Acute Stroke Protocol if they meet the following criteria:

1. Patient has a known allergy to the drugs used in the Acute Stroke Protocol.
2. Patient has a known allergy to the drugs used in the Acute Stroke Protocol.
3. Patient has a known allergy to the drugs used in the Acute Stroke Protocol.
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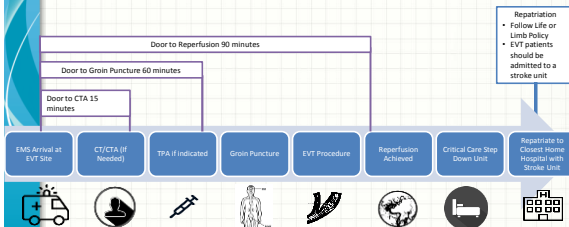
CAUTION: This prompt card is for reference only. The patient's condition must be assessed by the paramedic and the patient's condition must be documented in the patient's chart.

Ontario

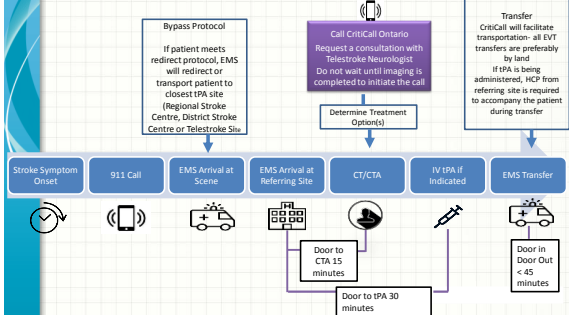
Central South Stroke Network Stroke Thrombolysis Providers



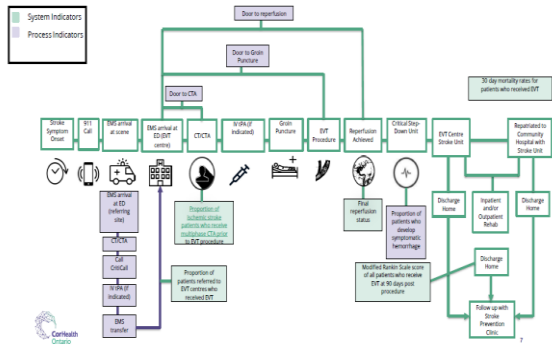
Endovascular Treating Centre Process Hamilton General Hospital



District Stroke Centres/Telestroke Sites



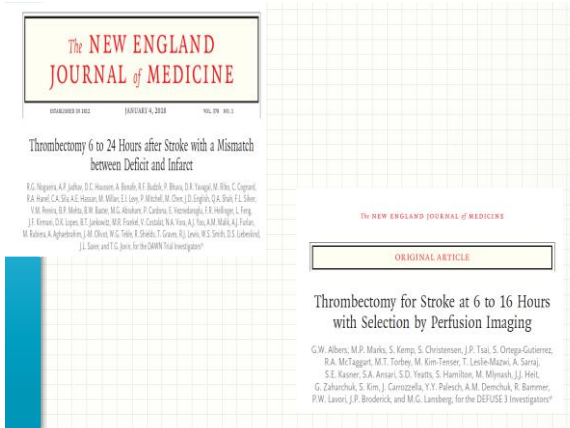
Overall proportion of ischemic stroke patients who received EVT



EMERGING STROKE ENDOVASCULAR THERAPY EVIDENCE

National Institute of Health Stroke Scale (NIHSS)

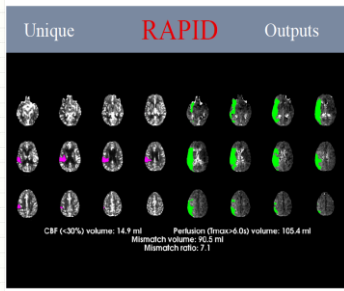
Score	Stroke Severity
0	No Stroke Symptoms
1 – 4	Minor Stroke
5 – 15	Moderate Stroke
16 – 20	Moderate to Severe Stroke
21 – 24	Severe Stroke



Inclusion Criteria	
DAWN	DEFUSE 3
Over 18 years. Last Known Well 6 to 24 hours. Pre-stroke score of 0 or 1 Modified Rankin Scale.	18 - 90 years. Last Known Well 6 to 16 hours. Baseline NIHSS ≥ 6 . Pre-stroke score of 0 – 2 on Modified Rankin Scale.
CTA/MRA shows occlusion of Internal Carotid Artery and proximal portion of Middle Cerebral Artery.	CTA/MRA shows occlusion of Internal Carotid Artery and proximal portion of Middle Cerebral Artery.

Inclusion Criteria	
DAWN	DEFUSE 3
Clinical Mismatch between severity of the stroke and the infarct volume (determined by CT Perfusion using RAPID Software)	Mismatch Profile on CT Perfusion of or MRI using RAPID Software:
Age >80 Age < 80 Age < 80	Ischemic Core Volume < 70 mL
NIHSS >10 NIHSS >10 NIHSS >20	And
Infarct Volume < 21 ml Infarct Volume < 31 ml Infarct Volume 31 – 51 ml	Mismatch Ratio > 1.8
	And
	Mismatch volume ≥ 15 ml

RAPID Software



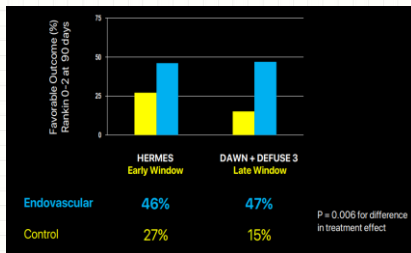
Baseline Characteristics & Outcomes

	DAWN (6 to 24 hours)	DEFUSE 3 (6 to 16 hours)
Time from Last Known Well to Randomization	12.2 hours (10.2 – 16.3)	10:29 hours (8.09 – 11:40)
Witnessed Onset of Stroke	10%	34%
Wake Up Stroke	63%	53%
Median NIHSS	17 (14 – 21)	16 (10 - 20)
Infarct Volume on CT Perfusion	7.6 (2.0 – 18.0)	19.4 (2.3 – 25.6)
Improved Functional Independence	35%	28%
NNT	2.8	2

Safety Outcomes

	DAWN (6 to 24 hours)	DEFUSE 3 (6 to 16 hours)
Symptomatic Intracranial hemorrhage at 90 days	6%	6.5%
Death from any cause at 90 days	19%	14%

Comparing Late Window Trial to Hermes Early Window Outcomes



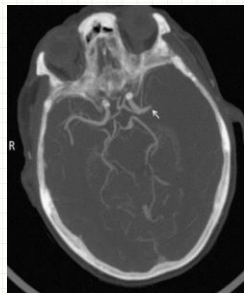
Late Window Paradox, Stroke, January 24, 2018

Case 3

- 81 year old woman was Last Known Well well by her family at 21:00 hours before she went to bed. She was found by her family at 11:25 hours sitting in a chair with aphasia, right sided weakness – NIHSS 22.
- CT/CTA showed showed no bleeding and little areas of infarction. CTA showed a left middle cerebral artery clot.
- She was transferred from a local telestroke site where she successfully underwent Stroke Endovascular Therapy and discharge back to her local stroke centre in 2 days with an NIHSS 0.

Who May be Eligible for Treatment Based on New Evidence?

- 20% of ischemic stroke patients.
- Those eligible and those ineligible for tPA.
- Disabling Stroke (NIHSS ≥ 6).
- Stroke Symptoms last seen well within 6 hours.
- May consider up to 16 hours from last seen well.
- Large blood vessel blockage with a reachable clot.
- Brain tissue that is still alive (ASPECTS ≥ 6).



What will be the Expanded Window EVT Referral Process?



MANAGEMENT OF THE ISCHEMIC STROKE PATIENT WHO HAS UNDERGONE STROKE ENDOVASCULAR THERAPY

Post Procedural Care of Stroke Mechanical Thrombectomy Patient

- Sheath Site Complications:
 - May occur within first 24 – 48 hours post sheath removal
 - Monitor femoral puncture site for:
 - Bruising
 - Pseudo-aneurysm (pulsatile, thrill, audible bruit)
 - Retroperitoneal Bleed (flank or back pain, abdominal distension, decreased urinary output)
 - Excessive Bleeding
- Peripheral Pulses first 24 – 48 hours

Post Procedural Care of Stroke Mechanical Thrombectomy Patient

- Monitor Kidney Function:
 - Patient has received CT contrast for CTA & during procedure so monitor kidney function post procedure
 - IV to flush contrast from kidneys
- Monitor for Fluid Overload/CHF
 - Watch for fluid overload especially in patients with cardiac co-morbidities
- Monitor for Cardiac Arrhythmias
 - Atrial Fibrillation
 - Daily ECG X3

Acute Stroke Management

- Blood Pressure:
 - After Mechanical Thrombectomy, BP will normally fall 20 mmHg
 - Maintain 140 and less than 180 depending on patient's previous norm
- Antithrombotic Therapy
 - Generally wait 24 hours post IV tPA/Mechanical Thrombectomy before starting antithrombotic therapy - Wait until 24 hours post CT is completed to rule out bleeding
- VTE Prophylaxis
 - Generally wait 24 hours post IV tPA/Mechanical Thrombectomy before starting pharmacological VTE – Wait until 24 hours post CT is completed to rule of bleeding
 - Mechanical Prophylaxis using Intermittent Pneumatic Compression Devices (SCD) may be considered. Do not apply SCD in leg with femoral sheath or for 8 hours post sheath removal.
- Monitor for post TPA Complications if received IV tPA
- Repatriation back to local Stroke Unit if regional case
- Implement Acute Ischemic Stroke Best Practices

References

1. Casaubon, L.K., Boulanger, J.M., on behalf of the Hyperacute and Acute Stroke Writing Group. (2015) *Hyperacute Stroke Care Module 2015*. In Lindsay MP, Gubitz G, Bayley M, and Smith EE (Editors) on behalf of the Canadian Stroke Best Practices and Advisory Committee. *Canadian Stroke Best Practice Recommendations*, 2015; Ottawa, Ontario Canada: Heart and Stroke Foundation.
2. Goyal, M., Menon, B.K., et al. for the Hermes Collaboration. (2016) Endovascular Thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomized trials. *Lancet*. 387: 1723 – 31.
3. Nogueira, R.G., Jadhav, A.P. et al. for the DAWN Trial Investigators. (2018) Thrombectomy 6 to 24 hours after Stroke with a Mismatch between Deficit and Infarct. *New England Journal of Medicine*. 378:11 – 21.
4. Albers, G.W., Marks, S. for the DEFUSE 3 Investigators (2018) Thrombectomy for Stroke at 6 to 16 hours with Selection by Perfusion Imaging. *New England Journal of Medicine*. 379: 1-11.



Questions



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