

'Top Studies in Vascular Neurology in 2021'

Diving into the evidence supporting the updated Canadian Stroke Best Practice Recommendations in SECONDARY PREVENTION.

Gord Gubitz MD, FRCPC

Stroke Neurologist, Dalhousie University

October 22, 2021



Conflict of Interest Slide

- Sadly, I have not received compensation (financial or otherwise) from any pharmaceutical or device company for many many years.
- I am a volunteer member of Heart and Stroke's Canadian Stroke Best Practice Recommendations Advisory Board.
- I provide support to writing groups and help to oversee the editorial processes of the the Canadian Stroke Best Practice Recommendations.

www.strokebestpractices.ca



**CANADIAN STROKE BEST PRACTICE
RECOMMENDATIONS**

Objectives

By the end of this session, participants will:

- Learn more about several recent landmark studies in cerebrovascular disease

An Aside...

Identifying 'LANDMARK' studies can be quite a subjective exercise, depending on the criteria used:

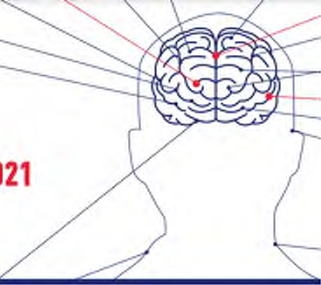
- Search strategy
- Language of publication
- Positive, negative, or neutral study
- *Number* of citations versus *quality* of citations
- Opinion / fatigue level / crankiness of the searcher
- Other biases NYD...

An Aside...

Tasks like this cause me to feel some degree of stress...



My Solution...



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Canadian Stroke Best Practices

Also...

There are a lot of exciting and promising topics in acute stroke that have *not yet* made their way into clinical practice:

- TNK versus tPA?
- tPA / TNK plus neuroprotection (NA-1)?
- Bypass lytics and go straight to EVT?
- EVT for Medium Vessel Occlusion (MeVO)?
- What to do about posterior circulation strokes?
- Reperfusion for non-disabling strokes?
- Reperfusion after XX hours / days from symptom onset?



Heart&Stroke

Stroke Best Practices

Driving evidence-based stroke care to achieve optimal patient outcomes and quality of care.

CANADIAN STROKE BEST PRACTICE RECOMMENDATIONS

Recommendations for the use of acetylsalicylic acid (ASA) for prevention of vascular events

Theodore Wein (First Author), M Patrice Lindsay (Corresponding Author), Norine Foley, David J Gladstone, Alexandre Poppe, Alan Bell, Leanne K Casaubon, Shelagh Coutts, Jafna Cox, James Douketis, Thalia Field, Laura Gioia, Jeffrey Habert, Eddy Lang, Shamir Mehta, Christine Papoushek, William Semchuk, Mikul Sharma, Jacob Udell, Stephanie Lawrence, Anita Mountain, Gord Gubitz, Dariush Dowlatshahi, Andrea de Jong, Anne Simard, and Eric E Smith (Senior Author) on behalf of the Prevention of Stroke Writing Group module 2019. In M. Patrice Lindsay, Anita Mountain, Gord Gubitz, Dariush Dowlatshahi, and Eric E Smith (Editors), Canadian Stroke Best Practice Recommendations Seventh Edition; on behalf of the Canadian Stroke Best Practice Advisory Committee, 2020; Ottawa, Ontario Canada: Heart and Stroke Foundation of Canada. In collaboration with the Canadian Stroke Consortium.

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March 2020

CANADIAN STROKE BEST PRACTICE RECOMMENDATIONS

MANAGEMENT OF SPONTANEOUS INTRACEREBRAL HEMORRHAGE

Seventh Edition - New Module 2020

Ashkan Shoamanesh (Co-chair), M. Patrice Lindsay, Lana A Castellucci, Anne Cayley, Mark Crowther, Kerstin de Wit, Shane W English, Sharon Hoosein, Thien Huynh, Michael Kelly, Cian J O'Kelly, Jeanne Teitelbaum, Samuel Yip, Dar Dowlatshahi, Eric E Smith, Norine Foley, Aleksandra Pikula, Anita Mountain, Gord Gubitz and Laura C. Gioia (Co-chair), on behalf of the Canadian Stroke Best Practices Advisory Committee in collaboration with the Canadian Stroke Consortium and the Canadian Hemorrhagic Stroke Trials Initiative Network (CoHESIVE).

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October 2020



CANADIAN STROKE BEST PRACTICE RECOMMENDATIONS

ACUTE STROKE MANAGEMENT:

PREHOSPITAL, EMERGENCY DEPARTMENT,

AND ACUTE INPATIENT STROKE CARE

Update 2018

*Boulanger JM, Butcher K (Writing Group Chairs), Gubitz G,
Stotts G, Smith EE, Lindsay MP*

*on Behalf of the Acute Stroke Management Best Practice Writing Group,
and the Canadian Stroke Best Practices and Quality Advisory Committees;
in collaboration with the Canadian Stroke Consortium
and the Canadian Association of Emergency Physicians*



**2021
update
coming
soon!**

Objectives

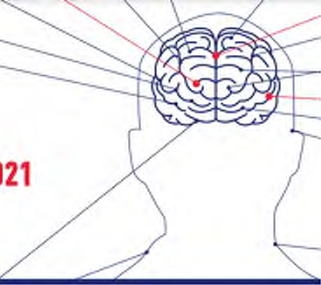
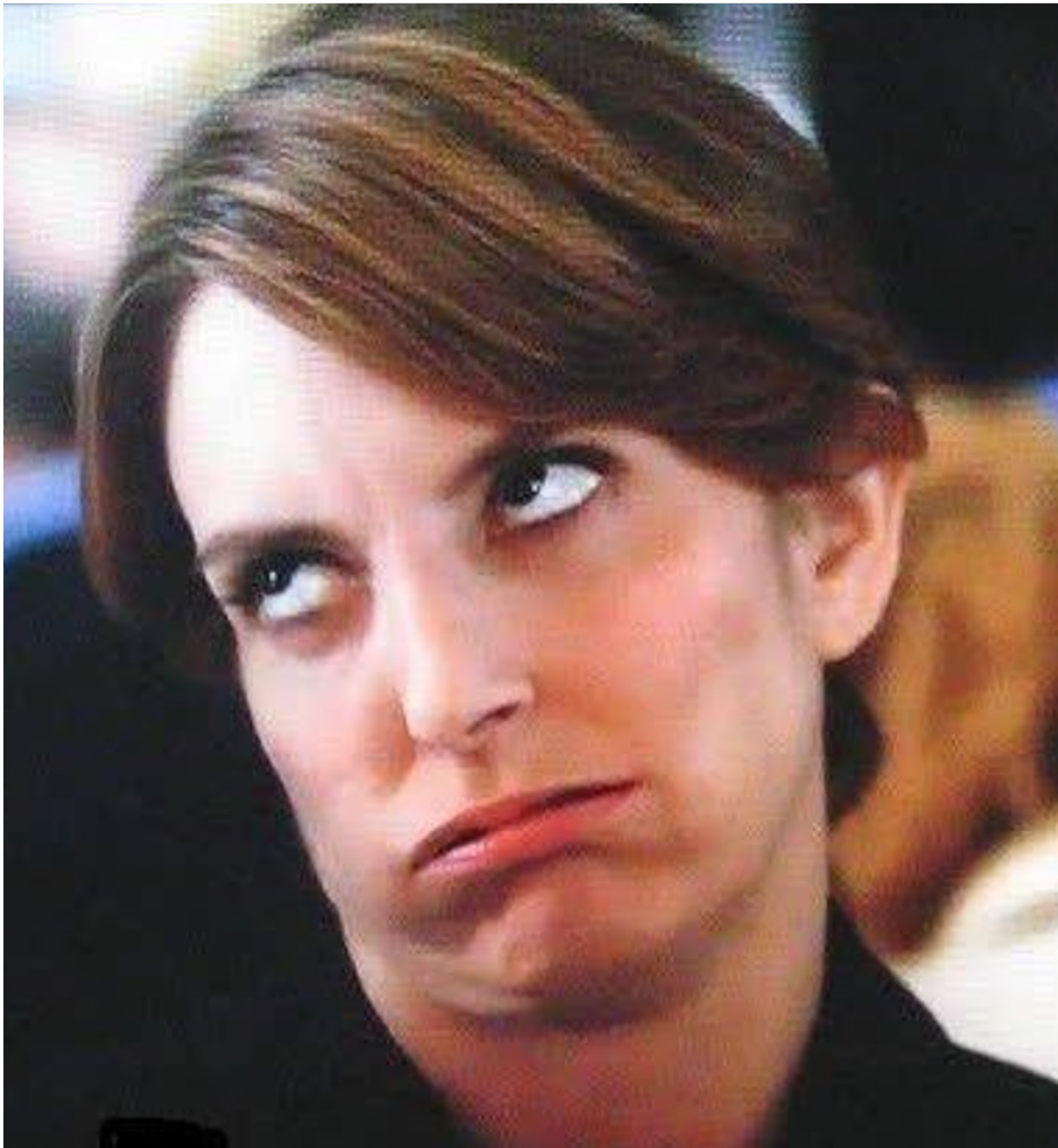
By the end of this session, participants will:

- Learn more about several recent landmark studies in cerebrovascular disease – *with a focus on secondary prevention.*
- Recognize the strengths and weaknesses of these studies.
- Be able to incorporate some of these new findings into clinical practice.

... But Secondary Prevention is Sooooo Boring...



- Target Blood Pressure to $< 140 / 90$ ($< 130/80$ for diabetics)
- Target LDL < 1.8
- Target A1c < 7
- Take aspirin or Plavix (or both, but not for too long)
- DOACs for Atrial Fibrillation if CrCl ok
- Endarterectomy (or Stenting) for $> 70\%$ carotid stenosis
- Stop smoking
- Eat a salad
- Go for a walk



**So why
bother
reviewing
secondary
prevention
today?**

Three Little Reasons...

1. Recurrent strokes contribute a disproportionate share to the overall national burden of stroke, principally due to costs associated with long-term disability (e.g. nursing home care and re-hospitalization) (Samsa et al., 1999).
2. Both men and women who have experienced a stroke have a significantly greater risk for MI than individuals with no history of stroke (RR= 1.6 and 1.9, respectively) (Appelros et al., 2011).
3. Successful, long-term secondary prevention helps to maintain regained function by reducing inpatient recidivism (Goldberg & Berger, 1988)



**Canadian Stroke
Best Practices**

CANADIAN STROKE BEST PRACTICE RECOMMENDATIONS

Secondary Prevention of Stroke

Seventh Edition, Update 2020

SECONDARY PREVENTION of STROKE Scientific Writing Group: David J. Gladstone (Co-Chair), Alexandre Y. Poppe (Co-Chair), James Douketis, William Semchuk, Aline Bourgoin, Afna Cox, John B. Falconer, Brett Brannam, Marilyn Labrie, Lena McDonald, Jennifer Manuzak, Amanda Rodgerson, Tammy Tebbutt, Carmen Tuchak, Jacob A Udell, Stephen van Gaal, Karina Villaluna, Dar Dowlatshahi, Shelagh Coutts, Theodore Wein, Rebecca McGuff, and M. Patrice Lindsay; on Behalf of the Canadian Stroke Best Practice Recommendations Advisory Committee, in collaboration with the Canadian Stroke Consortium.

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**Dr. Alex Poppe
(media darling)**

Recent evidence-based changes in treatment recommendations for secondary stroke prevention:

- A. Add on therapies for lipid lowering
- B. Short-term DAPT
- C. Anticoagulation for stroke and atrial fibrillation
- D. Extracranial carotid disease (dissection)
- E. Blood pressure in low-flow states
- F. Diabetes management

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A. Add-on therapies for lipid lowering

1. Ezetimibe for additional LDL lowering
2. PCSK9 inhibitors for additional LDL lowering
3. Icosapent ethyl for hypertriglyceridemia
4. A word about statin intolerance



1. Ezetimibe for additional LDL lowering

For individuals with ischemic stroke and atherosclerotic cardiovascular disease with an LDL > 1.8 mmol/L in spite of maximal tolerated statin therapy, ezetimibe may be considered for additional LDL lowering [Evidence Level B].

Amarenco et al. The Treat Stroke to Target Trial

The Treat Stroke to Target Trial

Amarenco et al. NEJM 2020;382:9-19

The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

JANUARY 2, 2020

VOL. 382 NO. 1

A Comparison of Two LDL Cholesterol Targets after Ischemic Stroke

P. Amarenco, J.S. Kim, J. Labreuche, H. Charles, J. Abtan, Y. Béjot, L. Cabrejo, J.-K. Cha, G. Ducrocq, M. Giroud, C. Guidoux, C. Hobeau, Y.-J. Kim, B. Lapergue, P.C. Lavallée, B.-C. Lee, K.-B. Lee, D. Leys, M.-H. Mahagne, E. Meseguer, N. Nighoghossian, F. Pico, Y. Samson, I. Sibon, P.G. Steg, S.-M. Sung, P.-J. Touboul, E. Touzé, O. Varenne, É. Vicaut, N. Yelles, and E. Bruckert, for the Treat Stroke to Target Investigators*

The Treat Stroke to Target Trial

Amarenco et al. NEJM 2020;382:9-19

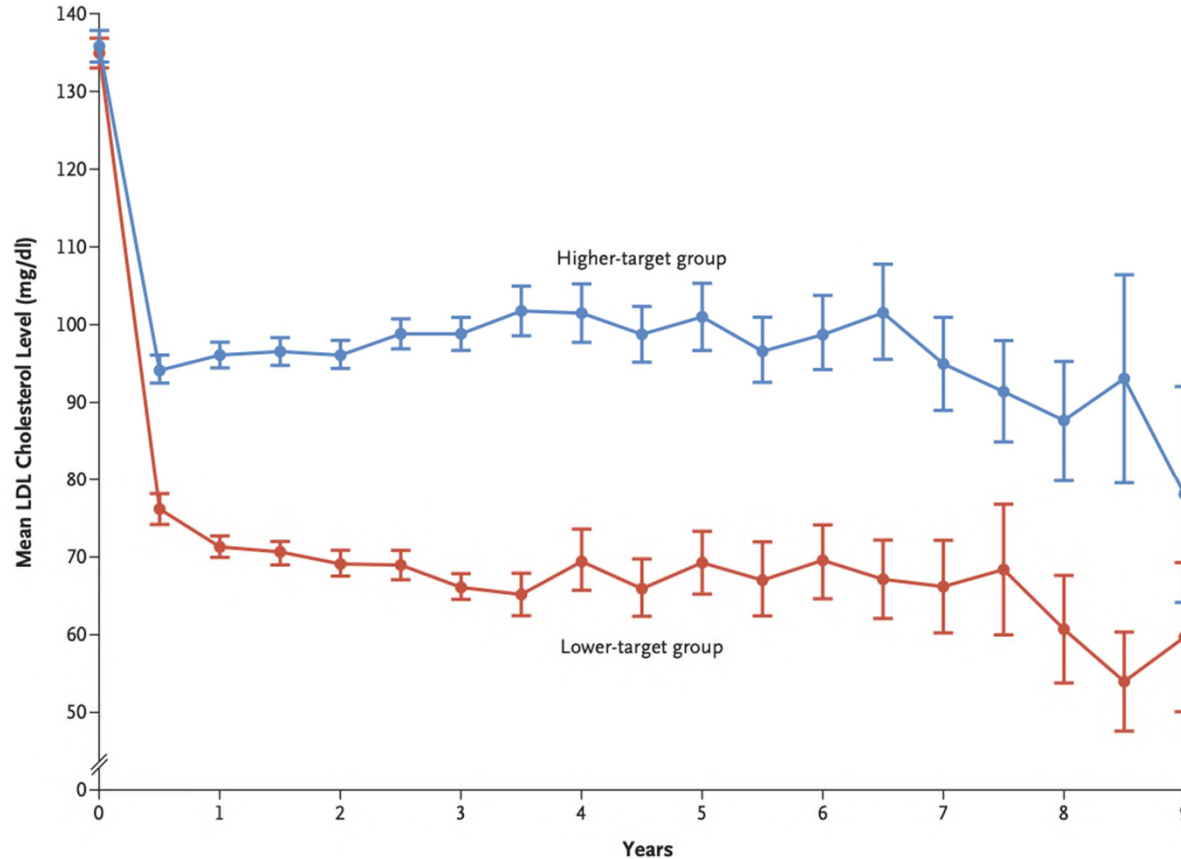
- 2,860 participants with ischemic stroke in the previous 3 months or a TIA within the previous 15 days, with confirmed atherosclerotic disease
- Randomized to a statin, or a statin + ezetimibe to achieve a target LDL cholesterol level of < 1.8 mmol/L, (lower-target group) or a target range of 2.3 to 2.8 mmol/L, (higher-target group), for the duration of the trial.
- After follow-up (mean 3.5 years), the mean LDL cholesterol was 1.7 mmol/L in the lower-target group and 2.5 mmol/L in the higher-target group.
- The primary outcome (risk of major cardiovascular events) was significantly lower in the lower-target group (8.5% vs. 10.9%, HR=0.78, 95% CI 0.61 to 0.98; $p=0.04$).

The Treat Stroke to Target Trial

Amarenco et al. NEJM 2020;382:9-19



A LDL Cholesterol Level, According to Target Group



No. at Risk

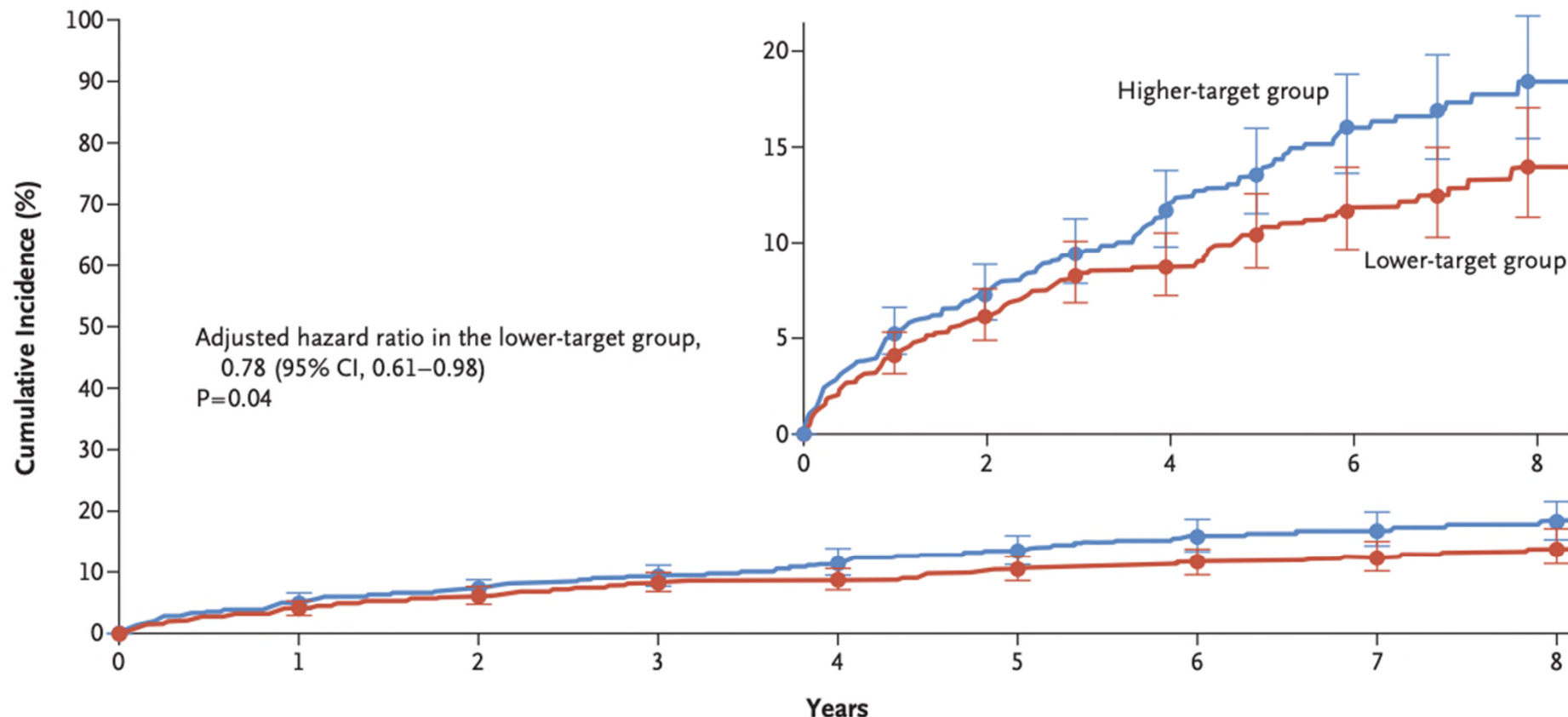
Higher target	1420	1115	989	787	792	681	598	292	242	185	164	133	114	80	83	67	31	22	5
Lower target	1414	1102	965	879	774	653	570	277	227	180	169	141	126	81	73	46	26	21	6
Absolute difference	-1.14	-18.3	-24.7	-26.1	-27.1	-29.8	-32.5	-36.6	-32.0	-32.8	-31.9	-29.5	-29.4	-34.6	-29.0	-23.2	-26.9	-39.2	-18.5



The Treat Stroke to Target Trial

Amarenco et al. NEJM 2020;382:9-19

B Primary End Point



No. at Risk

Higher target	1430	1146	973	730	590	487	392	253	106
Lower target	1430	1128	964	740	586	475	353	238	104

2. Addition of PCSK9 Inhibitors

PCSK9 = Pro-protein Convertase Subtilisin/Kexin type 9

evolocumab, alirocumab

*For individuals with concomitant atherosclerotic cardiovascular disease where target LDL level is not achievable, consider referral to a health professional with expertise in metabolic and lipid management, or stroke expertise for consideration of adding a PCSK9 inhibitor
[Evidence Level A].*

Schmidt et al. Cochrane Collaboration Systematic Review - 2020

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PCSK9 inhibitors for prevention of cardiovascular disease

Published:

20 October 2020

Authors:

Schmidt AF, Carter J-PL, Pearce LS,

Research question

What is the effectiveness and safety of PCSK9 inhibitors for cardiovascular disease (CVD) prevention?

Schmidt et al 2020

- Included the results of 20 RCTs examining the use of additional PCSK9 inhibitors in persons with and without established cardiovascular disease.
- Compared with placebo, at maximum follow-up of 6 - 36 months, treatment with a PCSK9 inhibitor was associated with a significantly reduced risk of any cardiovascular events (OR=0.86, 95% CI 0.80 to 0.92), and **any stroke** (OR=0.77, 95% CI 0.69 to 0.85).

Schmidt et al 2020

Authors' Conclusions:

The evidence for the clinical endpoint effects of ***evolocumab*** and ***alirocumab*** versus placebo were graded as high.

There is a strong evidence base for the benefits of PCSK9 monoclonal antibodies to people who might not be eligible for other lipid-lowering drugs, or to people who cannot meet their lipid goals on more traditional therapies, which was the main patient population of the available trials.

3. Icosapent ethyl for hypertriglyceridemia

*For ischemic stroke patients with established atherosclerotic cardiovascular disease or diabetes plus additional vascular risk factors, who have elevated serum triglyceride levels (≥ 1.5 mmol/L) despite statin therapy, **icosapent ethyl 2 g bid** may be considered to decrease the risk of vascular events [Level of Evidence B].*

Bhatt et al. The REDUCE-IT Trial

REDUCE-IT: Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia

Bhatt et al. NEJM 2019;380:11-22



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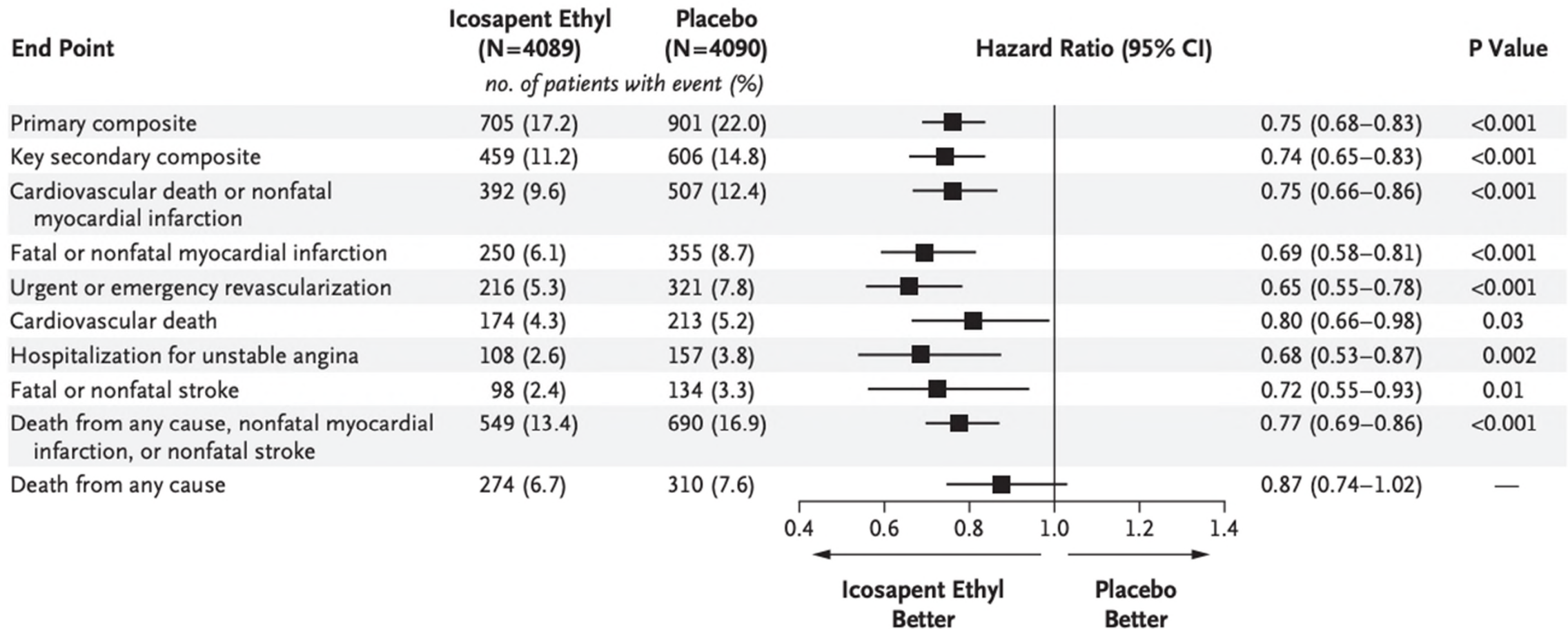
Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia

Deepak L. Bhatt, M.D., M.P.H., P. Gabriel Steg, M.D., Michael Miller, M.D., Eliot A. Brinton, M.D., Terry A. Jacobson, M.D., Steven B. Ketchum, Ph.D., Ralph T. Doyle, Jr., B.A., Rebecca A. Juliano, Ph.D., Lixia Jiao, Ph.D., Craig Granowitz, M.D., Ph.D., Jean-Claude Tardif, M.D., and Christie M. Ballantyne, M.D.,
for the REDUCE-IT Investigators*

REDUCE-IT: Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia

- 8,179 patients with established cardiovascular disease or with diabetes and other risk factors, who had a fasting triglyceride level of 1.52 to 5.63 mmol/L and an LDL level of 1.06 to 2.59 mmol/L were randomized to receive 2 grams of icosapent ethyl bid or placebo.
- After a median of 4.9 years, the risk of the primary outcome (composite of cardiovascular death, nonfatal MI, nonfatal stroke, coronary revascularization, or unstable angina), was significantly lower in the icosapent ethyl group (17.2% vs. 22%; HR=0.75, 95% CI 0.68-0.83, $p < 0.001$, NNT=21).
- The risk of ischemic stroke was also significantly lower in the icosapent ethyl group (2.0% vs. 3.0%, HR=0.64, 95% CI 0.49, 0.85).

REDUCE-IT: Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia



4. A Word About Statin Intolerance

For patients with an intolerance to statins (including persistent myalgias, persistent significant liver enzyme abnormalities or rarely, myopathy or rhabdomyolysis), the indication for statin therapy should be confirmed and in general, systematic evaluation of the contribution of statins to the patient's symptoms should be considered (including temporary statin cessation with observation of symptoms, dose-adjustment, use of alternate agents).

[Evidence Level C]

Recent evidence-based changes in treatment recommendations for secondary stroke prevention:

- A. Add on therapies for lipid lowering
- B. Short-term DAPT**
- C. Anticoagulation for stroke and atrial fibrillation
- D. Extracranial carotid disease (dissection)
- E. Blood pressure in low-flow states
- F. Diabetes management

B. Short-Term Dual Antiplatelet Therapy (DAPT)

1. ASA + ticagrelor
2. DAPT for symptomatic intracranial stenosis

1. ASA + Ticagrelor

A reasonable short-term dual antiplatelet treatment option is the combination of daily low-dose acetylsalicylic acid plus ticagrelor (180 mg loading dose, followed by 90 mg bid) for 30 days [Evidence Level B].

Johnston et al. The THALES Trial

Ticagrelor and Aspirin or Aspirin Alone in Acute Ischemic Stroke or TIA: THALES Trial

Johnston et al. NEJM 2020;383:207-17



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JULY 16, 2020

VOL. 383 NO. 3

Ticagrelor and Aspirin or Aspirin Alone in Acute Ischemic Stroke or TIA

S. Claiborne Johnston, M.D., Ph.D., Pierre Amarenco, M.D., Hans Denison, M.D., Ph.D., Scott R. Evans, Ph.D., Anders Himmelmann, M.D., Ph.D., Stefan James, M.D., Ph.D., Mikael Knutsson, Ph.D., Per Ladenvall, M.D., Ph.D., Carlos A. Molina, M.D., Ph.D., and Yongjun Wang, M.D., for the THALES Investigators*

Ticagrelor and Aspirin or Aspirin Alone in Acute Ischemic Stroke or TIA: THALES Trial

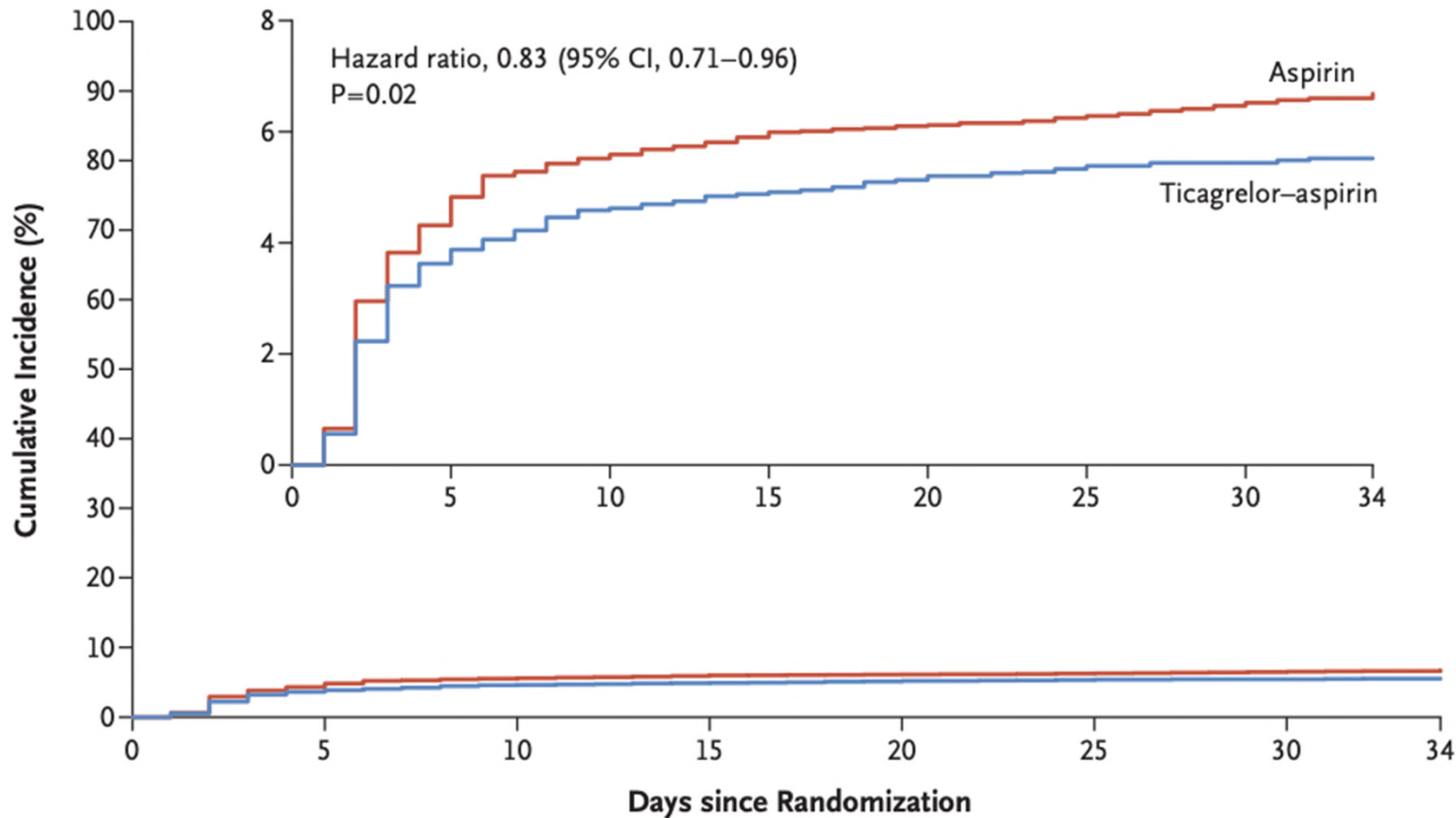
Johnston et al. NEJM 2020;383:207-17

- 75 to 100 mg of aspirin daily combined with 90 mg of ticagrelor bid significantly reduced the risk of recurrent stroke or death when compared with aspirin alone (5.5% vs. 6.6%, HR=0.83, 95% CI 0.71-0.96, $p=0.02$).
- The risk of ischemic stroke was also significantly lower in the ticagrelor–aspirin group (5.0% vs. 6.3%, HR=0.79, 95% CI 0.63-0.94, $p=0.04$), although **the risk of severe bleeding and intracranial hemorrhage or fatal bleeding** were each four times higher in the ticagrelor–aspirin group.

Ticagrelor and Aspirin or Aspirin Alone in Acute Ischemic Stroke or TIA: THALES Trial

Johnston et al. NEJM 2020;383:207-17

A Probability of Stroke or Death



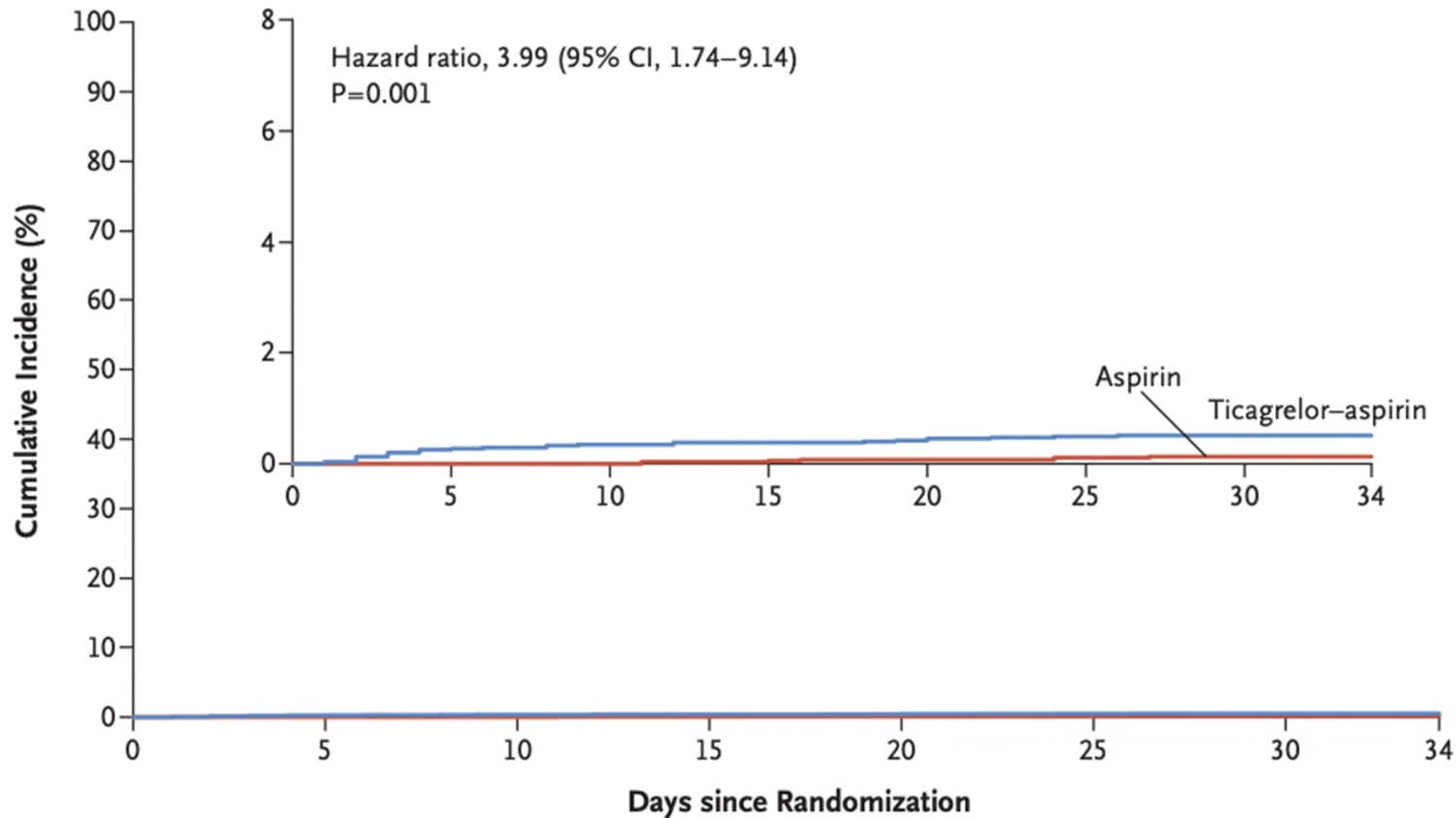
No. at Risk

Ticagrelor-aspirin	5523	5314	5257	5241	5227	5215	5209	1091
Aspirin	5493	5253	5181	5159	5146	5138	5126	1135

Ticagrelor and Aspirin or Aspirin Alone in Acute Ischemic Stroke or TIA: THALES Trial

Johnston et al. NEJM 2020;383:207-17

B Probability of Severe Bleeding



No. at Risk

Ticagrelor-aspirin	5523	5495	5471	5467	5463	5457	5456	1146
Aspirin	5493	5486	5464	5459	5454	5451	5450	1216

2. DAPT for symptomatic intracranial stenosis

*For patients with a recent stroke or transient ischemic attack due to symptomatic intracranial atherosclerotic stenosis of 70-99%, and a low estimated bleeding risk, the **SAMMPRIS protocol** should be considered, which includes:*

- dual antiplatelet therapy (acetylsalicylic acid and clopidogrel) for the first 3 months, followed by*
- antiplatelet monotherapy thereafter,*
- in addition to intensive lipid-lowering therapy with high-dose statin, blood pressure treatment, and structured lifestyle modification addressing smoking cessation, exercise and diet.*

[Evidence Level B]

SAMMPRIS Protocol

NEJM 2011;365:993-1003

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis

Marc I. Chimowitz, M.B., Ch.B., Michael J. Lynn, M.S., Colin P. Derdeyn, M.D.,
Tanya N. Turan, M.D., David Fiorella, M.D., Ph.D., Bethany F. Lane, R.N.,
L. Scott Janis, Ph.D., Helmi L. Lutsep, M.D., Stanley L. Barnwell, M.D., Ph.D.,
Michael F. Waters, M.D., Ph.D., Brian L. Hoh, M.D., J. Maurice Hourihane, M.D.,
Elad I. Levy, M.D., Andrei V. Alexandrov, M.D., Mark R. Harrigan, M.D.,
David Chiu, M.D., Richard P. Klucznik, M.D., Joni M. Clark, M.D.,
Cameron G. McDougall, M.D., Mark D. Johnson, M.D., G. Lee Pride, Jr., M.D.,
Michel T. Torbey, M.D., M.P.H., Osama O. Zaidat, M.D.,
Zoran Rumboldt, M.D., and Harry J. Cloft, M.D., Ph.D.,
for the SAMMPRIS Trial Investigators*

Recent evidence-based changes in treatment recommendations for secondary stroke prevention:

- A. Add on therapies for lipid lowering
- B. Short-term DAPT
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- D. Extracranial carotid disease (dissection)
- E. Blood pressure in low-flow states
- F. Diabetes management

C. Anticoagulation for Stroke and Atrial Fibrillation

For patients with atrial fibrillation who experience ischemic stroke or transient ischemic attack *in spite of* anticoagulant therapy, we recommend the following:

- (1) identify and address medication nonadherence;
- (2) ensure correct DOAC dosing or warfarin INR control;
- (3) avoid DOACs drug-drug interactions;
- (4) investigate for and treat other potential stroke etiologies, and
- (5) promote general vascular risk factor modification.

[Evidence Level C]

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- E. Blood pressure in low-flow states
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D. Extracranial Carotid Disease (Dissection)

- Antithrombotic therapy for stroke prevention is recommended for individuals with a diagnosis of an acute or recent extracranial carotid or vertebral artery dissection.
[Evidence Level B]

D. Extracranial Carotid Disease (Dissection)

- There is **uncertainty about the comparative efficacy of antiplatelet therapy vs. anticoagulation** with heparin or warfarin; either treatment is considered reasonable based on current evidence.
[Evidence Level B]
- Decisions should be based on individual risk/benefit analysis taking into consideration the imaging features of the dissection (presence and degree of stenosis, intraluminal thrombus, vessel occlusion, pseudoaneurysm), brain imaging, patient characteristics, and estimated bleeding risk.
[Evidence Level C]

Antiplatelet Therapy vs Anticoagulation Therapy in Cervical Artery Dissection

Markus et al JAMA Neurol. 2019;76(6):657-664

JAMA Neurology | **Original Investigation**

Antiplatelet Therapy vs Anticoagulation Therapy in Cervical Artery Dissection

The Cervical Artery Dissection in Stroke Study (CADISS) Randomized Clinical Trial Final Results

Hugh S. Markus, FMedSci; Christopher Levi, MD; Alice King, PhD; Jeremy Madigan, FRCR; John Norris, MD; for the Cervical Artery Dissection in Stroke Study (CADISS) Investigators



Antiplatelet Therapy vs Anticoagulation Therapy in Cervical Artery Dissection

Markus et al JAMA Neurol. 2019;76(6):657-664

- Two hundred fifty patients were randomized (118 carotid and 132 vertebral), 126 to antiplatelet therapy and 124 to anticoagulation.
- The recurrent stroke rate at 1 year was 6 of 250 (2.4%) on ITT analysis.
- There were no significant differences between treatment groups for any outcome.
- Of the 181 patients with confirmed dissection and complete imaging at baseline and 3 months, there was no difference in the presence of residual narrowing or occlusion between those receiving AP (n = 56 of 92) vs those receiving AC (n = 53 of 89) (P = .97).



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- E. **Blood pressure in low-flow states**
- F. Diabetes management

BP in low-flow states

- For patients with a non-revascularized critical intracranial or extracranial arterial stenosis who are experiencing neurological symptoms attributed to hemodynamic (low flow) cerebral or retinal ischemia (e.g. orthostatic TIAs), it is reasonable to aim for higher than usual blood pressure targets (i.e. permissive hypertension), and avoidance of hypotension, for prevention of hemodynamic stroke.
- If such patients are asymptomatic, then usual blood pressure targets should be followed in the post-acute phase of stroke.

Clinical Consideration

Recent evidence-based changes in treatment recommendations for secondary stroke prevention:

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- E. Blood pressure in low-flow states
- F. **Diabetes management**

Diabetes Management

- In patients with stroke and type 2 diabetes in whom glycemic targets are not achieved with standard oral antihyperglycemic medications, an antihyperglycemic agent with demonstrated benefit on major cardiovascular outcomes (for example, SGLT-2 inhibitors or GLP-1 receptor agonists) should be considered [Evidence Level B].

As discussed by Dr. Carpentier in his presentation earlier today!

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Secondary Prevention Is Crucial for our Patients



- *Target Blood Pressure to $< 140 / 90$ ($< 130/80$ for diabetics)*
- *Target LDL < 1.8*
- *Target A1c < 7*
- *Take aspirin or Plavix (or both, but not for too long)*
- *DOACs for Atrial Fibrillation if CrCl ok*
- *Endarterectomy (or Stenting) for $> 70\%$ carotid stenosis*
- **Stop smoking**
- **Eat a salad**
- **Go for a walk**

Thank you!!

www.strokebestpractices.ca



Canadian Stroke Best Practices