Evidence Development and Standards Branch at Health Quality Ontario

Special Report

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Perioperative Heparin Bridging Therapy Following Warfarin Interruption

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Context

Opinion varies about how to manage patients on anticoagulant medication who need to undergo surgery or another invasive procedure. The risk of bleeding must be counterbalanced with the risk of arterial thrombosis.

Research Question

Which patients should receive bridging with low molecular weight heparin or unfractionated heparin during warfarin interruption for surgical and other invasive procedures?

Conclusion

Although heparin bridging reduced the risk of thromboembolism by about 17%, risk of major bleeding or pocket hematoma was approximately 4 times higher in patients who received heparin bridging than in those who did not. Weighing these competing risks in the context of the individual patient is critical for preventing undesirable outcomes.

Methodology

Research questions are developed by Choosing Wisely Canada, in consultation with experts, end users, and/or applicants in the topic area. Evidence Development and Standards then produces one of two types of rapid reviews, or a special report to answer the research question. A rapid review of Systematic Reviews is conducted when a systematic literature search identifies relevant systematic reviews, health technology assessments, or meta-analyses that meet the inclusion criteria specified in the methods section. A rapid review of primary studies is conducted when none of the aforementioned study designs are available. On occasion, a special report may be provided that does not strictly follow the rapid review methodology set out by HQO. These reports are completed in a 2- to 8-week time frame. For more detail on rapid review methodology, please visit the Health Quality Ontario website at: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/rapid-reviews.

Context

Choosing Wisely Canada is a national campaign that aims to help physicians and patients engage in informative conversations about tests, treatments, and procedures, and help physicians and patients make smart and effective choices to ensure high-quality care. It will support physicians as they work with patients to ensure they not only get the care they need, but avoid tests, treatments, and procedures that have no value and could cause them harm.

As part of this campaign, Health Quality Ontario (HQO) has developed rigorous, evidence-based reviews of tests, treatments, and/or procedures that may be overused. Choosing Wisely Canada has made recommendations based on the evidence provided by HQO. These recommendations are available on the Choosing Wisely Canada website.

Objective

The objective was to investigate the safety and effectiveness of heparin bridging therapy during warfarin interruption for surgical and invasive procedures.

Clinical Need and Target Population

Description of Disease/Condition

Opinion varies about how to manage patients on anticoagulant medication who need to undergo surgery or another invasive procedure. The risk of bleeding during and after the procedure must be counterbalanced with the risk of arterial thrombosis if the anticoagulant medication is disrupted.

The risk of bleeding is affected by the type of surgery or invasive procedure; for example, radiofrequency catheter ablation or atrial fibrillation can be safely performed without increased risk of bleeding and do not require interruption of anticoagulants. (1) The risk of thrombus formation is also related to the type of surgery or procedure, and it varies by individual patient characteristics; for example, a patient with atrial fibrillation and a previous stroke might be at a greater risk than a patient without previous stroke.

Technology/Technique

Bridging therapy is the administration of a short-acting anticoagulant—such as low molecular weight heparin (LMWH) or unfractionated heparin (UFH)—while a long-acting anticoagulant such as warfarin is withheld. (2) However, a lack of high-quality data has made it difficult for clinicians to follow a standardized strategy for the management of patients on anticoagulant medications who are undergoing a surgical or invasive procedure. The need for bridging therapy depends on the risk of thrombosis during anticoagulant disruption.

The American College of Chest Physicians (ACCP) guidelines recommend stopping vitamin K antagonists (VKAs) and starting bridging anticoagulation 5 days before major surgery in patients with a mechanical heart valve, atrial fibrillation, or venous thromboembolism (VTE) who are at high risk of thromboembolism. (3) For similar patients at low risk for thromboembolism, the guidelines suggest using no bridging anticoagulation.

Question, Methods, and Findings

Research Question

Which patients should receive bridging with low molecular weight heparin or unfractionated heparin during warfarin interruption for surgical and other invasive procedures?

Methods

See Appendix 1 for a detailed description of the search strategy, including terms and results.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2009, and July 29, 2014
- systematic reviews, meta-analyses, and health technology assessments that investigated outcomes of perioperative heparin bridging and no heparin bridging during warfarin interruption
- studies reporting thromboembolic and bleeding events as outcomes

Exclusion Criteria

- reports on patients less than 18 years of age
- studies comparing continued warfarin versus heparin bridging
- studies comparing outcomes of patients on heparin bridging versus those of patients not on chronic anticoagulation therapy
- studies with unclear reporting of thromboembolic or bleeding events

Outcomes of Interest

- rate of thromboembolism as reported by the authors
- rate of major bleeding events as reported by the authors
- hospital stay (days)
- mortality

Findings

The database search yielded 201 citations published between January 1, 2009, and July 29, 2014 (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

Two systematic reviews (4;5) met the inclusion criteria. The reference lists of the included studies were hand-searched to identify other relevant studies, but no additional citations were included.

One of the systematic reviews (4) was conducted in the Netherlands and included 17 studies; the other (5) was conducted in Canada and included 34 studies. However, because a number of studies from the 2 systematic reviews were ineligible for inclusion in our analysis, we undertook a review of primary studies. Nineteen studies were single-arm; 8 appeared in both reviews; and 13 were unrelated to the

research question (studies comparing heparin bridging with uninterrupted warfarin, studies comparing uninterrupted warfarin with warfarin cessation with no bridging, studies comparing heparin bridging with no prior chronic anticoagulation therapy, and studies comparing different bridging protocols). The remaining 11 studies were selected for analysis.

For each included study, the study design was identified and is summarized below in Table 3, a modified version of a hierarchy of study design by Goodman, 1996. (6)

Table 3: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCTs	
Systematic review of RCTs	
Large RCT	
Small RCT	
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with contemporaneous controls	4
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	
Database, registry, or cross-sectional study	
Case series	
Retrospective review, modelling	7
Studies presented at an international conference	
Expert opinion	
Total	**11**

Abbreviations: RCT, randomized controlled trial.

Table 4 shows study characteristics and outcomes for a range of surgical and invasive procedures; Table 5 shows study characteristics and outcomes for cardiac device implantation.

Table 4: Patients Undergoing Different Types of Surgical and Invasive Procedures

Study	Design, Follow-up	Patients	Procedure	Heparin	Bridged/Not Bridged					
					N	Thrombo-embolism, N (%)	Major Bleeding, N (%)	Minor Bleeding, N (%)	Mean Hospital Stay, Days	Mortality, %
McBane et al, 2010 (7)	Prospective cohort, 3 months	VTE	Orthopedic: 26% GI: 24% Urologic: 11%, Cardiothoracic: 9% Gynecologic: 7% Neurosurgical: 6% Other: 17%	LMWH	499/256	10/499 (2.0) 6/256 (2.3)	14/499 (2.8) 2/256 (0.8)	20/499 (4.0) 3/256 (1.2)	NR	2.0/1.2
Jaffer et al, 2010 (8)	Prospective cohort, 1 month	AF: 43.1% VTE: 28.7% MHV: 10.4% Multiple indications: 8.1% Other: 9.8%	Minor (ophthalmic, hand and foot, arthroscopic, cutaneous, dental, endoscopic): 62.7% General (abdominal, retroperitoneal): 12.6% Angiography: 11.8% Major orthopedic: 8.9% Other major: 4.1%	Heparin/ LMWH	161/263	0/161 (0) 3/263 (1.1)	11/161 (6.8) 3/263 (1.1)	11/161 (6.8) 4/263 (1.5)	NR	0.6/0
Daniels et al, 2009 (9)	Retrospective cohort, 3 months	MHV	GI endoscopy: 19.1% General, vascular, and gynecologic surgery: 15% Urologic surgery and procedures: 14% Orthopedic surgery: 10.3% Angiography/ transcatheter interventions: 10.5% Other: 31.1%	LMWH or UFH	342/213	4/342 (1.2) *LMWH: 2/243 (0.8)* *UFH: 2/99 (2.0)* 1/213 (0.5)	15/342 (4.4) *LMWH: 9/243 (3.7)* *UFH: 6/99 (6.1)* 5/213 (2.3)	21/342 (6.1) *LMWH: 13/243 (5.3)* *UFH: 8/99 (8.1)* 13/213 (6.1)	NR	NR
Wysokinski et al, 2008 (10)	Prospective cohort, 3 months	Non-valvular AF	Orthopedic: 21% GI: 20% Urologic: 18% Cardiovascular: 14% Ophthalmologic: 5%	LMWH	204/182	3/204 (1.5) 3/182 (1.6)	6/204 (2.9) 4/182 (2.2)	9/204 (4.4) 2/182 (1.1)	NR	0/0

Study	Design, Follow-up	Patients	Procedure	Heparin	Bridged/Not Bridged					
					N	Thrombo-embolism, N (%)	Major Bleeding, N (%)	Minor Bleeding, N (%)	Mean Hospital Stay, Days	Mortality, %
			Dental extraction: 5% Vascular: 5% Neurologic: 4% Gynecologic: 2% Other: 7%							
Garcia et al, 2008 (11)	Prospective cohort, 1 month	Mostly AF, VTE, and MHV	Colonoscopy, oral, and ophthalmic surgery	LMWH	108/ 1,185	0/108 (0) 7/1,185 (0.6)	4/108 (3.7) 2/1,185 (0.2)	10/108 (9.3) 7/1,185 (0.6)	NR	NR
Krane et al, 2008 (12)	Retrospective cohort	AF: 58% History of TE event: 22% Other: 20%	Robotic-assisted radical prostatectomy	LMWH	14/43	0/14 (0) 1/43 (2.3)	**Blood Transfusion** 3/14 (21.4) 1/43 (2.3) P = 0.042		2.2/1.2 P = 0.049	NR

Abbreviations: AF, atrial fibrillation; GI, gastrointestinal; LMWH, low molecular weight heparin; MHV, mechanical heart valve; NR, not reported; TE, thromboembolic; UFH, unfractionated heparin; VTE, venous thromboembolism.

Table 5: Patients Undergoing Cardiac Device Implantation

Study	Design, Follow-up	Device Implanted	Heparin	Bridged/Not Bridged				
				N	Thrombo-embolism, N (%)	Bleeding, N (%)	Mean Hospital Stay, Days ± SD	Mortality, %
Li et al, 2011 (13)	Retrospective cohort, 4 weeks	PM or ICD	LMWH or UFH	199/243	1/199 (0.5) 0/243 (0)	**Bleeding** 14/199 (7.0) 5/243 (2.1) PM: 7/131 (5.3) vs. 3/151 (2.0) ICD: 3/23 (13) vs. 0/8 (0) CRT: 0/19 (0) cs. 1/31 (3.2) Generator replacement: 4/19 (21.1) vs. 1/50 (2.0) Lead revision: 0/7 (0) vs. 0/3 (0) **Blood Transfusion** 5/199 (2.5) 0/243 (0)	6.0/1.0 (median)	NR

Study	Design, Follow-up	Device Implanted	Heparin	Bridged/Not Bridged				
				N	Thrombo-embolism, N (%)	Bleeding, N (%)	Mean Hospital Stay, Days ± SD	Mortality, %
Ahmed et al, 2010 (14)	Retrospective cohort, 4 weeks	PM or ICD	LMWH	123/114	**TIA** 1/123 (0.8) 4/114 (3.5) **Stroke, DVT, PE** 0/0	**Pocket Hematoma** 7/123 (5.7) 2/114 (1.75) No hemothorax, pericardial temponade, or other major bleeding	2.27 ± 0.21 1.23 ± 0.13	0/0
Ghanbari et al, 2010 (15)	Retrospective cohort, 4 weeks	CRT-D	LMWH or UFH	29/74	NR	**Pocket Hematoma** 6/29 (20.7) 3/74 (4.1) OR, 6.17 (1.6–24); P = 0.014	3.7 ± 3.2 1.6 ± 1.6 P < 0.001	NR
Tompkins et al, 2010 (16)	Retrospective cohort	PM or ICD	LMWH or UFH	155/258	**Stroke/TIA** 1/155 (0.7) 1/258 (0.4) **MI** 0/155 (0) 0/258 (0) **DVT/UE** 0/155 (0) 1/258 (0.4)	**Significant Bleeding**[a] 23/155 (14.8) 11/258 (4.3) P < 0.001	NR	NR
Chow et al, 2010 (17)	Retrospective cohort	Permanent PM	LMWH or IV heparin	32/46	NR	**Pocket Hematoma** 21/32 (65.6) 0/46 (0)	Median with hematoma: 8 Median without hematoma: 1	NR

Abbreviations: CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization with PM and ICD function; DVT, deep vein thrombosis; ICD, implantable cardioverter defibrillator; LMWH, low molecular weight heparin; MI, myocardial infarction; OR, odds ratio; PE, pulmonary embolism; PM, pacemaker; NR, not reported; TIA, transient ischemic attack; UE, upper extremity; UFH, unfractionated heparin; VTE, venous thromboembolism.

[a]Significant bleeding was defined as the need for pocket exploration, blood transfusion, hematoma requiring pressure dressing, change in medical therapy, or prolonged hospitalization

We performed meta-analyses to obtain pooled summary estimates for the risk of thromboembolism and major bleeding or pocket hematoma. The results of the meta-analyses are displayed in Figures 1 and 2. There was no heterogeneity among studies for the outcomes investigated.

There was no significant difference in risk of thromboembolism between patients who received heparin bridging and those who did not.

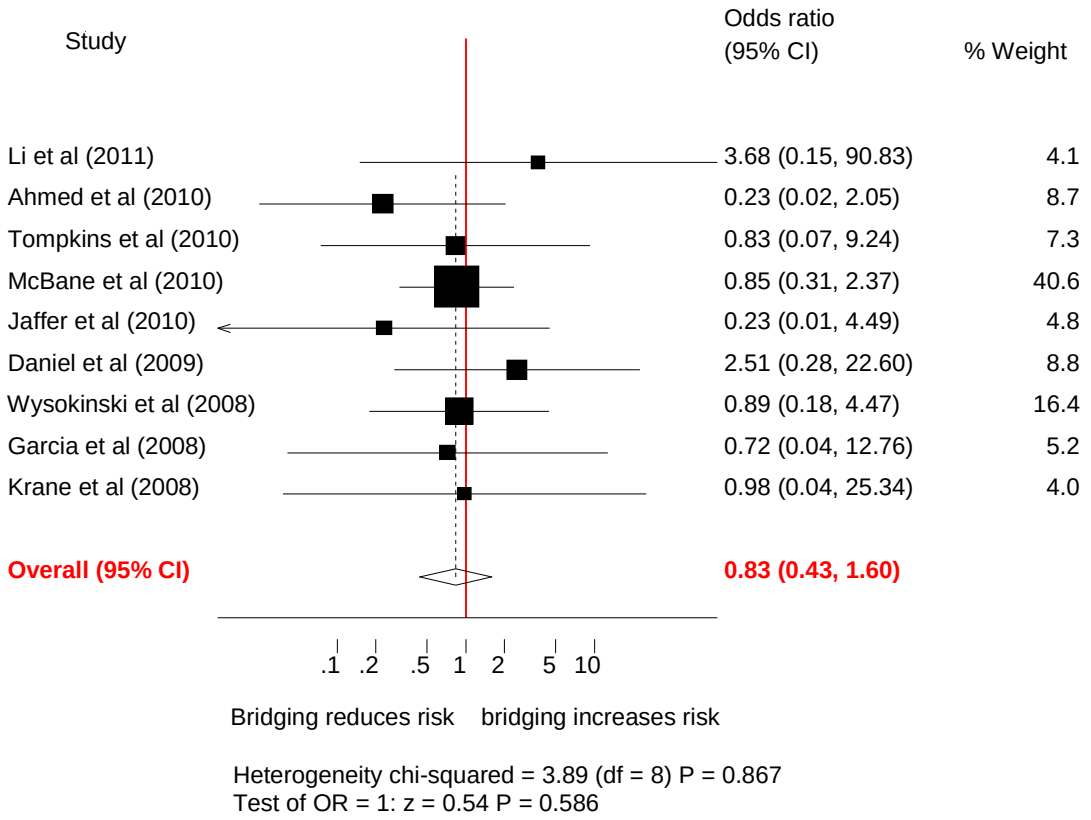

Figure 1: The Effect of Heparin Bridging on the Risk of Thromboembolism
Abbreviations: CI, confidence interval; df, degrees of freedom; OR, odds ratio.

There was a significant increase in the risk of major bleeding or pocket hematoma between patients who received heparin bridging and those who did not. Removing the outlier study by Chow et al (17) from the analysis did not significantly affect the point estimate.

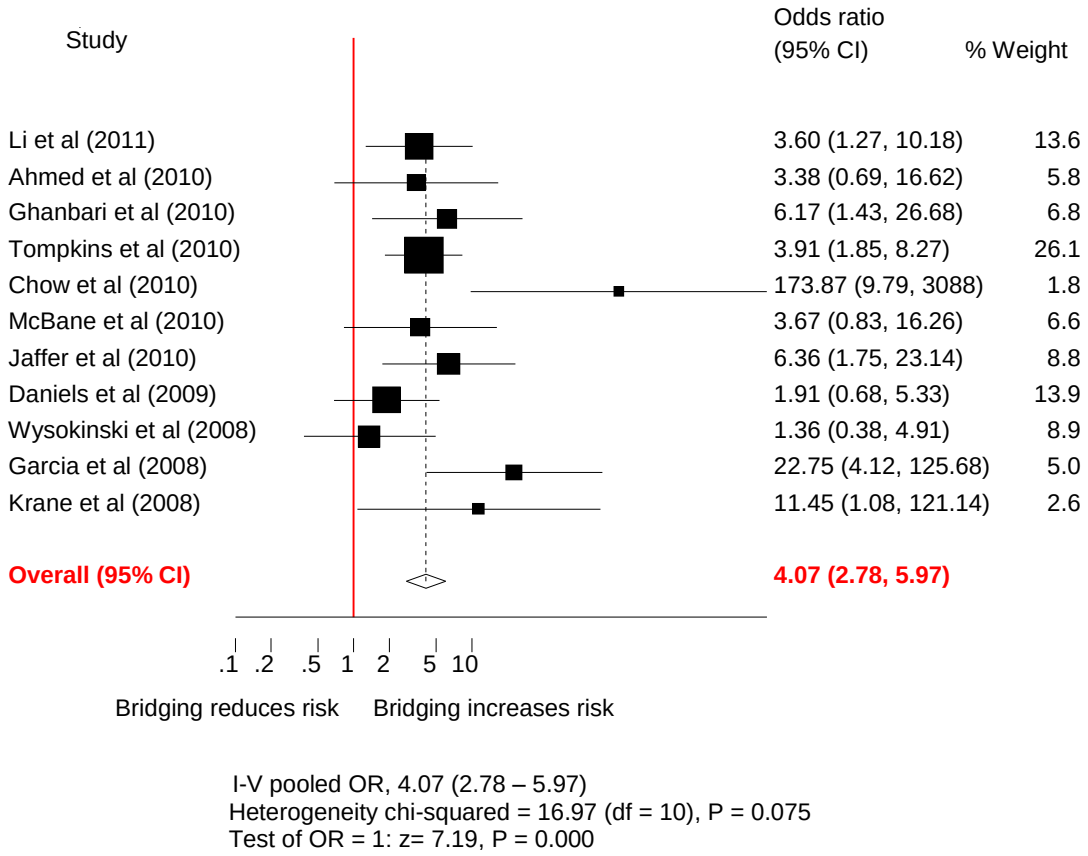

Figure 2: The Effect of Heparin Bridging on the Risk of Bleeding
Abbreviations: CI, confidence interval; df, degrees of freedom; I-V, instrumental variable; OR, odds ratio.

Length of hospital stay was reported by 5 studies. (12-15;17) Two studies (12;18) reported a significantly higher length of hospital stay for patients who received heparin bridging compared to those who did not.

Mortality was reported in 4 studies (7;8;10;14), but 2 of these reported no mortality in either arm. Due to the low event rate, no further analysis was performed for this outcome.

Conclusions

Low-quality evidence showed that although heparin bridging reduced the risk of thromboembolism by about 17%, risk of major bleeding or pocket hematoma was approximately 4 times higher in patients who received heparin bridging than in those who did not. Because thromboembolism is associated with significant morbidity, weighing these competing risks in the context of the individual patient is critical for preventing undesirable outcomes.

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Appendices

Appendix 1: Research Methods

Literature Search Strategy

A literature search was performed on July 29, 2014, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid Embase, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), and EBM Reviews, for studies published from January 1, 2009, to July 29, 2014. Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Search Results

Search date: July 29, 2014
Librarians: Caroline Higgins and Corinne Holubowich
Databases searched: Ovid MEDLINE, Ovid MEDLINE In-Process All EBM Databases (see below)

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 2014>, EBM Reviews - ACP Journal Club <1991 to July 2014>, EBM Reviews - Database of Abstracts of Reviews of Effects <2nd Quarter 2014>, EBM Reviews - Cochrane Central Register of Controlled Trials <June 2014>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <2nd Quarter 2014>, EBM Reviews - NHS Economic Evaluation Database <2nd Quarter 2014>, Ovid MEDLINE(R) <1946 to July Week 3 2014>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <July 28, 2014>

Search Strategy:
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1 Perioperative Care/ or Intraoperative Care/ or Preoperative Care/ or Perioperative Period/ or Intraoperative Period/ or Preoperative Period/ (92483)
2 (pre?operat* or pre?an?esthe* or pre-surg* or peri?operat* or intra?operat*).ti,ab. (321927)
3 Warfarin/ (15861)
4 (warfarin or marevan or coumadin or coumadine or warfant or aldocumar or tedicumar or ((anticoagula* or antagonist*) adj vitamin K)).mp. (24668)
5 or/1-4 (387815)
6 Heparin/ or exp Heparin, Low-Molecular-Weight/ (60069)
7 (heparin or heparinic or LMWH).mp. (91602)
8 or/6-7 (93249)
9 5 and 8 (8306)
10 Meta Analysis.pt. (50472)
11 Meta-Analysis/ or Meta-Analysis as Topic/ or exp Technology Assessment, Biomedical/ (72636)
12 (((systematic* or methodologic*) adj3 (review* or overview*)) or pooled analysis or published studies or published literature or hand search* or handsearch* or medline or pubmed or embase or cochrane or cinahl or data synthes* or data extraction* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab. (185390)
13 (meta analy* or metaanaly* or health technolog* assess*).mp. (134212)
14 or/10-13 (265722)
15 9 and 14 (454)
16 limit 15 to (english language and yr="2009 -Current") [Limit not valid in CDSR,ACP Journal Club,DARE,CLCMR; records were retained] (218)
17 remove duplicates from 16 (207)

Appendix 2: Evidence Quality Assessment

Evaluation of Evidence

The quality of the body of evidence for each outcome was examined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. (19) The overall quality was determined to be high, moderate, low, or very low using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials (RCTs) are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that may raise the quality of evidence were considered: the large magnitude of effect, the dose response gradient, and any residual confounding factors. (19) For more detailed information, please refer to the latest series of GRADE articles. (19)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of the effect

Table A1: GRADE Evidence Profile for Comparison of Outcomes of Heparin Bridging Following Warfarin Interruption

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
Risk of Thromboembolism							
9 (observational)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	No serious limitations	Undetected	None	⊕⊕ Low
Risk of Bleeding							
11 (observational)	Serious limitations (–1)[a]	No serious limitations	No serious limitations	No serious limitations	Undetected	None	⊕⊕ Low

[a]Observational studies.

Table A2: Risk of Bias Among Observational Trials for the Comparison of Thromboembolic Rates

Author, Year	Appropriate Eligibility Criteria	Appropriate Measurement of Exposure	Appropriate Measurement of Outcome	Adequate Control for Confounding	Complete Follow-Up[a]
McBane et al, 2010 (7)	No limitations	No limitations	No limitations	No limitations	No limitations
Jaffer et al, 2010 (8)	No limitations	No limitations	No limitations	No limitations	Limitations[a]
Daniels et al, 2009 (9)	No limitations	No limitations	No limitations	No limitations	No limitations
Wysokinski et al, 2008 (10)	No limitations	No limitations	No limitations	No limitations	No limitations
Garcia et al, 2008 (11)	No limitations	No limitations	No limitations	No limitations	Limitations[a]
Krane et al, 2008 (12)	No limitations	No limitations	No limitations	No limitations	Limitations[a]
Li et al, 2011 (13)	No limitations	No limitations	No limitations	No limitations	Limitations[a]
Ahmed et al, 2010 (14)	No limitations	No limitations	No limitations	No limitations	Limitations[a]
Tompkins et al, 2010 (16)	No limitations	No limitations	No limitations	No limitations	Limitations[a]

[a]Guidelines have designated 3 months as the necessary requirement for thromboembolic events.

Table A3: Risk of Bias Among Observational Trials for the Comparison of Bleeding Rates

Author, Year	Appropriate Eligibility Criteria	Appropriate Measurement of Exposure	Appropriate Measurement of Outcome	Adequate Control for Confounding	Complete Follow-Up
McBane et al, 2010 (7)	No limitations	No limitations	No limitations	No limitations	No limitations
Jaffer et al, 2010 (8)	No limitations	No limitations	No limitations	No limitations	No limitations
Daniels et al, 2009 (9)	No limitations	No limitations	No limitations	No limitations	No limitations
Wysokinski et al, 2008 (10)	No limitations	No limitations	No limitations	No limitations	No limitations
Garcia et al, 2008 (11)	No limitations	No limitations	No limitations	No limitations	No limitations
Krane et al, 2008 (12)	No limitations	No limitations	No limitations	No limitations	No limitations
Li et al, 2011 (13)	No limitations	No limitations	No limitations	No limitations	No limitations
Ahmed et al, 2010 (14)	No limitations	No limitations	No limitations	No limitations	No limitations
Ghanbari et al, 2010 (15)	No limitations	No limitations	No limitations	No limitations	No limitations
Tompkins et al, 2010 (16)	No limitations	No limitations	No limitations	No limitations	No limitations
Chow et al, 2010 (17)	No limitations	No limitations	No limitations	No limitations	No limitations

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Disclaimer

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Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

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To create its CWC reports, the Evidence Development and Standards branch and its research partners review the available scientific literature, making every effort to consider all relevant national and international research and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

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