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ORIGINAL ARTICLE

Extended-duration thromboprophylaxis for abdominopelvic surgery: Development and evaluation of a risk-stratified patient decision aid to facilitate shared decision making

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Abstract

Background: Extended-duration thromboprophylaxis is used to decrease risk of venous thromboembolism (VTE) after surgery but may increase the risk of bleeding. The decision to complete a course of extended-duration thromboprophylaxis can be challenging.

Objective: The objective of this study was to develop an acceptable patient decision aid (PtDA) to facilitate shared decision making for the use of extended-duration thromboprophylaxis following major abdominal surgery.

Methods: An evidence-based, risk-stratified PtDA was created. The evidence on benefits and harms of a 28-day postoperative course of low-molecular-weight heparin (LMWH) versus in-hospital prophylaxis only were synthesized. Outcomes included minor bleeding, major bleeding, clinically significant VTE, and fatal VTE. Risks were calculated and reported by Caprini score. Alpha testing of the PtDA draft with various stakeholders was performed using a 10-question survey to assess acceptability of the PtDA with patients, thrombosis experts, and surgeons. The primary outcome was the acceptability of the PtDA.

Results: Acceptability testing was performed with 11 patients, 11 thrombosis experts, and 11 surgeons. Most responders felt the language on the PtDA was easy to follow (28/33, 85%), and that the information was well balanced between management options (9/11 [82%] patients; 17/21 [80%] clinicians). Most patients (9/11, 82%) and clinicians (18/22, 82%) believed it would be a useful clinical tool, and were satisfied with the overall quality of the PtDA (27/33, 82%).

Conclusions: A risk-stratified, evidence-based PtDA was created to facilitate shared decision making for the use of extended-duration LMWH following major abdominal

Name of Institution where work was carried out: The Ottawa Hospital, Ottawa, ON, Canada

surgery. This clinical tool was acceptable with patients and physicians and is available at https://decisionaid.ohri.ca/decaids.html.

KEYWORDS
decision aid, decision support techniques, decision making, surgery, venous thromboembolism

Essentials

- A patient decision aid for extended use of blood thinners was created.
- This decision aid was acceptable to patients and clinicians.
- Eighty-two percent of patients who used it recommend this decision aid for other patients.
- Eighty-two percent of clinicians plan to use this decision aid in their practice.

1 | INTRODUCTION

Clinically detected venous thromboembolism (VTE) as a complication of surgery has been historically associated with a significant risk of mortality.[1,2] Asymptomatic deep vein thrombosis detected on screening ultrasound is often used as a surrogate outcome measure in VTE-related research given the low incidence of symptomatic or fatal VTEs.[3–8] However, the clinical significance and patient importance of these asymptomatic VTEs remains uncertain.

The efficacy of thromboprophylaxis using low-molecular-weight heparin (LMWH) to prevent postoperative VTE events during hospitalization is common practice, but the optimal duration of thromboprophylaxis after surgery is largely unknown.[9] Extended-duration thromboprophylaxis involves the administration of pharmacological thromboprophylaxis beyond hospital discharge using LMWH for 28 days after surgery. A Cochrane review on extended duration thromboprophylaxis pooled the results of four clinical trials that used asymptomatic VTE as the primary outcome. The results of this review led to guidelines from several professional societies supporting the use of extended-duration thromboprophylaxis following major abdominal or pelvic surgery, including those from the American Society of Colorectal Surgeons,[10] the American Society of Clinical Oncology,[11] and the American Society of Hematology (ASH).[12] Despite these recommendations from clinical practice guidelines, an American study of Medicare beneficiaries reported only 1.5% of patients receive and fill a prescription for its use.[13]

The risks and benefits of pharmacological thromboprophylaxis following major surgery vary among individuals based on patient, disease, and procedural factors.[14] Individualized VTE risk stratification using the 2005 Caprini score[15] is recommended to predict VTE risk and assist clinicians in identifying patients who should receive pharmacological thromboprophylaxis, including extended-duration thromboprophylaxis for patients undergoing abdominopelvic surgery for cancer.[16] The Caprini risk assessment model uses patient-level factors to estimate an individual's risk of VTE and has been validated in many settings and populations.[17–22] This risk stratification was used by Pannucci et al.[14] to describe the rates of postoperative VTE in four different groups of patients categorized by Caprini score: 3–4, 5–6, 7–8, and 9 or greater. The study by Pannucci et al.[14] found that the rate of VTE increases across each group and is highest in Caprini score 9 or greater.

The evidence supporting the use of extended-duration thromboprophylaxis to prevent clinically meaningful and patient-important VTEs is limited, leading to clinical equipoise regarding the risk-to-benefit ratio associated with its use following all major abdominal surgeries.[23] This results in challenging conversations between patients and physicians when reviewing the benefits and harms of extended-duration thromboprophylaxis and likely leads to significant variability in clinical practice. Patient decision aids (PtDA) are one clinical tool that provides information in a patient-centered way and helps facilitate shared decision making. A review of 105 PtDAs found that patients who used a decision aid had improved knowledge of their management options, were more informed, and had more accurate expectations of the benefits and harms of their options compared to patients who did not have access to a PtDA.[24] A subanalysis of 24 included studies with PtDAs based on the Ottawa Decision Support Framework showed similar outcomes.[25]

Given the difficult decision patients and physicians face regarding the use of extended-duration thromboprophylaxis after major abdominal surgery and the lack of high-quality patient-centered resources to inform this decision, we sought to develop an evidence-based PtDA to promote shared decision making for patients undergoing major abdominal surgery, such as abdominal surgeries for resection of gastrointestinal malignancies or benign conditions, such as inflammatory bowel disease or diverticular disease. The objective of this study was to create and assess the acceptability of a novel PtDA developed to facilitate shared decision making between patients and health care providers deciding whether to use extended-duration thromboprophylaxis following major abdominal surgery.

2 | METHODS

Institutional ethics board approval was obtained for this study (OHSN-REB 20200570-01H). The Ottawa Decision Support

Framework (ODSF)[26] and the International Patient Decision Aids Standards[27] (IPDAS) were used to guide the development of the PtDA. The structured process for developing a high-quality PtDA described by McAlpine et al.[28,29] was followed.

2.1 | Needs assessment

Many hospitals in the province of Ontario (Canada) have not systematically implemented extended-duration thromboprophylaxis after all major abdominal surgeries. This is largely because the data supporting the practice is based on surrogate outcomes, and the cost of LMWH (approximately $300 for 30 days [Canadian funds]) is not always covered by provincial health insurance providers.[30] Furthermore, a survey of Canadian thrombosis experts demonstrated clinical equipoise among 80% of respondents regarding the benefits of pharmacological thromboprophylaxis after discharge following hospitalization for major abdominal surgery.[23] The clinical equipoise and lack of universal implementation of extended-duration LMWH following major abdominal surgery results in many patients unaware that this is an option. A previous study highlighted a limited public awareness of VTE and its consequences and called for campaigns to increase public awareness of VTE.[31] Additionally, a randomized control trial investigating the effect of extended-duration LMWH on disease-free survival, postoperative bleeding, and VTE compared to the standard of care stopped recruitment early, as 35% declined participation because they were not interested in taking extended-duration LMWH, with 10% specifically citing not wanting daily injections (R. Auer, personal communication, February 3, 2022). The potential benefits and harms of extended-duration thromboprophylaxis depend on personal risk factors, further indicating the need to discuss this decision with patients using a tailored approach with best practices for risk communication.[32] These studies support the need for a PtDA to engage patients in understanding their personal risk of VTE, and the benefits and harms of extended-duration thromboprophylaxis.

2.2 | Creation of steering committee

A team of content and process experts was assembled to form the steering committee for the development of this PtDA. The steering committee was composed of a surgeon (RA); a thrombosis expert (MC); a medical student (VI); a surgical fellow (KM); and a world expert in the development, testing, and implementation of PtDAs (DS).

The steering committee discussed the various components of the PtDA including the intended patient population, the management options, and the clinically relevant and patient-important outcomes.

2.3 | Literature review for rates of benefits and harms

Once the steering committee determined the management options and the relevant benefits and harms to include on the PtDA, a thorough literature review was performed. PubMed and Ovid Medline databases were searched for the highest-quality evidence on the risk of VTE with and without the use of extended-duration thromboprophylaxis following major abdominal surgery. Literature that stratified risk of postoperative VTE based on the Caprini score was collected. The literature was reviewed by the steering committee, and the rates included for each outcome on the PtDA were agreed upon by consensus.

2.4 | Formation of first draft

A prototype of the PtDA was created using the ODSF template (e-training at https://www.decisionaid.ohri.ca).[25] Patient-friendly language was used to highlight important background information including the descriptions of VTEs and extended-duration thromboprophylaxis. A validated, patient-administered Caprini score was included at the beginning of the decision aid with the intention of patients calculating their own Caprini score. The information on the rates of VTE and risk-to-benefit ratio of extended-duration thromboprophylaxis was divided into four sections based on Caprini score. The four risk-stratified sections included Caprini scores 3–4, 5–6, 7–8, and 9 or greater. Patients were instructed to proceed to the appropriate section of the document for them based on their Caprini score.

Knowledge questions were included to test patients' understanding of the information on the PtDA. A validated scoring tool used to assess decisional conflict was included.[33] A section of the PtDA also included an explicit values clarification exercise to allow patients to clarify and communicate their values and preferences regarding each of the management options.

2.5 | Alpha testing

Clinicians and patients were invited to complete alpha testing. Clinician participants included surgeons and thrombosis experts who routinely see patients after major abdominal surgery and prescribe extended-duration thromboprophylaxis. Patient participants included patients who previously underwent major abdominal surgery, defined as abdominal laparotomy or laparoscopy lasting more than 45 min, and faced the decision of receiving extended-duration thromboprophylaxis or not (Table 1). Patients were contacted via email after discharge from the hospital inviting them to participate. The number of clinicians and patient participants who were included in this study was based on previous studies assessing the acceptability testing of a PtDA in a similar setting.[28,34–37] Alpha testing

TABLE 1 Patient demographics

Variable	Total cohort of patients ($n = 11$)
Age, years, median (range)	64 (39–78)
Sex, *n* (%)	
Female	7 (64)
Male	4 (36)
Marital status, *n* (%)	
Single	1 (9)
Married	9 (82)
Not reported	1 (9)
Preferred language, *n* (%)	
English	9 (82)
French	2 (18)

involved participants reviewing the PtDA draft, and then completing a 10-question online survey that was based on a validated acceptability instrument.[38] The results of the alpha testing were reviewed by the steering committee and used to update the PtDA into a finalized format.

3 | RESULTS

A novel, evidence-based PtDA was created to facilitate shared decision making regarding the choice to receive extended-duration pharmacological thromboprophylaxis using LMWH or not after major abdominal surgery. The ODSF and IPDAS were followed to guide the systematic development of this decision aid.

3.1 | Results of steering committee

The steering committee determined that a risk-stratified PtDA was necessary to present accurate risks and benefits to an individual patient. The Caprini score was agreed upon as the tool that would be included to allow for postoperative VTE risk stratification. Risks and benefits of LMWH were grouped into four risk categories: Caprini scores 3–4, 5–6, 7–8, and 9 or greater.

The steering committee decided that the important outcomes to present on the PtDA included the rates of symptomatic nonfatal VTEs, fatal VTEs, major bleeding, and clinically relevant nonmajor bleeding following major abdominal surgery. The impact of completing a course of extended-duration thromboprophylaxis or not on the clinical outcomes was also agreed upon as an important aspect of the information that should be provided to patients on the PtDA.

3.2 | Synthesis of the literature

The results of the literature review highlighted the limited data available on the risk-stratified rates of clinically relevant outcomes following major abdominal surgery. A summary of the evidence available is shown in Table 2. Two systematic reviews and meta-analyses provided the highest quality of evidence to inform the outcomes on the PtDA.[14,39] One meta-analysis pooled the results of four randomized controlled trials on the risk ratio for VTE without pharmacological thromboprophylaxis.[39] The second meta-analysis reported the benefits and harms of thromboprophylaxis among surgical patients stratified by Caprini scores.[14] In addition to these meta-analyses, one observational study and one clinical guideline (ASH, 2021) used to inform the rates quoted on the PtDA.[12,40] We used the data reported in these studies to extrapolate the benefit and harm rates to inform the PtDA due to the limited risk-stratified data.

Once the summary-of-evidence table was created, the steering committee reviewed the data available and reached consensus on the rates for each benefit and harm to include on the PtDA. The benefits included preventing symptomatic nonfatal VTE and preventing death as a result of VTE. The harms included clinically relevant minor bleeding and major bleeding events requiring transfusion, repeat surgery, or death. The rates for each benefit and risk were stratified into four groups on the PtDA for each management strategy: Caprini scores 3–4, 5–6, 7–8, and 9 or greater.

3.3 | Patient decision aid prototype

The PtDA prototype was 11 pages total. There were two common pages, two risk-tailored pages for each risk strata, plus a final page indicating references and authors. Including all aspects essential to high-quality PtDAs (Table 3), the PtDA met all six IPDAS qualifying criteria, all six certification criteria, and 19 of 23 quality criteria (Table 3).[41] Patient-friendly language was used, and the Flesch–Kincaid score for readability level was 8.7, indicating an eighth-grade reading level. The PtDA used both descriptive text and numbers to represent the data in a patient-centered manner. An example of how the outcomes were reported on the PtDA is shown in Figure 1.

3.4 | Results of alpha testing

Seventeen patients who had previously made the decision to take or decline extended-duration LMWH following their major abdominal surgery at one academic center were contacted by email via their surgeon if they met inclusion criteria. Eleven patients responded and completed alpha testing, giving a response rate of 65%. Eleven thrombosis experts and 11 surgeons also completed alpha testing. All respondents completed the full 10-question survey with the exception of one clinician who missed one question (Table 4).

The language of the PtDA was felt to be easy to follow by 28 of 33 (85%) of all responders (95% confidence interval [CI], 0.68–0.95; 82% [9/11] patients [95% CI, 0.48–0.98]; and 86% [19/22] clinicians [95% CI, 0.65–0.97]). The information provided on the management options was reported to be well balanced by 9 of 11 (82%) patients

TABLE 2 Summary of evidence

Study characteristics				Outcomes								
Author	Year	Study Type	Population	Rate of major bleeding with LMWH	Rate of major bleeding without LMWH	Rate of minor bleeding with LMWH	Rate of minor bleeding without LMWH	Rate of VTE with LMWH	Rate of VTE without LMWH	Rate of fatal VTE without LMWH	Rate of fatal VTE with LMWH	Comments
Rausa[39]	2018	Meta-analysis	Postoperative patients $n = 1525$, 649 extended-duration thromboprophylaxis, 641 conventional	1.37 (RR)	—	1.42 (RR)	1.2 (RR)	0.47 (RR)	—	—	—	—
Pannucci[14]	2017	Meta-analysis	11 studies, $n = 14{,}776$ contained risk-stratified VTE data, 8 studies	—	—	—	—	—	3–4: 0.7% 5–6: 1.8% 7–8: 4.0% >8: 10.7%	—	—	VTE rate stratified by Caprini score
Douketis[40]	2007	Prospective cohort	2052 patients who recently discontinued anticoagulation	—	—	—	—	—	—	0.002%	—	—
Lyman[12]	2021	American Society of Hematology 2021 guidelines	—	—	1.0 (RR)	—	—	—	—	—	—	—

Abbreviation: RR, Risk Ratio.

TABLE 3 International patient decision aid standards criteria met by patient decision aid

Item Dimension	Qualifying Criteria	Certification Criteria	Quality Criteria
Information	Describes health condition or problem for which PtDA is required	Shows the negative and positive features of options with equal detail	Describes natural course of health condition or problem if no action is taken
	Explicitly states decision that needs to be considered		Makes it possible to compare positive and negative features of available options
	Describes options available		
	Describes positive features of each option		
	Describes negative features of each option		
Probabilities			Provides information about outcome probabilities associated with options
			Specifies defined group of patients for who the outcome applies
			Allows user to compare outcome probabilities across options using the same time period
			Allows user to compare probabilities across options using the same denominator
			Specifies event rates for outcome probabilities
			Provides more than 1 way of viewing probabilities
Values	Describes what it is like to experience the consequences of the options		Asks patients to think about which positive and negative features of options matter most to them
Guidance			Provides step-by-step way to make a decision
			Includes tools like worksheets or lists of questions to use when discussing options with practitioner
Development			Included a need assessment with clients or patients
			Included a needs assessment with health professionals
			Included review by patients not involved in producing the PtDA
			Included review by professionals not involved in producing the PtDA
			Field tested with patients facing the decision
			Field tested with practitioners who counsel patients
Evidence		Provides citations to evidence selected	PtDA or associated documentation describes how research evidence was selected or synthesized
		Provides a production or publication date	
		Provides information about the update policy	Patient decision aid or associated documentation describes quality of research evidence used
		Provides information about level of uncertainty around event or outcome probabilities	
Disclosure		Provides information about funding source used for development	Includes authors/developers credentials or qualifications
Plain language			Reports readability levels
Evaluation		Describes what test is designed to measure[a]	Evidence that PtDA improves match between preferences of informed patient and option that is chosen.
			Evidence that patient decision aid helps patients improve their knowledge about options' features.

Note: Red text: Criteria that will be met once beta testing is completed. Green shaded boxes: PtDA meets these criteria.
[a]Applicable only for decision aids designed to facilitate decisions regarding tests.

(95% CI, 0.68–0.95), and 17 of 21 (80%) of clinicians (95% CI, 0.58–0.95). Most clinicians (19/22 [86%; 95% CI, 0.65–0.97]) and patients (8/11 [73%; 95% CI, 0.39–0.94]) were satisfied with the overall quality of the decision aid. The length of the decision aid was felt to be appropriate by 9 of 11 (82%) of patients (95% CI, 0.48–0.98) and 12/22 (54%) of clinicians (95% CI, 0.32–0.75).

Most patients felt that the PtDA would have been helpful in their decision making regarding extended-duration thromboprophylaxis following major abdominal surgery (9/11; 82% [95% CI, 0.48–0.98]), and most clinicians believed the PtDA would be a useful tool when counseling a new patient on the use of extended duration thromboprophylaxis in the future (18/22; 82% [95% CI, 0.60–0.95]).

Narrative feedback from responders consistently commented that the PtDA was easy to follow and clearly written. Strengths identified by patients included the PtDA's explanation of why thromboprophylaxis is used after surgery and the ability of the PtDA to facilitate informed decision. Patients also appreciated the ability to improve their knowledge of VTEs and their associated risks. Strengths identified by clinician participants included the use of a risk-stratified presentation of outcomes and the attention to pharmacological thromboprophylaxis in the setting of postsurgical care. Suggested areas for improvements from both clinicians and patients largely focused on the instructions and use of calculating the Caprini score. This was described as a potential area for confusion, and

FIGURE 1 Example of outcome presentation on patient decision aid

(A) Caprini score 3-4

Benefits	Take blood thinner	Decline
If **1000** people with a Caprini score of 3-4 take a blood thinner for 1 month following surgery, **4 more people will avoid a blood clot** compared to those who do not take a blood thinner. *A blood clot may cause pain and discomfort, and require treatment from your doctor. A blood clot can also have no symptoms – which means you will not notice it unless your doctor is using specific tests to find it (these tests are not normally done).*	**997** avoid a blood clot, **~3** will get one	**993** avoid a blood clot, **7** will get one

(B) Caprini score 9 or more

Benefits	Take blood thinner	Decline
If **1000** people with a Caprini score of 9 or more take a blood thinner for 1 month following surgery, **57 more will avoid a blood clot** compared to those who decline a blood thinner. *A blood clot may cause pain and discomfort, and require treatment from your doctor. A blood clot can also have no symptoms – which means you will not notice it unless your doctor is using specific tests to find it (these tests are not normally done.*	**950** avoid a blood clot, **~50** will get one	**893** avoid a blood clot, **107** will get one

concern was raised that many future patients would not be able to accurately calculate their personal score.

3.5 | Final PtDA

The results of the alpha testing were reviewed in detail by the steering committee and used to update the PtDA. Based on the alpha-testing feedback, the PtDA was adjusted such that a member of the health care team would assist patients in calculating their Caprini score, and then patients would proceed to complete the appropriate risk-stratified section of the PtDA independently. The final version is freely available on the Ottawa Hospital Research Institute's A to Z Inventory of PtDAs (https://decisionaid.ohri.ca/decaids.html) and is presented in Appendix S1.

4 | DISCUSSION

The decision of whether to complete a course of extended-duration thromboprophylaxis with LMWH following major abdominal surgery is a challenge and is faced routinely by patients and clinicians. To facilitate shared decision making we created a novel, evidence-based, risk-stratified PtDA following best practices to create high-quality PtDAs.[26,41] Our PtDA was found to be acceptable among patients, surgeons, and thrombosis experts. Most surgeons and thrombosis experts plan to use this tool in their clinical practice, and most patients responded that they would recommend this PtDA to future patients facing this decision. This indicates that the tool is acceptable among important stakeholders and fulfills a previously unmet need.

The decision to use extended-duration thromboprophylaxis or not following major abdominal surgery is complex given the limited evidence available on its effect on symptomatic VTE and bleeding rates. There are many factors that influence patients' risk of VTE following surgery, and it remains a challenge for clinicians to stratify patients and identify high-risk populations. While several professional societies recommend extended-duration thromboprophylaxis for high-risk populations, there is no consensus on how to identify these patients.[10–12] This leads to inconsistent practice between hospitals and clinicians based on their preferences and previous experience with the use of extended-duration thromboprophylaxis.[42] The Caprini risk score is one tool that clinicians can use to help identify who is at high risk of developing VTE. While there are additional factors that may influence one's risk of VTE such as specific procedure or type of procedure, the Caprini score remains a validated tool that can help clinicians identify which patients may be at higher risk of developing VTE. Of concern is when patients are excluded from the decision-making process because the decision is complex and somewhat controversial. There are effective interventions such as PtDAs that can support them to participate actively in decision making.

A PtDA to facilitate shared decision making regarding the use of extended-duration thromboprophylaxis after major abdominal surgery aims to support patients facing this decision. Patients are provided information on the important outcomes and the potential risks and benefits of extended-duration thromboprophylaxis to ensure that they are informed and adequately understanding of their options. This includes having a better understanding of their personal risk of VTE. Use of this PtDA will also allow clinicians to gain a better understanding of patients' values and preferences with respect to extended-duration LMWH. Patients at high risk of VTE may be more interested in accepting the risks of LMWH, while patients at low risk of VTE may be less inclined; however, this largely depends on the value each individual patient places on the potential benefits and harms of extended-duration thromboprophylaxis. We anticipate that this PtDA will be used by patients as part of their discharge planning following their major abdominal surgery. The clinician could introduce the decision to be made and provide the patient with our PtDA, allowing them time to review the information on options and clarify their values and preferences. Once the patient has completed the PtDA, the clinician could use a shared decision-making approach to verify patients' understanding, answer their questions, elicit their

TABLE 4 Patient and clinician survey results

Question	Patients ($n = 11$)	Clinicians ($n = 22$)
Language in decision aid, *n* (%)		
Appropriate	9 (82)	19 (86)
Difficult to read	2 (18)	1 (4)
Neutral		2 (9)
Amount of Information provided, *n* (%)		
About right	6 (54)	10 (45)
More than desired	3 (27)	10 (45)
Less than desired	2 (18)	2 (9)
Length of decision aid, *n* (%)		
Appropriate	9 (82)	12 (55)
Too long	2 (18)	10 (45)
Harms and benefits included, *n* (%)		
Well-balanced	82% (9)	17 (80)[a]
Biased toward taking LMWH	18% (2)	4 (20)
Overall quality of decision aid, *n* (%)		
Satisfied	73% (8)	19 (86)
Not satisfied	27% (3)	1 (4)
Neutral		2 (9)
Benefits and harms easy to follow, *n* (%)		
Agree	9 (82)	N/A
Disagree	2 (18)	
PtDA would be helpful during decision making, *n* (%)		
Helpful	9 (82)	N/A
Neutral	1 (9)	
Not helpful	1 (9)	
Would recommend this tool for future patients, *n* (%)		
Yes	9 (82)	N/A
No	2 (18)	
Agree with benefits and harms reported, *n* (%)		
Agree	N/A	19 (86)
Disagree		1 (4)
Neutral		1 (4)
Believed this is a useful tool for counseling, *n* (%)		
Yes	N/A	18 (82)
No		3 (14)
Neutral		1 (4)
Anticipate using PtDA in practice (n, %)		
Agree	N/A	10 (45)
Disagree		4 (18)
Neutral		8 (36)

Abbreviations: N/A, not applicable; PtDA, patient decision aid.
[a]$n = 21$.

values and preferences, and come to agreement on whether or not to prescribe extended-duration thromboprophylaxis.

Risk-stratified outcomes within our PtDA provides for a personalized approach to the decision-making process for patients trying to decide whether they want to receive extended-duration thromboprophylaxis of not after surgery.[43] The process of assessing an individual patient's risk of VTE compared to the risk of bleeding is challenging and often confusing, which makes it time consuming to review with patients. This PtDA uses the Caprini score to highlight patients' risk of VTE based on their personal circumstances and provides risk-stratified data to patients and clinicians in a patient-friendly manner. The information in the PtDA allows patients to understand the risks and benefits of extended-duration thromboprophylaxis in a personalized way and allows them to make a truly informed decision based on their values and preferences. Patients who reviewed the PtDA during alpha testing recommend its use for future patients, highlighting that this is a useful and patient-friendly tool.

Patient decision aids educate and inform patients about their management options including the associated evidence-based outcomes to support shared decision-making.[44] A systematic review examining patient-reported barriers and facilitators to shared decision making found that many patients believe they are unable to be involved in medical decision making.[45] The information presented in a PtDA is designed to facilitate shared decision making by helping patients clarify and communicate their values and preferences and to more completely understand the benefits and harms associated with their options. This process can help patients personalize the information, understand their role in the decision, and appreciate the scientific uncertainty despite the best available evidence.[46]

This PtDA is novel, and to the best of our knowledge, there has never been a PtDA created to facilitate the shared decision making for the use of extended-duration thromboprophylaxis after major abdominal surgery before. Despite the novelty of this tool, there are some limitations of this study. First, the benefits and harms included on the PtDA represent the best available evidence at this time. As new evidence becomes available, the rates of these outcomes will need to be modified to reflect the most accurate information available. Second, beta testing has not yet been performed. Beta testing the final PtDA can be done by comparing patients' knowledge scores or decisional conflict scores before and after using the PtDA in clinical practice.[29,41] Previous articles that outline the PtDA development process suggest that beta testing is not required prior to implementation when a validated process is used for development.[29,47] Future studies may also assess whether this PtDA would lead to better patients outcomes, including the experience and results of the decision-making process. Third, we did not include surgeons or thrombosis experts who practice at community hospitals in the alpha testing for this PtDA. It is possible that their practice varies from an academic practice in a way that may mean this PtDA is not as useful. Given that the cost of LMWH is a factor that may influence some patients' decisions, it is a relevant source of information to include, but we chose not to include it given that costs of thromboprophylaxis medications vary by country. Information on participant education level, race, ethnicity, and socioeconomic status were not available for this study. This may limit the results of the study, as the population may not represent the target audience. Finally, we used the Caprini score to stratify patients' risk of VTE for this PtDA;

however, other factors such as specific procedure or length of procedure may impact patients' risk of VTE and may have been missed, as they are not included in the Caprini score.[48,49]

5 | CONCLUSION

We used a systematic approach to develop a novel PtDA to facilitate shared decision making for the use of extended-duration thromboprophylaxis following major abdominal surgery. This PtDA was acceptable to patients, thrombosis experts, and surgeons and meets a gap in resources available for patients on this topic. The PtDA is freely available for international use at https://decisionaid.ohri.ca/decaids.html.

AUTHOR CONTRIBUTIONS

VI contributed to study design and data and statistical analysis and wrote the manuscript. KM contributed to the study design and data analysis and provided key revisions to the manuscript. ED and DS contributed to study design and provided key revisions to the manuscript. MC and RA were responsible for study conception and planning and provided key revisions to the manuscript.

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RELATIONSHIP DISCLOSURE

The authors declare the following financial interests/personal relationships, which may be considered as potential competing interests: VI, KM, ED, DS, and RA do not have any relevant conflicts to disclose. MC has received research funding from BMS, Pfizer, and Leo Pharma. He has also received honoraria from Bayer, Sanofi, Servier, BMS, Pfizer, and Leo Pharma.

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SUPPORTING INFORMATION

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