Indefinite anticoagulation with reduced-intensity direct oral anticoagulants in patients with splanchnic vein thrombosis. An international practice survey

Aurélien Delluc[a], Marc Carrier[a], Mandy Lauw[b], Adam Cuker[c], Laurent Bertoletti[d], Jan Beyer-Westendorf[e], Marcello Di Nisio[f], Camille Simard[g], Guillaume Roberge[h], Amye Harrigan[a,i], Sudeep Shivakumar[i], Leslie Skeith[j], Walter Ageno[k] and Nicoletta Riva[l]

Introduction **Low-dose direct oral anticoagulants (DOACs) could be beneficial for secondary prevention of splanchnic vein thrombosis (SVT) in subgroups of patients at high risk for recurrence. In the absence of direct evidence, we aimed to identify the practice preferences of physicians managing patients with SVT in an international web-based survey.**

Methods and results **An anonymous questionnaire was sent via E-Mail between April and July 2023 to members of 14 national and international scientific societies. We received 236 responses of which 175 were complete responses. After an initial 3–6 months of SVT treatment, more than 80% of respondents would continue anticoagulation in the presence of cancer, myeloproliferative neoplasms, or in case of unprovoked SVT. If anticoagulation is continued, 45.8–68.6% would use reduced-intensity dosing of DOACs. In case of compensated cirrhosis or controlled inflammatory bowel disease (IBD), 54.3% and 44.4% of respondents would continue anticoagulation and 68.8% and 73.3% would opt for reduced-intensity DOAC dosing, respectively. Gastroenterologists were more likely to discontinue anticoagulation in SVT associated with cancer, controlled IBD, or unprovoked event, and more likely to continue anticoagulation in compensated cirrhosis compared to other specialists. Overall, 96% of respondents supported prospective evaluation of low-dose DOACs for the secondary prevention of SVT.**

Conclusion **This survey showed that physicians adapt duration and intensity of anticoagulation therapy depending on the patient's specific condition and risk factors even in the absence of high-quality evidence. Prospective evaluation is awaited.** ***Blood Coagul Fibrinolysis*** **36:364–370**

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[a]Department of Medicine, Ottawa Hospital Research Institute, University of Ottawa, Ottawa, ON, Canada, [b]Department of Hematology, Erasmus University Medical Center, Rotterdam, The Netherlands, [c]Department of Medicine and Department of Pathology & Laboratory Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania , USA, [d]Université Jean Monnet Saint-Étienne, CHU Saint-Étienne, Mines Saint-Etienne, INSERM, SAINBIOSE U1059, CIC 1408, Département of Médecine Vasculaire et Thérapeutique, INNOVTE network, all in F-42055, Saint-Etienne, France, [e]Division ''Thrombosis & Hemostasis''; Department of Medicine 1, University Hospital ''Carl Gustav Carus'', Dresden, Germany, [f]Department of Medicine and Ageing Sciences, University G. D'Annunzio Chieti-Pescara, Chieti, Italy, [g]Department of Medicine, Lady Davis Institute for Medical Research, McGill University, Montréal, [h]Department of Medicine, Laval University, Québec, QC, [i]Department of Medicine, Dalhousie University, Halifax, NS, [i]Department of Medicine, University of Calgary, Calgary, AB, Canada, [k]Department of Medicine and Surgery, University of Insubria, Varese, Italy and [l]Department of Pathology, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

Correspondence to Aurélien Delluc, MD, PhD, Ottawa Hospital Research Institute – University of Ottawa, 501 Smyth Road, Ottawa, ON K1H 8L6, Canada.
E-mail: adelluc@toh.ca

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Splanchnic vein thrombosis (SVT) is an unusual site of venous thromboembolism (VTE) with a reported incidence of 1.7–3.8 new cases per 100 000 persons per year [1], and refers to thrombosis in the abdominal veins that drain visceral organs (portal, mesenteric, splenic, hepatic veins [Budd–Chiari syndrome]). Common causes of SVT include liver cirrhosis, malignancies (especially hepatocellular and pancreatic cancer), myeloproliferative neoplasms, and abdominal infections or surgeries. Unprovoked SVT is relatively rare compared to lower extremity deep vein thrombosis (DVT) or pulmonary embolism (PE). SVT is associated with high short-term mortality rates, particularly in patients with mesenteric vein thrombosis and bowel infarction or hepatic vein thrombosis and acute liver failure, or in those with acute bleeding from portal hypertension. Long-term morbidity and mortality rates, due to complications of portal hypertension and recurrent thrombosis, are also increased [2]. In its recent guidance document, the International Society on Thrombosis and Haemostasis (ISTH) suggests starting early therapeutic doses of anticoagulant therapy in patients with symptomatic acute SVT and no active bleeding or other contraindications [3]. The choice of anticoagulation should be tailored depending on underlying conditions: therapeutic dose DOAC or low molecular weight heparin (LMWH)/vitamin K antagonist (VKA) in noncirrhotic patients, LMWH and a switch to VKA or DOACs if not contraindicated by severity of

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liver dysfunction in case of liver cirrhosis, and LMWH or DOACs in cancer patients. The suggested duration of anticoagulation is at least 3 months, irrespective of thrombosis extension and underlying risk factors with the possibility of indefinite treatment duration in patients at high risk of recurrence, and indefinite anticoagulation for patients with Budd–Chiari syndrome.

Patients with unprovoked DVT and/or PE or with persistent risk factors for VTE have a high risk for recurrent VTE after completing an initial course of 3 months of anticoagulation (7–10% annually) [4]. Previous literature has indicated that these patients should be kept on extended duration anticoagulation [5]. Extended duration of anticoagulation beyond 3 months may also be beneficial in individuals with SVT at high risk for VTE recurrence such as patients with unprovoked SVT, a history of bowel ischemia, SVT extending beyond the portal vein or with incomplete recanalization, recurrent SVT, and SVT associated with a persistent risk factor, such as major inherited thrombophilia, underlying cancer, myeloproliferative neoplasms, or cirrhosis [3].

The concept of using reduced-intensity DOACs (e.g., apixaban 2.5 mg twice daily or rivaroxaban 10 mg daily) for extended treatment of VTE has been explored over the last 15 years [6–8]. The rationale is that extended duration with a DOAC at a lower intensity might be similarly effective for secondary prevention but also associated with a lower risk of bleeding than therapeutic dosing. The RENOVE trial compared reduced-dose and full-dose DOACs (apixaban or rivaroxaban) in patients with VTE at high risk of recurrence who had completed 6–24 months of anticoagulation. Although the trial did not meet noninferiority criteria for recurrence prevention [adjusted hazard ratio (HR) 1.32, 95% confidence interval (CI) 0.67–2.60], recurrence rates were low in both groups (~2% at 5 years). Importantly, the reduced-dose group experienced a substantial reduction in clinically relevant bleeding (HR 0.61, 95% CI 0.48–0.79), with favourable net clinical benefit. These results suggest reduced-dose DOACs may be an acceptable option for extended anticoagulation in selected patients, although further research is needed to define optimal strategies [9].

The use of reduced-intensity DOAC for secondary prevention in patients with SVT has never been investigated. A recent randomized controlled trial (RIPORT Trial; $N = 111$) comparing intermediate dosing of rivaroxaban (15 mg daily) to observation in noncirrhotic patients with chronic portal vein thrombosis stopped enrolment early following an unplanned interim analysis requested by the independent data and safety monitoring board (DSMB) [10]. The incidence rate of recurrent VTE was 0 per 100 person-years in the rivaroxaban group and 19.71 per 100 person-years in the no anticoagulation group (log-rank $P < 0.001$) after a median follow-up of 11.8 months. Although this trial suggested use of continued anticoagulation may be beneficial, and that the dose of DOAC could be lowered to intermediate dosing, it did not assess the reduced-intensity DOAC regimens applied for extended treatment of DVT and/or PE. Furthermore, the investigators did not recruit patients at high risk for bleeding, such as patients with liver cirrhosis or malignancy, who may benefit the most from a lower dose of anticoagulant therapy.

Herein, we aimed to identify the practice preferences of using extended duration of reduced-intensity DOAC for secondary prevention in patients with SVT in an international web-based survey.

Materials and methods

Using the LimeSurvey platform (Limesurvey GmbH. / LimeSurvey: An Open Source survey tool /LimeSurvey GmbH, Hamburg, Germany. URL: http://www.limesurvey.org), an anonymous questionnaire was sent via E-Mail between April 16 and July 24, 2023 to members of the Canadian Venous Thromboembolism Research Network (CanVECTOR), Thrombosis Canada, the French INvestigation Network On Venous Thrombo-Embolism (INNOVTE), the Thrombosis Research Italian Partnership (TRIP), the German thrombosis network, the Dutch Thrombosis Network (DTN), the Venous thromboEmbolism Network U.S. (VENUS), the Irish Network for VTE Research (INViTE), the Thrombosis and Haemostasis society of Australia and New Zealand (THANZ), the German Gesellschaft für Thrombose und Hämostaseforschung (GTH), the Belgium Society on Thrombosis and Haemostasis (BSTH), the International Network of VENous Thromboembolism Clinical Research Networks (INVENT), the Vascular Liver Disease Group (VALDIG), and the ISTH. The total number of unique emails sent could not be confirmed because of overlapping network membership and inability to confirm all E-Mail addresses.

Specific items on the questionnaire included circumstances under which anticoagulation is continued for secondary prevention of SVT, circumstances under which DOAC dose would be lowered to reduced-intensity dosing, perceived rationale for considering DOAC dose reduction, acceptability of a clinical trial of reduced-intensity DOAC for the secondary prevention of SVT, and physician demographic information (Appendix I, Supplemental Digital Content, http://links.lww.com/BCF/A190).

The questionnaire was piloted among five thrombosis experts to assess clarity and face validity. Most questions were closed-ended with defined choices, but some included free-text fields ('Other, please specify'). Open responses were reviewed thematically by two investigators. Due to the anonymous nature of the survey, we could not characterize nonrespondents.

Multivariable Cox proportional hazard analysis was undertaken when appropriate, odds ratios (OR) and their 95% CIs were reported. Analyses were performed using STATA14 (StataCorp, College Station, TX, USA). Missing data were not replaced.

The study protocol was approved by The Ottawa Hospital Research Institute ethics committee (20230058-01H).

Results

A total of 236 respondents started the survey of which 175 completed it. A plurality of the respondents were from Italy (27.0%), self-identified as thrombosis specialists (32.8%), practiced in an academic setting (82.6%), and managed 10–25 SVT cases per year (46.2%) (Table 1). Half (49.1%) of the respondents had at least 15 years of experience with management of SVT.

Figure 1 summarizes responses on the management of anticoagulation after an initial 3–6 months of treatment according to different clinical frameworks. More than 80% of respondents would continue anticoagulation in the presence of cancer, MPN, or in case of unprovoked SVT (Fig. 1a) and would reduce the intensity of anticoagulation in 47.1%, 45.8%, and 68.6% of these situations, respectively (Fig. 1b). For compensated cirrhosis or controlled IBD, 54.3% and 44.4% of respondents would continue anticoagulation (Fig. 1a) and use reduced-dose DOAC in 68.8% and 73.3% of the cases, respectively (Fig. 1b). More than 67% of respondents declared they would use reduced-intensity dosing of DOACs for secondary prevention in their SVT practice. Figure 1c reports the proportion of patients (per respondent) in whom dose reduction would apply.

Table 1 **Participants characteristics**

Characteristics	*N* (%)
Years in practice	(171)[a]
< 5 years	24 (14.0%)
5–15 years	63 (36.8%)
>15 years	84 (49.1%)
Area of practice	(174)[a]
Thrombosis	57 (32.8%)
Hematology	37 (21.3%)
Vascular medicine	28 (16.1%)
General internal medicine	25 (14.4%)
Gastroenterology-hepatology	15 (8.6%)
Other	12 (6.9%)
Type of practice	(174)[a]
Academic	144 (82.6%)
Nonacademic	29 (16.7%)
Community	1 (0.6%)
Country of practice	(174)[a]
Italy	47 (27.0%)
Canada	23 (13.2%)
France	19 (10.9%)
USA	11 (6.3%)
The Netherlands	10 (5.75%)
Other (<10 response per country)	64 (36.8%) Africa (n=1), Asia/Australasia (n=19), Europe (n=37), South America (n=4), not reported (n=3)
Number of SVT cases seen annually	(171)[a]
<10	47 (27.5%)
10–25	79 (46.2%)
25–50	25 (14.6%)
>50	20 (11.7%)

SVT, splanchnic vein thrombosis. [a]Number of complete responses.

Participants were asked whether they would lower the dose of DOAC according to the site of SVT (Table 2). The decision to use reduced-intensity dosing of DOACs was consistent across all different sites of SVT when taken separately (51.9–63.7%) except for hepatic vein thrombosis (Budd-Chiari syndrome) for which only 29.7% of respondents would lower DOAC dosing. Likewise, in the presence of multiple-site SVT, only 37.3% of the respondents would use reduced-intensity dosing regardless of underlying thrombosis risk factors.

For all sites of SVT, including multiple sites, reduced-intensity DOAC dosing was commonly selected (62.5–73.1%) when SVT was unprovoked or occurred in the context of liver cirrhosis or controlled IBD as compared with cancers of all types (40.7–57.0%) (Appendix II, Supplemental Digital Content, http://links.lww.com/BCF/A190).

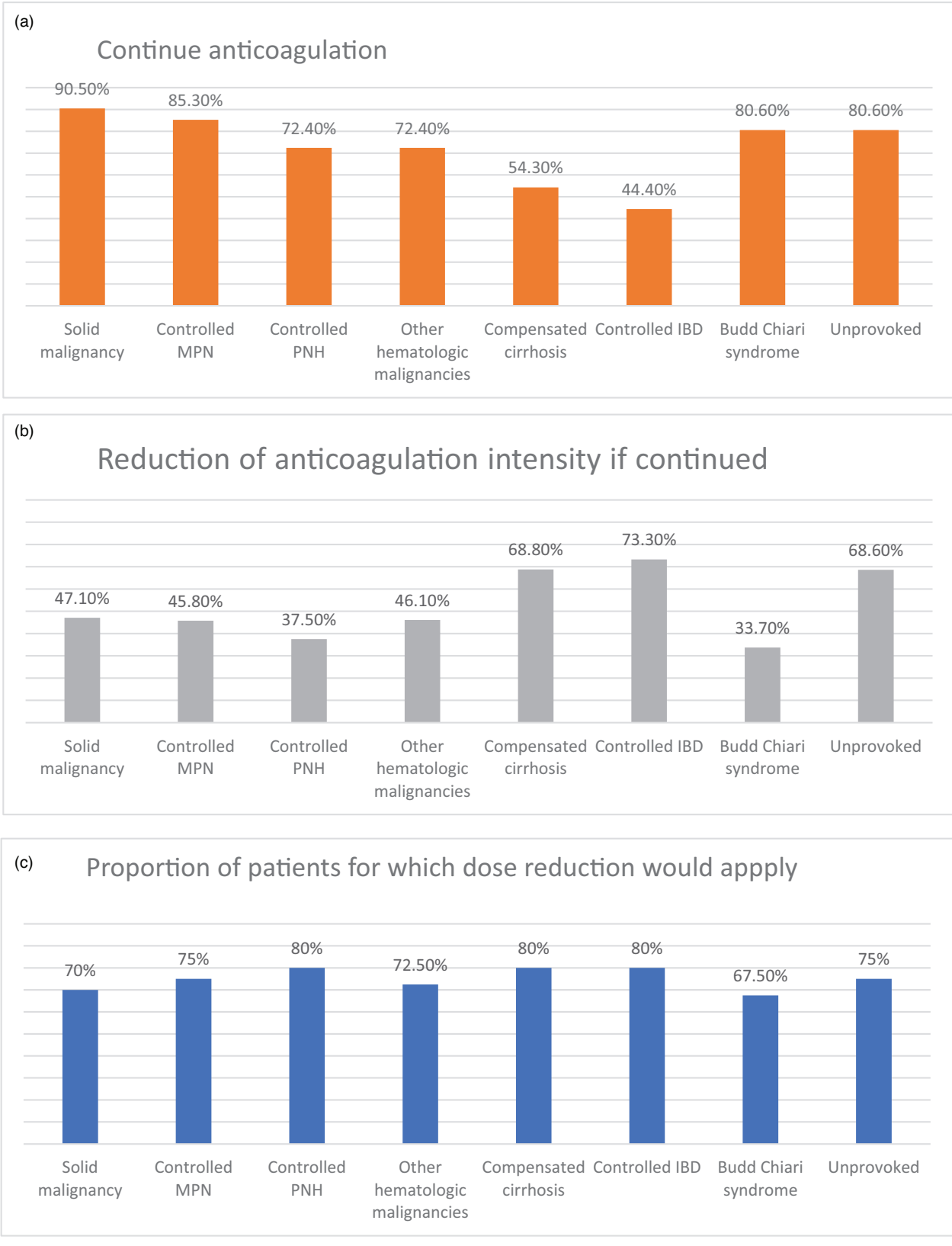
The perceived high risk of bleeding in SVT patients requiring indefinite anticoagulation was the number one reason for considering reduced-intensity dosing (80.6% of respondents), followed by a perceived lower risk for recurrent VTE (49.7%) (Table 2). There were 31.4% of respondents who indicated that reduced-intensity DOAC dosing for indefinite anticoagulation was already their standard practice in SVT.

Most respondents (71.3%) would not change their acute management based on the presence of symptoms at SVT diagnosis (i.e., symptomatic *vs.* incidental). However, 74.0% of the 28.7% of respondents who would change their management based on the presence of symptoms would discontinue anticoagulants after the initial 3–6 months of therapy in case of incidental SVT (i.e.: SVT found on an imaging test ordered for indications other than suspected SVT).

Predictors for extending anticoagulation by type of provoking factors

Multivariable analysis accounting for the collected confounders showed a trend in practice differences between gastroenterologists and other specialists in all clinical settings (Appendix III, Supplemental Digital Content, http://links.lww.com/BCF/A190): gastroenterologists were more likely than other specialists to discontinue anticoagulation in SVT associated with cancer (OR: 0.06; 95% CI 0.00–0.78), controlled IBD (OR: 0.19; 95% CI: 0.04–0.86), or unprovoked SVT (OR: 0.21; 95% CI: 0.05–0.91), whereas they were more likely to continue anticoagulation in compensated cirrhosis (OR: 3.89; 95% CI 0.73–20.73).

Fig. 1



Summary of responses for circumstances under which anticoagulation is continued for secondary prevention of splanchnic vein thrombosis. IBD, inflammatory bowel disease; MPN, myeloproliferative neoplasm; PNH, paroxysmal nocturnal hemoglobinuria.

Table 2 Summary of responses for circumstances under which direct oral anticoagulant dose would be reduced

Proportion of respondents who would lower DOAC dose after an initial 3–6 months of anticoagulation for the following thrombosis locations, regardless of underlying cause ($n=212$)	
Portal vein thrombosis	128 (60.4%)
Superior mesenteric vein thrombosis	110 (51.9%)
Inferior mesenteric vein thrombosis	120 (56.6%)
Splenic vein thrombosis	135 (63.7%)
Multiple	79 (37.3%)
Hepatic vein	63 (29.7%)
Rationale for considering DOAC dose-reduction after an initial 3–6 months of treatment with full-dose anticoagulation ($n=175$):	
High risk of bleeding	141 (80.6%)
Low risk of recurrent VTE	87 (49.7%)
Standard practice	55 (31.4%)
Other	17 (9.7%)
Impact on treatment choice in case of asymptomatic or incidentally detected SVT as opposed to symptomatic. ($n=174$)	
No impact	124 (71.3%)
Change in management:	
Stop anticoagulation after 3–6 months	37 (74.0%)
DOACs not an option after 3–6 months	2 (4.0%)
No dose-reduction	2 (4.0%)
Other	28 (8.0%)
Opinion of respondents regarding the use of low-dose DOAC if they were able to perform similarly to warfarin (annual incidence of the composite of recurrent splanchnic vein thrombosis, VTE at other locations, arterial thrombotic events, and major bleeding would be 2.8/100 patient-years with an upper limit of the 95% confidence interval of 4.84%) ($n=179$):	
An acceptable option	43 (24.6%)
A preferred option	136 (77.7%)
An inferior option	0 (0%)
Need for prospective evaluation of low-dose DOACs for secondary prevention in splanchnic vein thrombosis patients after 3–6 months of anticoagulation ($n=175$)	
Yes	168 (96.0%)
No	7 (4.0%)

DOAC, direct oral anticoagulant; VTE, venous thromboembolism.

Country of practice was not associated with change in the management of anticoagulation for solid malignancy, compensated cirrhosis, controlled IBD and PNH, Budd-Chiari syndrome, and unprovoked SVT. However, French practitioners were more likely to report they would continue anticoagulation in controlled MPN and Canadians practitioners were more likely to report they would continue anticoagulation in other hematologic malignancy, in comparison with Italians practitioners (largest group of respondents taken as reference, see Appendix III, Supplemental Digital Content, http://links.lww.com/BCF/A190).

Need for prospective evaluation of low-dose DOACs for the secondary prevention of SVT

Overall, 96.0% of respondents supported the need for prospective evaluations of DOACs for the secondary prevention of SVT. When physicians were asked if they would consider reduced-intensity DOAC dosing for the secondary prevention of SVT if they would perform similarly to warfarin (i.e., incidence of 2.8/100 patient-years with an upper limit of the 95% confidence interval of 4.8% for the composite outcome of recurrent SVT, VTE at other locations, arterial thrombotic events, and major bleeding), 24.6% answered this would be an acceptable option, 77.7% a preferred option, and none declared this would be an inferior option.

Discussion

This international survey of practice explored how physicians manage the secondary prevention of SVT in different clinical settings. Our findings highlight the complex nature of the decision to use indefinite anticoagulation in patients with SVT, which is often influenced by the preexisting medical conditions of the patient.

A consensus appeared among respondents regarding the need for indefinite anticoagulation in cancer-associated SVT and unprovoked SVT. Around 50% of respondents would lower the dose of DOACs to reduced-intensity dosing after an initial 3–6 months of treatment in patients with cancer-associated SVT. This reflects a preference to minimize bleeding risk, but also the absence of strong evidence supporting the efficacy of reduced-intensity DOAC dosing in secondary prevention of cancer-associated VTE. Conversely, for unprovoked SVT, more than 80% of respondents felt more comfortable lowering the DOAC dose, probably extrapolating results from two major clinical trials showing an acceptable benefit-risk profile of reduced-intensity DOAC dosing for the secondary prevention of unprovoked lower limb DVT and PE [7,8].

In the presence of compensated cirrhosis, 54.3% of respondents would continue anticoagulation and 68.8% would prefer to lower the DOAC dose. This suggests that physicians are willing to manage SVT with anticoagulation in cirrhotic patients for as long as their liver disease is stable, but also reflects a perceived equipoise in continuing or stopping anticoagulation given the high bleeding risk of this patient population. Conversely, when the risk of recurrent thrombosis was perceived to be higher or would lead to a more severe event (e.g., multiple site thrombosis, hepatic vein thrombosis) respondents largely opted to continue anticoagulation and were less likely to lower the dose of DOACs (37.3% and 29.7%, respectively).

The results of our multivariable analysis suggest that there are differences in practice patterns between gastroenterologists and other specialists. These differences were particularly marked for the management of SVT in the context of compensated liver cirrhosis for which gastroenterologists were more likely than thrombosis specialists to continue anticoagulation. This observation was independent from geographic region of practice, years in practice, and number of SVT cases seen annually. Gastroenterologists may be more inclined to discontinue

anticoagulation in cancer-related SVT due to concerns about gastrointestinal bleeding, especially in gastrointestinal malignancies. This finding may reflect a nuanced risk-benefit assessment that differs from thrombosis specialists. Future trials could explore whether tailored strategies by specialty lead to different outcomes. Gastroenterologists and thrombosis specialists may have different approaches to managing SVT based on their areas of expertise and focus. Thrombosis specialists may be more concerned about variceal bleeding than gastroenterologists and be more apt to discontinue anticoagulation after the acute treatment period of 3–6 months. Conversely, gastroenterologists may be more inclined to continue anticoagulation with the goal of preventing recurrent SVT and the potential for exacerbating the patient's underlying liver disease. A systematic review with competing-risk meta-analysis showed that anticoagulation may improve survival in patients with cirrhosis and portal vein thrombosis (adjusted OR: 3.45; 95% CI: 2.22–5.36) [11]. A possible mechanism hypothesized for this finding is the reduction of portal hypertension secondary to sustained recanalization of the portal system. The preservation of patency of the splanchnic vein is also a major concern in preparation for liver transplant, which may also explain the difference in management of SVT between gastroenterologist and other specialists.

Although a majority of physicians reported treating symptomatic and incidental SVT similarly during the acute phase, a meaningful minority (28.7%) considered symptom status when making decisions about long-term management. Among these, most (74.0%) would favour discontinuing anticoagulation after 3–6 months in the case of incidental SVT. This practice pattern diverges somewhat from current guideline trends, which often do not differentiate incidental to symptomatic SVT [3]. The hesitancy to extend anticoagulation in incidental cases may reflect a lower perceived risk of recurrence or uncertainty about the clinical relevance of asymptomatic thrombosis.

We confirmed the need for prospective evaluation of reduced-intensity dosing of DOACs for the secondary prevention of SVT with 96% of the respondents in favour. Respondents also reported that at least 70% of their patients with SVT having an indication for indefinite anticoagulation would potentially be eligible to participate such trials. This survey determined the acceptable threshold to consider reduced-intensity DOAC dosing as an option for the secondary prevention of SVT. An incidence of 2.8/100 patient-years with an upper limit of the 95% confidence interval of 4.8% for the composite outcome of recurrent SVT, VTE at other locations, arterial thrombotic events, and major bleeding was set based on observation from a large international multicentre cohort study [12].

Capturing clinicians' opinions can be an invaluable tool for informing the design of clinical trials. By integrating clinicians' preferences, experiences, and insights into treatment guidelines and guidance, researchers can develop more relevant, acceptable, and impactful interventions that improve patient outcomes and advance evidence-based practice. Nevertheless, surveying clinicians online comes with several limitations, including the potential for response bias. Respondents who choose to respond to online surveys may not be representative of the entire population of clinicians. Those with strong opinions or personal interest in the survey topic may be more likely to respond, while others might ignore the survey. Furthermore, online surveys may not capture the full diversity of the physician population. We were unable to provide a response rate because of the overlap in distribution list and accuracy of E-Mail addresses. Although most respondents declared working in academic centres, we were able to collect responses from specialists working all over the world, at different stages of their practice, with different levels of exposure to SVT, and with different specialties involved in the management of SVT. Lastly, respondents from Asia, South America, and Africa were underrepresented, and this may limit the generalizability of our findings to those regions.

In conclusion, this survey confirms that physician tailor the duration and dosing of anticoagulation for secondary prevention in patients with SVT based on the patient's specific condition and associated risk factors, even in the absence of high-quality direct evidence with clinical equipoise in case of compensated cirrhosis. It further supports the need for prospective evaluations of reduced-intensity DOAC dosing for the secondary prevention of recurrent events in this patient population.

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Conflicts of interest

There are no conflicts of interest.

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