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Brief Communication

## Sensitivity of a questionnaire for data collection on venous thrombosis<sup>B</sup>

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### Introduction

In clinical research, questionnaires are an important tool available for population and large family studies to gather information on a patient's medical history. In 1989, we described a large kindred of French-Canadian descent with an 8-fold increased risk of venous thrombosis due to the 3363C insertion in the protein C gene [1]. We developed a questionnaire for use in this family to assess general information on social status, current health, current medication use and medical history, and detailed information on risk factors for venous thrombosis and a history of

venous thrombosis, arterial disease and bleeding episodes. The aim of the present study was to test the ability of the questionnaire to obtain accurate and detailed information on venous thrombosis events, i.e. the phenotype. We assessed the sensitivity of this questionnaire, designed for clinical research purposes, for detecting a history of venous thrombosis and obtaining accurate information on details of venous events among patients previously investigated for venous thrombosis by comparing the questionnaire results to medical record information.

### Materials and methods

#### Subjects

We invited 86 consecutive adult patients evaluated for venous thrombosis by a single physician (M.C.) at the Vermont Center for Thrombosis and Hemostasis between July 2000 and January 2002. An inclusion criterion was that they were not actively treated for cancer at evaluation. Patients

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were referred to the Center for evaluation and management of thrombosis, and were evaluated using a standardized history and physical examination, which included review of radiology reports and medical records confirming thrombosis episodes whenever these could be obtained. A total of 66 individuals agreed by telephone to participate (of the 86 patients, 3 refused, 2 were deceased, and 15 could not be reached), and received a questionnaire. We mailed questionnaires to these patients together with a consent form that was approved by the Institutional Review Board of the University of Vermont. The signed consent form was returned by mail with the completed questionnaire. Patients who did not return the questionnaire were mailed the questionnaire again as a reminder.

## Questionnaire

The questionnaire included questions on demographic characteristics, medication use, medical, surgical and obstetric history, risk factors for thrombosis, personal history of venous thrombosis, arterial disease, bleeding episodes and quality of life. We mailed the complete questionnaire to all patients. In order to simplify questionnaire completion, we performed a telephone interview asking each patient questions about major clinical events such as bleeding episodes, fractures and surgeries. The telephone interview allowed selective deletion of questions in the mailed questionnaire that asked for details of these events. The questionnaire included a reference page describing the most common types and symptoms of venous thrombosis. The questionnaire was re-mailed to 25 subjects, of whom 5 (20%) responded. A total of 45 of the 66 mailed questionnaires were returned (68%).

## Validation of questionnaire

Prior to viewing the completed questionnaires, for validation of the questionnaire, a member of the investigator team (C.V.) extracted details from the chart on the thrombosis history using a standardized form. We thus only determined the sensitivity of questions regarding the patient's thrombosis history. Sensitivity of questions in the questionnaire that we could validate through chart review was defined as the percentage of individuals who reported correct information. Unfortunately, information on the location of the event, whether they were hospitalized and detailed treatment information (start date treatment, type

of treatment) could not be found in most of the charts. We first calculated the sensitivity of reporting a history of venous thrombosis, i.e. the percentage of all individuals who returned the questionnaire who reported to have had venous thrombosis. Second, we determined the percentage of patients who reported the correct number of venous thrombotic events when they reported a history of venous thrombosis. Third, of all reported events also mentioned in the charts, we determined the percentage of patients reporting correct details on the events, including type of event, date of event, location of event, use of anticoagulation treatment at the time of the event, and whether an objective test was performed to diagnose the event (e.g., ultrasound or ventilation–perfusion–scan). For the validation of dates, we allowed a difference of 1 month if the full date was mentioned in the chart, otherwise the date had to be less than 1 month apart or in the same year as mentioned in the chart. For 8 patients the dates in the charts consisted only of the year.

## Statistical methods

Sensitivity of questions was calculated by dividing the number of individuals who reported correct information by the total number of individuals who answered that particular question. Sensitivity of multiple questions at once was calculated by dividing the number of individuals reporting correct information by the number of individuals who answered all questions. Individuals with missing information on one of the questions in the chart were only included when they failed to report another question correctly. For each sensitivity measure, we calculated the exact 95% confidence interval, which is based on the binomial distribution for a given sample size [2].

## Results

The characteristics of the 45 individuals who returned the questionnaire and the 24 individuals who did not agree to participate ( $n=3$ ) or did not return the questionnaire ( $n=21$ ) are depicted in [Table 1](#). Respondents were more likely to be female and were older than non-respondents. No differences were seen between the two groups regarding type of thrombosis. The number of patients with a recent event, i.e. after 2000, was slightly lower in the participant group. Only patients in the parti-

**Table 1** Characteristics of all patients reached by telephone

	Participated fully (n=45)	Refused or did not respond (n=24)
Mean age, years (range) <sup>a</sup>	44 (20–79)	39 (18–76)
Male sex, N (%)	13 (29%)	13 (54%)
Major venous events, N (%) <sup>b</sup>	45 (100%)	23 (96%)
STP only, N (%)	0 (0%)	1 (4%)
>1 event (non-concurrent), N (%)	25 (56%)	14 (58%)
Recent event (after 2000), N (%)	17 (38%)	11 (46%)
Cancer history, N (%)	5 (11%)	0 (0%)

Abbreviation: STP, superficial thrombophlebitis.

<sup>a</sup> Age at filling out the questionnaire or at the start of the study (April 4, 2002).

<sup>b</sup> Deep venous thrombosis, pulmonary embolism or major events at other locations (arm, brain, kidney or vena cava).

participant group had a past cancer history. For one individual we could not validate the questionnaire information due to missing historical information in the medical record, and this patient was excluded from all analyses.

**Sensitivity of detecting a history of venous thrombosis**

The sensitivity for reporting a history of venous thrombosis was high (98%; 95% CI: 88–100%) (Table 2): one person reported no prior events, but experienced three deep venous thromboses and one pulmonary embolus according to the chart.

Of the 43 patients reporting a history of venous thrombosis, 31 individuals (72%; 95% CI: 56–85%)

reported the correct number of events. Patients with multiple non-concurrent events seemed to have more difficulty in reporting all events compared with patients with one event (including concurrently diagnosed events) in the chart. The difference was, however, not significant (95% CI of difference: –1% to 49%). Misreported events included venous events mentioned in another section of the questionnaire (n=2), under reported venous events (n=4), and over reported venous events and arterial events reported as venous events (n=7).

**Correct report of detailed information on venous thrombotic events**

For events mentioned both in the chart and the questionnaire, we found a high sensitivity for reporting the type of thrombosis, the date of the event, information on whether a test was performed to confirm the venous event, or information on whether the event occurred while using anticoagulants. Sensitivity was in subjects with multiple non-concurrent events significantly lower for reporting risk factors that preceded the event compared with correctly reporting the type of thrombosis and the use of anticoagulants at the time of the event (95% CIs of the differences were 6–54% and 4–54%, respectively) (Table 2). Errors in answering the question on risk factors preceding an event included: patients not filling out the question (n=2), patients not mentioning all risk factors or any risk factor (n=8), and patients mentioning a risk factor whereas the event was spontaneous according to the chart (n=1).

For reporting all details on venous thrombosis, sensitivity was low, especially in patients with multiple non-concurrent events in their chart

**Table 2** Sensitivity of questions on venous thrombotic events

	Sensitivity N with correct answer/total N (%; 95% CI)		
	All subjects	Subjects with 1 event in chart <sup>a</sup>	Subjects with >1 event in chart
Venous thrombosis history mentioned?	43/44 (98; 88–100)	20/20 (100; 83–100)	23/24 (96; 79–100)
Correct number of venous events reported?	31/43 (72; 56–85)	17/20 (85; 62–97)	14/23 (61; 39–80)
<i>Correct report of details on events<sup>b</sup></i>			
Type of thrombosis correct?	40/43 (93; 81–99)	20/20 (100; 83–100)	20/23 (87; 66–97)
Date of thrombosis correct?	35/43 (81; 67–92)	17/20 (85; 62–97)	18/23 (78; 56–93)
Diagnosed with objective test?	35/41 (85; 71–94)	19/20 (95; 75–100)	16/21 (76; 53–92)
Precipitants reported correctly?	32/43 (74; 59–86)	19/20 (95; 75–100)	13/23 (57; 34–77)
Correct report of use of anticoagulants at event?	36/40 (90; 76–97)	18/19 (95; 74–100)	18/21 (86; 64–97)
Correct report all details? <sup>c</sup>	22/42 (52; 36–68)	13/19 (68; 43–87)	9/23 (39; 20–61)

<sup>a</sup> Including patients with concurrent events (e.g., deep venous thrombosis and pulmonary embolism).

<sup>b</sup> Subjects with more than one event in the chart had to fill out the details correctly for all events to meet a correct report.

<sup>c</sup> Individuals with missing information on one of the questions in the chart were excluded unless they failed to report another question correctly.

(Table 2). The 95% confidence interval of the difference was, however, wide and non-significant (0–58%).

### Influence of type of thrombosis and time between event and questionnaire

We assessed whether sensitivity differed among patients older or younger than 45 years at the time of study inclusion. The sensitivity for reporting all details on venous events appeared lowest in patients with multiple non-concurrent events who were above the age of 45 at study inclusion (Table 3). No major differences were seen either among patients with spontaneous or provoked events, or among the patients with multiple events who experienced their first event before 1999 ( $N=14$ ) or after 1999 ( $N=9$ ) (results not shown). All individuals with one event experienced their event after 1999.

## Discussion

We determined the sensitivity of a self-administered questionnaire for assessing information on a history of venous thrombosis in an unrelated cohort of patients referred for evaluation of thrombosis. The sensitivity of the questionnaire was high for detecting a history of venous thrombosis (98%), but the accuracy ranged widely for detailed questions. Sensitivity seemed higher for detailed questions among patients who had a single thrombosis compared to those with multiple episodes. Patients with multiple, non-concurrent events seemed to

have particular difficulty in reporting risk factors preceding the events, especially those who were above the age of 45 at study inclusion (Table 3).

The overall response to the questionnaire was 65% (45 returned the questionnaire out of 69 reached). Men tended to be more reluctant in responding. Most non-respondents did agree to participate at first but did not return the questionnaire (20 out of 25; 80%) even after a reminder was sent, which could be due to the length of the questionnaire: the questionnaire included many other questions on general health and quality of life.

Despite the fact that a history of venous thrombosis for clinical research purposes can only be obtained reliably by taking a history and reviewing the medical record, and not by physical examination or post-facto imaging, only one other study is available that validated a questionnaire for obtaining a history of venous thrombosis [3]. The study by Frezzato et al. [3] found a similar response rate for cases of 64%, but reported a lower sensitivity for detecting a history of venous thrombosis in cases (84%). They reported a higher sensitivity for detecting a history of venous thrombosis (93%) when they combined the question on whether they thought they had ever experienced a deep vein thrombosis or superficial vein thrombosis with either a question on whether they were ever admitted to a hospital for a pulmonary embolism or a question on whether a diagnosis of venous thromboembolism was ever made by a physician. Their study did not show a difference in sensitivity between cases discharged recently (in the previous 5 years) or earlier (in the previous 20 years).

**Table 3** Sensitivity for detailed information on venous events stratified by age of the patients at inclusion

Correct report of details on events <sup>a</sup>	Sensitivity $N$ with correct answer/total $N$ (%; 95% CI)			
	Subjects with 1 event in chart <sup>b</sup>		Subjects with >1 event in chart	
	Age below 45 years	Age 45 years or older	Age below 45 years	Age 45 years or older
Type of thrombosis correct?	11/11 (100; 72–100)	9/9 (100; 66–100)	12/13 (92; 64–100)	8/10 (80; 44–97)
Date of thrombosis correct?	9/11 (82; 48–98)	8/9 (89; 52–100)	12/13 (92; 64–100)	6/10 (60; 26–88)
Diagnosed with objective test?	11/11 (100; 72–100)	8/9 (89; 52–100)	10/11 (91; 59–100)	6/10 (60; 26–88)
Precipitants reported correctly?	10/11 (91; 59–100)	9/9 (100; 66–100)	9/13 (69; 39–91)	4/10 (40; 12–74)
Correct report of use of anticoagulants at event?	11/11 (100; 72–100)	7/8 (88; 47–100)	12/12 (100; 74–100)	6/9 (67; 30–93)
Correct report all details? <sup>c</sup>	8/11 (73; 39–94)	5/8 (63; 24–91)	7/13 (54; 25–81)	2/10 (20; 3–56)

<sup>a</sup> Subjects with more than one event in the chart had to fill out the details correctly for all events to meet a correct report.

<sup>b</sup> Including patients with concurrent events (e.g., deep venous thrombosis and pulmonary embolism).

<sup>c</sup> Individuals with missing information on one of the questions were excluded unless they failed to report another question correctly.

Some potential weaknesses of this study include the following issues. The results regarding the response rate and the sensitivity of the questionnaire for detecting a history of venous thrombosis might not be fully generalisable to family studies. Both the response rate and sensitivity could be higher in the present study, since patients in this study were educated in a thrombosis subspecialty clinic during their visit to the Vermont Center for Haemostasis and Thrombosis. However, it is far more common for individuals to have received their clinical care in a general medical setting where they would be less likely to be exposed to the same level of education about venous thromboembolic disease, as a result they might be more hesitant to fill out the questionnaire and might remember fewer details of their thrombotic event(s). In addition, 95% confidence intervals were wide for the sensitivity of questions due to the small number of participants. As only patients with a history of venous thrombosis filled out the questionnaire, we could not estimate specificity, which would give useful information on how likely the questions would have been answered as positive by patients without venous thrombotic disease.

In conclusion, the questionnaire we developed has a high sensitivity for detecting a history of venous thrombosis, but presence of more than one previous thrombosis was associated with less agreement between self-reported history and chart information on details on venous events. The latter finding suggests that chart review is needed for optimal ascertainment of a detailed thrombosis history in individuals with an extensive history of venous thrombosis. Further study should include assessment of the utility of personal or telephone interviews for ascertaining details on thrombosis history, especially among patients with multiple thromboses.

## Summary

Patient questionnaires represent a commonly used tool to gather clinical information in clinical research. However, in the field of venous thrombosis, only one previous study is available that has validated a questionnaire for obtaining a medical history of venous thrombosis. We determined the

sensitivity of a recently developed questionnaire for assessing the medical history of venous thrombosis in a clinical research setting. We included consecutive patients referred to the Vermont Center for Thrombosis and Hemostasis. Details were extracted from the chart on the thrombosis history of the patients using a standardized form, and compared to the answers given in questionnaires. Sensitivity was defined as the percentage of individuals who reported correct information. A total of 45 of the 66 patients who agreed to participate (68%) returned the questionnaire. The sensitivity for reporting a history of venous thrombosis was high (98%) with 72% of the patients reporting the correct number of events. For detailed questions about events, the sensitivity ranged widely and appeared better among patients who had a single thrombosis compared to those with multiple episodes. Thus, chart review appears necessary in clinical research for optimal ascertainment of a detailed thrombosis history in individuals with an extensive history of venous thrombosis.

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## Appendix A. Supplementary Materials

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.thromres.2004.06.024](https://doi.org/10.1016/j.thromres.2004.06.024).

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