

A Prospective Study Evaluating Patterns of Responses to the Caprini Score to Prevent Venous Thromboembolism After Interventional Treatment for Varicose Veins

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Abstract

Background: Venous thromboembolism (VTE) is a critical complication of varicose vein treatments. The Caprini Score (CS) is an established tool to assess patients' VTE risks. One disadvantage is the number of questions required, some of them referring to a low incidence of disease, even lower in patients seeking an elective procedure. These elements take time and may result in filling errors if the CS is not filled out by a properly trained health professional.

Objective: To establish a response pattern in CS, with emphasis on questions that usually have a negative answer and propose a simpler adaptative digital version without changing the original structure of the tool.

Methods: two hundred and twenty-seven patients in the pre-surgical treatment of varicose veins were enrolled prospectively and submitted to the CS evaluation.

Results: The pattern of dichotomous responses could be divided arbitrarily into four subgroups considering the percentage of positive responses: none (11 items), less than 3% (13 items), between 3% and 20% (5 items), and more than 20% (8 items). Of the 12 CS questions related to illnesses that occurred in the last month, ten had no responses, and 2 were less than 3%.

Conclusion: There is a pattern in the CS responses of patients with an indication of surgical treatment of varicose veins. Many of the CS questions are not helpful in this scenario and may result in filling errors performed by untrained providers. An adaptative version of the CS might benefit varicose veins surgery VTE risk stratification

Keywords

venous, risk assessment, vascular disease, thromboembolism, varicose veins

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Introduction

Venous thromboembolism (VTE) is a frequent complication of surgical procedures with high morbidity and mortality rates. It is estimated that about 2 million people annually suffer a VTE, and one-third of these episodes are pulmonary embolisms (PE).¹ In 25% of PE episodes, the clinical presentation is sudden death, and 16% of survivors die within 3 months.²

Those who survive can suffer from other syndromes, such as post-thrombotic syndrome (PTS) and chronic pulmonary hypertension, impacting the quality of life.³

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Surgeons must implement strategies to mitigate VTE risk. Among the possible triggers of deep-venous thrombosis (DVT), post-surgical events are the leading preventable cause.⁴ Furthermore, primary prophylaxis is a safe and efficient strategy for preventing VTE-related complications.⁵

Surgical treatment for varicose veins is a frequent procedure and is considered safe.⁶ The advent of less invasive techniques such as thermal ablation, chemical ablation through ultrasound-guided sclerotherapy, or combined procedures maintains similar rates of VTE incidence, suggesting that the concern for prevention should be the same, regardless of the technique.⁷

There are some barriers to using chemoprophylaxis (anticoagulants) in patients undergoing surgical treatment, and many surgeons do not establish a routine to assess their patients' VTE risks correctly.⁴ A possible postoperative increased bleeding rate and uncertainty of the ideal duration of prophylaxis are some concerns.⁸ Still, the main barrier is the lack of recognition by the surgeon that his patient is at high risk.⁹

The Caprini Score (CS) is an established tool to identify patients at higher risk of VTE. Created by Prof. Joseph Caprini and his team, it is a hybrid model combining evidence-based

Table I. Exemplifies the odds of having a positive response to list one items in the population during the last month. The Incidence (annual) had to be recalculated to month incidence or surveillance window incidence for those one off events lasting more than one month plus the prevalence of chronic diseases.

INCIDENCE IN POPULATIONS (LITERATURE)		
ITEM	Incidence (annual)	Month Incidence
Arthroplasty	0.30	0.025
Heart Attack	1.00	0.083
Stroke	0.30	0.025
Central Vein Access	1.50	0.125
Trauma	0.50	0.042
Paraplegia	0.05	0.0004
INCIDENCE IN POPULATION (LITERATURE)		
ITEM	Incidence (annual)	Surveillance window Incidence
Fracture*		
Plaster**	14.20	3.550
Pregnancy***	5.80	3.383
PREVALENCE IN POPULATION (LITERATURE)		
ITEM	Prevalence	
Congestive Heart Failure	1.5	
Bed Rest	1.17	
Total (month and surveillance window incidence + Prevalence)	9.91	

*To simplify, we assume that all Fracture uses plaster, and this item covers it

** On average, a patient remains 45 days with the plaster, adding up to 2.5 months of surveillance window for this item

*** We assume that a pregnancy lasts nine months, adding up to 10 months of surveillance window for this item. As 70% of our sample is childbearing female, we also correct this variable with this factor

medicine associated with logistic regression and the experience of a group working with risk stratification in VTE since 1981.¹⁰ The most validated version was proposed in 2005 when nine new items were added to the original 1991 version. Currently, it is composed of 39 items in which the absence of the factor does not add points, but the presentation can be graded between 1 and 5 points. The sum of the scores stratifies patients into low, medium, high risk, and very high risk, and the management must be individualized for each patient.

One advantage of the CS is the amount of work and data validating the predictive value of risk stratification. In 2011, Prof. Caprini and his group used the baseline data from the National Surgical Quality Improvement Program to identify a correlation between the incidence of VTE within 30 days after the surgical procedure and the CS outcome.¹¹

In contrast, a possible disadvantage is many items (39 in all) are covered in the questionnaire. The portion of questions that refer to diseases of high severity but with a low prevalence in the general population and, probably, even lower in patients preparing for surgical treatment of varicose veins, might be rarely positive. In North America, for example, the one-month annual incidence of acute myocardial infarction is 1%, stroke 0.3%, and recent spinal cord injury 0.05%.^{12,13}

These items increase the time taken to complete the questionnaire, transmitting a sense of wasted effort on the health team's part, and discouraging the use of the tool, as they correlate the future procedure with events with severe outcomes, generating anxiety and discomfort in patients.

In addition, according to the Classical Test Theory (CTT), questions, where the evaluator can anticipate a low rate of positive answers (expected answer in this scenario) tend to move the accurate Score away from the obtained Score as they increase the probability of error response (false positive response). According to the CTT, dichotomous questions, whose distribution of responses is around 50%, best classify individuals between two categories.¹⁴ Fortunately, this type of error can be mitigated by the proper coaching of the health practitioner who is in charge of the interview and having the patients pre-fill the answers with the patient-completed CS.¹⁵ This strategy enables a double check by the health team and prevents the use of leading questions that suggest a particular reply.

We proposed identifying patterns of responses to CS questions in the specific group of patients who will be undergoing an elective varicose vein procedure. Once the design is established, we will propose adaptive versions for future studies. This adaptative version would be a simplified CS for varicose vein procedures, aiming to spread the use of the tool and, consequently, mitigate the risk of post-surgical VTE.

Objective

To determine if there is any pattern in the Caprini Score responses of patients with indication of surgical treatment of varicose veins, emphasizing questions that usually have a negative answer.

Secondary Objectives

To propose an adaptive digital version that reduces the number of questions addressed to the patient without changing the original structure of the questionnaire.

Methods

This is a cross-sectional study. Consecutive patients in preparation for surgical treatment of varicose veins from 4 different sites (the private offices of 3 researchers and from the Brazilian Public Health Care System – SUS at the “Center for Integration of Education and Health” - CIES ambulatory) were screened for treatment from October to November of 2021 and submitted to the CS questionnaire.

To determine the sample size, we estimated the incidence/prevalence of diseases listed in list 1, which are expected to have a negative response pattern in our population (Table 1). Acute illnesses such as heart attack, stroke, and others, had a one-month surveillance window computed, and, therefore, the annual incidence was corrected to 1/12. Events with a computable duration, such as pregnancy and use of immobilization, had the average duration period added to the observation window. Chronic diseases such as congestive heart failure and bed rest had their prevalence computed. Even though not all fractures need a plaster cast, it was understood that fracture incidence was already covered in the plaster cast incidence.

List 1:

- Acute myocardial infarction in the last month
- Congestive heart failure (CHF) in the last month
- Stroke in the last month
- Pregnancy
- Central venous catheter in the last month
- Polytrauma in the last month
- Fracture in the last month
- Lower limb immobilization in the last month
- Restriction to bed in the last month
- Paraplegia in the last month
- Hip or knee replacement in the last month

We estimate that, in about 90% of the population, we would not have any positive response to the items above. To conclude that finding it in varicose vein surgery candidates is even lower, with 80% statistical power, a sample of more than 200 scores with all negative responses to list 1 item was necessary. Two hundred twenty-seven forms were computed, 117 from Public Health Care Service patients and 110 from private clinic patients related to the clinics of 3 of the project researchers.

Inclusion Criteria

- Patients over 18 years old who had an indication for surgical treatment of varicose veins by a vascular surgeon

Exclusion Criteria

- Patients who do not authorize the use of their answers in our study through digital or physical acceptance of the Informed Consent Form (ICF)

Research Procedures

After signings ICF, patients of the recruitment ambulatories who were candidates for surgical treatment of varicose veins were interviewed by the researchers to calculate the risk of post-operative DVT using a digital version of the Caprini Score in Portuguese created on the Redcap platform. All original questions have been included with the adaptive changes already implemented in Prof. Joseph Caprini’s official online tool¹⁶ listed below:

- Age ranges grouped as a one multiple-choice question turning 4 items into 1 multiple question;
- Duration of surgery grouped as a multiple-choice question turning 2 items into 1 multiple question
- Bed restriction duration options grouped as a multiple-choice question turning 3 items into 1
- All blood tests indicating an increased risk of blood clotting are grouped as one yes or no question turning 8 items into 1

Those changes reduce the 39 items into 3 multiple choice questions, 1 yes or no complex question that involves all 8 options to prothrombin mutations and the 22 remaining items totaling 26 questions.

- Inclusion of the binary question for biological sex between female or male, omitting the questions related to pregnancy and menstrual/female hormonal cycle of those patients who claim to be male (Figure 1 depicts the flow for data collection).

These adaptative change prevents all males of answering 3 unnecessary questions, totaling 24 questions for males and 27 for females.

As there is a low agreement between the BMI reported directly by patients and its quantification by others, weight and height were addressed separately. The Body Mass Index (BMI) was calculated automatically.

Patients either signed the informed consent (IC) during the interview or via email with the digital version of the IC.

Results

As a cross-sectional study, only the frequencies of the different Caprini Score responses were analyzed.

Only those responses with digital acceptance or physical signature of the ICF were considered in our database (227 out of 269).

The cohort consisted predominantly of women (77%) between the ages of 41 and 60 years (63%) and with an average BMI of 26. There was no statistical difference

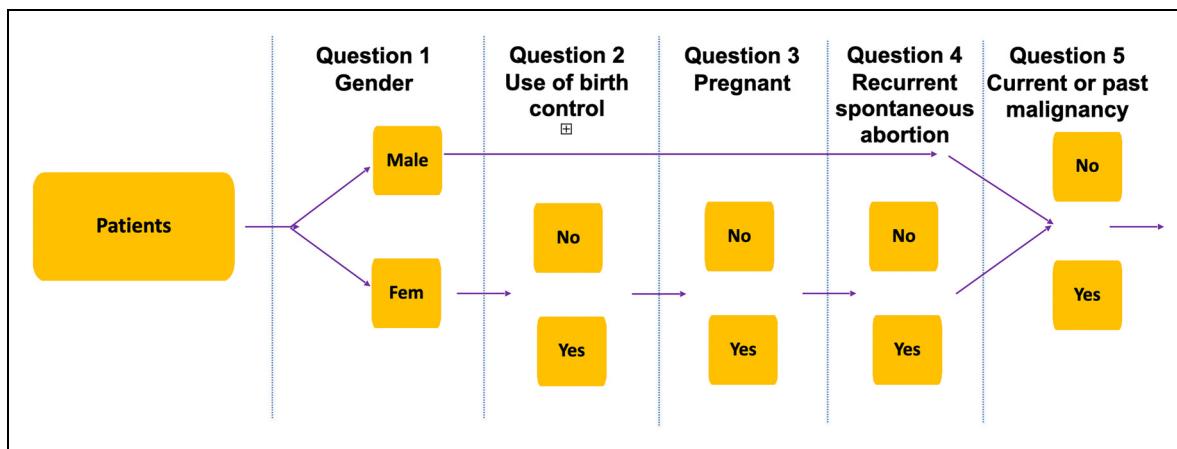


Figure 1. Example of an adaptive questionnaire. Note that male patients do not have to answer questions about the female reproductive system.

between the group of patients from the Public Health Care System and patients from the private clinics.

The pattern of dichotomous responses was divided arbitrarily into four subgroups considering the percentage of positive responses: none, less than 3%, between 3% and 20%, and more than 20% (Figure 2).

The items on list 1 formed the groups with no positive response.

- Acute myocardial infarction in the last month
- Congestive heart failure (CHF) in the previous month
- Stroke during the last month
- Pregnancy
- Central venous catheter in the previous month
- Polytrauma in the previous month
- Fracture in the previous month
- Immobilization of lower limb in the previous month
- Bed restriction during the previous month
- Paraplegia during the previous month
- Hip or knee replacement during the previous month

There were also few responses (less than 3% or more than 97%) to 6 items (list 2)

- Infection in the last month (2.6%)
- Chronic obstructive pulmonary disease (1.7%)
- Inflammatory Bowel Disease (1.7%)
- Major surgery in the previous month (2.2%)
- Family or personal history of blood tests indicating a tendency to venous thrombosis (2.6%)
- Presence of visible varicose veins (97%)

The third group is formed by questions regarding the use of hormones (12.7%), personal history of cancer (4.4%), history of repeated abortion or stillbirth with fetal restriction (3.5%), and history of personal or family DVT (3.5 and 5.7% respectively).

The questions that had the most impact on the characterization of preoperative risk for DVT were:

1. Presence of lower limb edema. This question practically divided the sample into two equivalent parts, with 50.2% of the patients presenting this characteristic.
2. Procedure size. 62.1% of the procedures were planned with local anesthesia or lasted less than 45 min, meaning that this subgroup did not accumulate points for this item.
3. BMI presented a normal-like distribution with a median of 26.32, just above the cut-off to add 1 point to the Score, which is 25, with 142 individuals adding 1 point due to weight (63%).
4. Age. In the original version of the Score, age was addressed by four separate dichotomous questions, where the question was asked yes or no if the patient belonged to that age group. The updated version of Prof. Caprini's website¹⁷ was used in our questionnaire. They transformed four items regarding age into multiple-choice, which proved to be adequate due to the distribution of answers around the subgroup with the population average.

If we observe the answers to the 12 items related to health problems in the last month, ten were classified as “no responses” and two as “less than 3%”. It was rare to find any positive answer to this group of questions (only 11 positive answers in 2724 questions or 0.4%), indicating a possible track to create an adapting version.

Discussion

Observing the pattern of responses to the CS in patients who are candidates for surgical treatment of varicose veins allows us to create strategies to improve the use of this tool. CS, in digital version, can be more assessable, concise and practical without changing its core. The questions related to severe health problems that occurred in the last month have a trend to be negative.

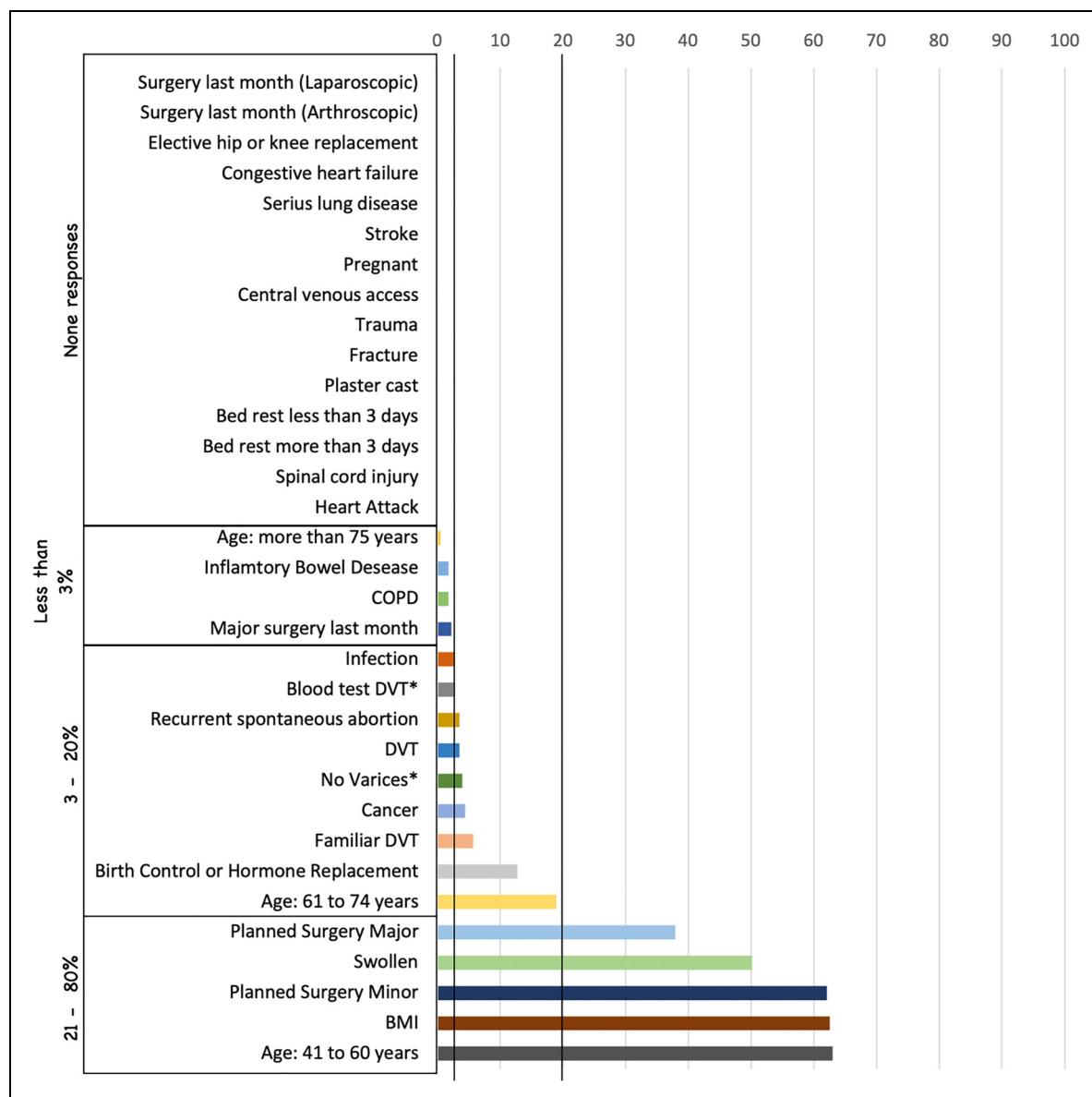


Figure 2. Chart with positive responses percentages to CS items. * The presence of varices was inverted to “No Varices” for didactic purposes

Ten out of 12 had no positive responses, and 2 less than 3%. A possible and impactful adaptation motivated by the pattern of the answers would be to gather these items by adding, for example, a new non-punctual question, the same way it was already done with gender in the Caprini official online tool, such as: Did you have any health problems in the previous month that motivated you to look for a Health Service?

If the answer is no, all the items below could be hidden:

- Major surgery in the last month / Hip or knee replacement in the last month
- Acute myocardial infarction in the last month
- Congestive heart failure (CHF) decompensated in the last month
- Stroke in the last month

- Pregnancy
- Central venous catheter in the last month
- Polytrauma in the last month
- Fracture in the last month
- Lower limb immobilization in the last month
- Restriction to bed in the last month
- Paraplegia in the last month
- Infection in the last month

If the answer is yes, whoever fills out the questionnaire will have access to the previously hidden questions, as depicted in Figure 3.

Another trend in our database was negative answers to chronic illness, with most chronic illness items less frequent than 3%. The exceptions were varicose veins and edema that

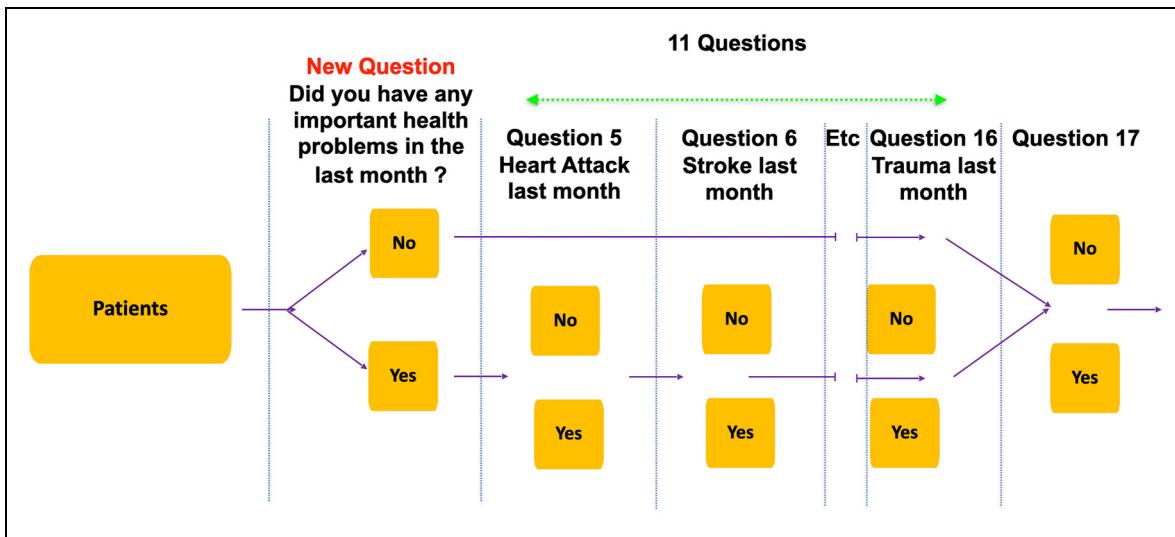


Figure 3. Patients' answers flow. Note that patients who did not have serious health problems in the last month would be spared from answering at least another 11 items

were frequent in our group and could be grouped in multiple questions related to lower limbs and Cancer, which, in our opinion, should be kept separately due to their relevance. As has typically been done in clinical semiology, another possible adaptive question would be asked: Do you have a chronic illness such as a lung, heart, or bowel problem?

Again, if the answer is no, the items below would be hidden

- Congestive heart failure (CHF) decompensated in the last month*
- Restriction to bed in the last month*
- Central venous catheter in the last month*
- Chronic obstructive pulmonary disease
- Inflammatory bowel disease

* These items would appear in both non-punctual questions

And again, if the answer is yes, whoever fills out the questionnaire will have access to the previously hidden questions.

A last adaptative strategy was speculated for pregnancy. Indeed, and in line with our numbers, pregnant patients were not expected to be prepared to do an elective surgical procedure; regardless of this, it is also not expected to find pregnant women using birth control pills or over 61 years of age. Therefore, for women who fit these two conditions (half of our sample), the question about pregnancy could simply be omitted.

On the other hand, questions shared with all risk assessment models validated for aesthetic surgery,¹⁷ such as BMI, age, and procedure duration, were classified in the 21-80% group, inferring their importance in the decision-making process in health patients who will perform elective procedures. Still, other relevant risk factors, such as a history of DVT and Cancer and items covered exclusively by the CS, such as obstetrical related questions, had frequency between 3-20%, corroborating their importance. Although any adaptative change in those items won't be

proposed, we suggest placing them at the beginning of the electronic form.

These adaptative changes would make little difference for those who are used to the CS because that is exactly the rationale behind our initial idea; the adaptative changes we are proposing already have been used "unofficially" by the majority of those who are familiar with this tool. Nevertheless, this shorter version will be more friendly for those not familiar with the CS and could engage more practitioners to use it.

Translational research is the type of study that aims to narrow knowledge production with a clinical application. A good example is the patient-completed CS,¹⁵ a validated version of CS, designed to be filled by the patients and only reviewed by the health team. Although there are papers proposing new scores¹⁸ or changing the core of CS¹⁹ as far as we know, there are no other translational studies regarding CS.

As an observational study, none of these suggestions have been tested yet. More research is needed to understand the real impact of an adaptive version of CS. Another limitation is that only patients with varicose veins were examined; probably, the answers patterns in different elective procedures, such as hip or knee replacement, may follow another trend, and the advantages of this method should be evaluated.

Overall, rescore the patients from our database using the changes proposed above, for more than 90% of patients, the questionnaire would be reduced to approximately half of the questions of the current version (12 for men, 14 / 15 for women instead of 24 for men, and 27 for women). Yet, the adaptive version would have fewer questions than the current one for virtually all the remaining patients. The only exception would be a patient for which both non-scoring questions would be positive, adding two questions to the regular twenty-four.

Fundamentally, the intention of this study was to simplify the CS for an elective procedure, which is rarely performed in sick patients. Additionally, we propose that this will also

expand the use of CS and ultimately reduce the risk of VTE in patients undergoing varicose vein surgery, as well as other elective procedures.

Conclusions

There is a pattern in the CS responses of patients with an indication of surgical treatment of varicose veins. Many of the CS questions are not helpful and may result in filling errors.

Based on our results, we will propose an adaptive digital version that reduces the number of questions addressed to the patient without changing the original structure of the CS questionnaire.

New studies are needed to establish a different adaptative version of the CS and understand which one will help us create a better tool. These studies are currently underway.

Conflict of Interest

None to disclose

Ethics and Patient Consent

Ethical approval to report this case was obtained from Comitê de Ética em Pesquisa em Seres Humanos da Santa casa de São Paulo, number CAAE 39847420.20000.0070.

Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article

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