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ORIGINAL ARTICLE

Post-thrombotic syndrome after upper extremity deep vein thrombosis: An international Delphi consensus study

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Abstract

Objectives: Primary deep vein thrombosis of the upper extremity (UEDVT) is a rare condition but up to 60% of patients may develop post-thrombotic syndrome in the upper extremity (UE-PTS) with significant morbidity and decreased quality of life. However, there is no universally accepted method to diagnose and classify UE-PTS, hampering scientific research on UEDVT treatment. Through this international Delphi consensus study we aimed to determine what a clinical score for diagnosing UE-PTS should entail.

Methods: An online focus group survey among 20 patients treated for UEDVT was performed to provide clinical parameters before the start of a four round electronic Delphi consensus study among 25 international experts. The CREDES recommendations on Conducting and Reporting Delphi Studies were applied. Open text questions, multiple selection questions, and 9-point Likert scales were used. Consensus was set at 70% agreement.

Results: After four rounds, agreement was reached on a composite score of five symptoms and three clinical signs, combined with a functional disability score. The signs and symptom will each be scored on a severity scale of 0–3 and the total score expressed as an ordinal variable; no/mild/moderate/or severe PTS. The functional disability portion measures the impact of the signs and symptoms on the functionality of the patient's arm.

Conclusion: Consensus was reached on a composite score of signs and symptoms of UE-PTS combined with a functional disability score. Clinical validation of the UE-PTS score in a large patient cohort is mandatory to facilitate application in future research.

KEYWORDS
Delphi technique, diagnosis, post-thrombotic syndrome, thoracic outlet syndrome, upper extremity deep vein thrombosis

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In collaboration with the Upper Extremity PTS group (Appendix S1)

All authors have read and approved this article for submission.

1 | INTRODUCTION

Primary deep vein thrombosis of the upper extremity (UEDVT) is a rare condition with an estimated incidence of 1–3 per 100 000 people per year.[1–3] Contrary to the more common secondary upper extremity thrombosis, in primary UEDVT there is no clear provoking factor for thrombosis such as intravenous catheters or pacemaker wires. Hence, the treatment for primary UEDVT is more complex compared to secondary UEDVT. Moreover, complications after primary UEDVT are common and up to 60% of patients can develop chronic symptoms in the upper extremity, commonly attributed to the post-thrombotic syndrome (UE-PTS).[4–9] PTS refers to a set of signs and symptoms of chronic venous insufficiency that can occur after deep vein thrombosis. The UE-PTS related morbidity is significant and has a negative impact on patients' quality of life (QoL).[10] Therefore, prevention of UE-PTS is an important goal in both conservative and invasive treatment strategies for UEDVT.[11] In studies on UEDVT treatment, UE-PTS free survival has become a critical outcome parameter, but clinical tools to objectify and measure PTS in the upper extremity are still lacking. Currently a wide variation of outcome measures for symptom-free survival and/or UE-PTS after treatment of UEDVT are being used, making a comparison of studies unfeasible.

Research on diagnosis, prevention, and treatment of PTS primarily focuses on VTE in the lower extremity due to its much higher incidence. This has resulted in the development of several clinical scoring methods to diagnose lower extremity PTS (LE-PTS). The Villalta scale is considered the gold standard for diagnosing LE-PTS when combined with a venous disease–specific QoL questionnaire. In the past years, the Villalta scale has been slightly modified for use in the upper extremity.[12–14] However, the scale has been subject to criticism. The scoring method relies on subjective measures and can give false positive results.[15] More importantly the Villalta scale was designed for the lower extremity and focuses on specific signs and symptoms in the lower extremity, whereas UE-PTS has its own distinct presentation and symptoms that are not accounted for in the Villalta scale (e.g., loss of strength or function in arm or hand, reduced stamina etc.). Hence, the Villalta scale seems unsuited for use in the upper extremity. Some studies simply score the presence of UE-PTS as a binary variable, based on any residual symptoms reported at last follow-up. This approach not only lacks confirmation whether the residual symptoms are truly caused by PTS, but also fails to indicate how severe these symptoms are. Other studies measure the effect of surgical treatment for UEDVT by measuring the functional disability (often the QuickDASH score) of patients before and after surgery.[6,16] However, most of these functional disability scores are specifically designed to assess upper limb functionality in the context of orthopedic surgery for musculoskeletal injuries or disease and were never intended to diagnose a venous disease such as UE-PTS.[17,18] Finally, there are outcome measures that are specifically used in research regarding (venous) thoracic outlet syndrome (TOS) (e.g., the Derkash classification and the TOS disability scale).[11,16,19,20] These classifications merely focus on the postoperative improvement or deterioration of a patient's symptoms in the context of thoracic outlet decompression surgery for venous thoracic outlet syndrome and are unfit for use in the primary UEDVT population as a whole, nor were these scores validated for diagnosing UE-PTS.

ESSENTIALS

- There is no consensus on how to diagnose and classify upper extremity post-thrombotic syndrome (UE-PTS).
- We conducted a Delphi consensus study on what a diagnostic tool for UE-PTS should entail.
- Consensus was reached on signs, symptoms, and necessity for a functional disability score.
- Validation of the UE-PTS score is required before application in future research.

To allow comparison of future randomized controlled trials (RCT) or prospective registries it is vital to have an unambiguous and reproducible outcome measure to score UE-PTS. Furthermore, an easy-to-use clinical UE-PTS score may help to raise awareness of this syndrome making an early diagnosis and treatment possible. Thus, from both a scientific and a clinical point of view, a broadly accepted outcome measure is warranted to assess UE-PTS. Such a clinical score will need to: (1) represent a clinically relevant outcome for the patient; (2) be supported by a broad spectrum of experts in the field of PTS and VTE; and (3) be, where possible, an objective and reproducible scoring method. We aim to develop such a score through a multistep approach. The first step is to reach international consensus on what UE-PTS entails and how we can diagnose this ill-defined disease. The second step will be to test and fine-tune the proposed diagnostic algorithm in a large patient cohort. The final step will be the implementation of this method in daily practice and future research.

For the first step we developed this Delphi study with the aim to reach consensus among international experts on how to best diagnose UE-PTS, what the most important clinical signs and symptoms of UE-PTS are, and what a future clinical scoring method for diagnosing and measuring the severity of PTS in the upper extremity should look like.

2 | MATERIAL AND METHODS

For this study we used the Delphi approach, which is a widely used method to gain consensus among a panel of experts on a certain subject.[21,22] We followed the CREDES (Conducting and Reporting Delphi Studies) criteria.[23] Before the start of this Delphi study we performed a focus group survey among 20 patient volunteers (patient panel) from the Dutch patient association "Harteraad." All volunteers from the panel experienced UEDVT and the majority (80%) had residual symptoms after treatment (see Figure 1). We inquired

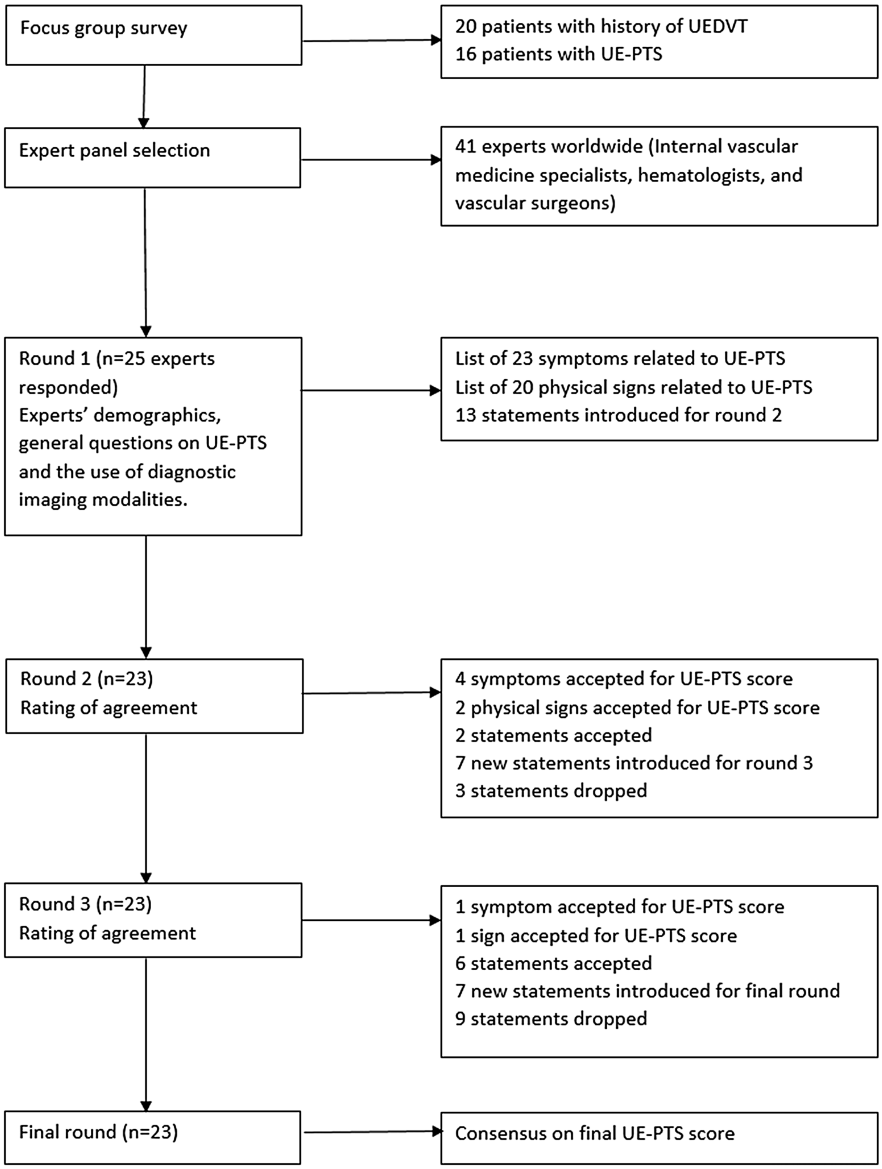

FIGURE 1 Flow diagram of the Delphi process. UE-PTS, upper extremity post-thrombotic syndrome *Accepted statements per round are presented in the list of accepted statements per round (see Appendix S2)

about residual symptoms and how these residual symptoms affected different aspects of their life on a scale from 1–5 (1 not affected, 3 moderately affected, and 5 very severely affected) and how they believed physicians should assess or measure their symptoms in the future.

We then formed an expert panel to participate in the Delphi consensus study. The experts were selected based on: (1) Involvement in the development of (inter)national guidelines on the diagnosis and treatment of (upper extremity) thrombosis; (2) membership in the International Network of VENous Thromboembolism Clinical Research Networks (INVENT-VTE); (3) those who were leaders in the field of UEDVT treatment and research illustrated by their publication track record. We attempted to assemble a heterogeneous and multidisciplinary group of internal vascular medicine specialists, hematologists, and vascular surgeons to ensure a broad support of the reached consensus.

We performed four Delphi rounds. For each round all responses were anonymously collected and analyzed. Round 1 consisted of open text questions on the experts' view on UE-PTS and what they believed are vital parameters to diagnose UE-PTS and its severity. The information gathered in round 1 combined with the answers provided in the focus group interviews provided the input for the statements in round 2. In the following rounds, the Delphi steering committee dropped, amended, and developed new statements based on the input provided in each round. An overview of the results of each round was presented back to the expert panel via e-mail and incorporated in the survey of the subsequent round. The statements that did not reach consensus in previous rounds were fed back in the next rounds to give the participants an opportunity to possibly amend their answers based on the other participants' opinions. This went on until either: (1) the threshold for consensus was reached for a statement, (2) a statement was dropped because consensus could not be reached, (3) the predefined study end of four Delphi-rounds was reached. The agreement threshold was calculated based on the provided answer options: (1) in multiple choice statements agreement was

	Absent (0 points)	Mild (1 point)	Moderate (2 points)	Severe (3 points)
Symptoms of PTS				
Edema/swelling of the arm				
Heavy feeling of the arm				
Fatigue on using arm				
Pain (chronic or during specific exercises)				
Functional limitations arm				
Clinical signs of PTS				
Swelling arm measured by circumference of upper and lower arm versus contralateral side				
Discoloration of arm/hand/fingers (red/white/cyanotic) in rest				
Collateralization or visible collateral veins around shoulder/chest				

Total signs and symptoms score: ..... (Max 24)

PTS severity: No/ Mild/ Moderate/ Severe PTS

+

Functional disability score: (specific score is yet to be determined)

FIGURE 2 UE-PTS score. UE-PTS, upper extremity post-thrombotic syndrome

set at 70%, and (2) in statements using a 9-point Likert scale ranging from 1 = completely disagree, 5 = neutral, and 9 = completely agree; 70% of the participants had to vote at least 7 or higher to reach consensus. The Delphi steering committee tasked to overlook the Delphi process consisted of eight members: three experts on vascular medicine and venous thrombosis (SM, MN, JW), four vascular surgeons with expertise on UEDVT treatment (ÇÜ, EvH, BP, GdB), and one PhD researcher (RdK).

Descriptive statistics were performed after each round using Statistical Package for the Social Sciences (SPSS version 25, IBM) and bar charts were used to present results between rounds.

3 | RESULTS

A total of 41 experts worldwide were contacted for this study of which 25 agreed to participate (62.5%). Of all respondents 68% had more than 20 years of clinical experience in the field of (upper extremity) deep vein thrombosis, 24% had 11–20 years of experience, and 8% had 6–10 years of experience. As could be expected with a rare disease such as UEDVT, the majority (64%) only treated up to 10 patients with UEDVT per year, 16% treated 10–25 patients per year, 12% treated 25–50 patients per year, and 8% treated 50–100 patients per year. Two experts dropped out after the first round, leaving a total of 23 experts that completed all four rounds of this Delphi study.

3.1 | Patient panel

The patient panel reported seven distinct signs and symptoms, all of which were also suggested by our expert panel in round 1. The most common suggestions for the UE-PTS score were to measure the level of pain and edema of the arm. The patient panel also reported that the residual symptoms had a great impact on their lives. UE-PTS had the biggest impact on the ability to play sports (75% at least moderately affected; 25% very severely), closely followed by emotional/mental status (75% at least moderately; 19% very severely), and job performance and the ability to perform household chores (both 69% at least moderately affected).

3.2 | Signs and symptoms of PTS

In round 1, the expert panel provided a total of 23 symptoms and 20 clinical signs of UE-PTS. In subsequent rounds, agreement was reached on a total of five symptoms: (1) edema/swelling of the arm, (2) heavy feeling of the arm, (3) fatigue on using arm, (4) pain (chronic or during specific exercises), and (5) functional limitations of the arm) and three clinical signs: (1) swelling of arm measured by circumference of upper and lower arm vs. contralateral side, (2) discoloration of arm/hand/fingers (red/white/cyanotic) in rest, and (3) collateralization or collateral veins around shoulder/torso/breast) of PTS to be incorporated into the PTS score. Furthermore, the expert panel agreed that the presence and severity of each sign and symptom should be scored on a 0–3 point scale (0 = absent, 1 = mild, 2 = moderate, 3 = severe; see Figure 2).

3.3 | Functional disability and quality of life

The expert panel strongly agreed (91%) on incorporating a standardized functional disability score to measure the impact of UE-PTS symptoms. However, no agreement could be reached on a specific functional disability scoring method (e.g., QuickDASH, DASH score, etc.). No agreement was reached on the use of a QoL questionnaire

as an integrated part of the UE-PTS score. When asked about the use of QoL questionnaires as an additional tool to measure the impact of PTS, the majority (78% agreement) voted against the use in daily clinical practice. However, a majority (61%, agreement threshold not reached) voted that QoL measurement might be of added value for scientific research purposes.

3.4 | Diagnostic imaging

In round 1 we asked the panel's opinion on a 5-point scale (1 = very useful, 3 = neutral, 5 = useless) on the use of diagnostic imaging to assist in diagnosing UE-PTS. Echo-duplex (36% very useful, 44% somewhat useful) and computed tomography (CT) venography (32% very useful, 32% somewhat useful) were considered to be the most useful imaging modalities. However, 25% of experts voted that diagnostic imaging was useless in diagnosing UE-PTS and overall, only a slight majority (52%) voted for the standardized use of diagnostic imaging. Furthermore, 26% of our expert panel voted that UE-PTS is a clinical diagnosis and therefore diagnostic imaging has no role in the diagnostic work-up. Due to the extent of these contradicting opinions, the diagnostic imaging statements were dropped from further rounds and we cannot provide any recommendations on the use of diagnostic imaging for diagnosing UE-PTS.

3.5 | PTS severity

In rounds 2 and 3 the expert panel was asked how the severity of UE-PTS could be measured. Agreement was reached that calculating a score by looking at the total number of positive signs and symptoms and their severity (0–3 point scale) is a reliable method to measure UE-PTS severity (74% agreement). An even greater majority (87% agreement) voted that the severity of UE-PTS symptoms must be determined by a validated functional disability score as a fixed part of the UE-PTS score.

Finally, after four Delphi rounds, agreement was reached on the following preliminary UE-PTS score (see Figure 2). (See Appendix S2 in supporting information for the list of accepted statements per round.)

4 | DISCUSSION

Research on the treatment of UEDVT is hampered by the absence of an accepted UE-PTS score by both clinicians and patients as a universal primary outcome measure. In this article we present an international consensus on what experts believe to be the most important clinical signs and symptoms of UE-PTS and what a clinical scoring method for UE-PTS should entail. With these five symptoms and three clinical signs of UE-PTS in combination with a scaling option for severity and an additional functional disability score, we made a proposal for a preliminary UE-PTS score.

Notably, there are some resemblances between the Villalta scale and the presented UE-PTS score, but there are several aspects that set the UE-PTS score apart. Not only are the proposed signs and symptoms now tailored to UE-PTS when compared to the Villalta scale but more importantly, a functional disability aspect has been added to the scoring method. This allows the physician to measure the impact of a patients' signs and symptoms on their functional capabilities. The experts thereby provided a clear statement that to properly measure UE-PTS a combination of typical signs and symptoms, and their impact on a patient's functional capabilities, are required. This is in line with the recently published Post-VTE Functional Status (PFVS) scale that was developed to better assess the functional limitations after VTE in the lower extremity.[24,25]

Although the expert panel did not reach consensus on several statements, a few are worth mentioning as they showed a tendency to consensus. More than half of the experts (61%) voted for the use of an additional QoL questionnaire to further assess the severity of PTS in a research setting, but deemed a QoL score impractical for implementation in a clinical scoring method. However, our patient panel confirmed that PTS had a significant negative impact on numerous aspects of their lives, varying from their mental status to the ability to play sports or practice their hobbies. Therefore, we would like to emphasize the possible additive value of a QoL assessment to better measure the impact of UE-PTS on a patient and to consider QoL as a secondary endpoint in future studies on UE-PTS.

Substantial disagreement between experts on the use of diagnostic imaging modalities was noted. Only half of the experts recommended standardized use of diagnostic imaging in the PTS work-up whereas a quarter of the experts indicated to never use diagnostic imaging as they consider PTS a clinical diagnosis. This disagreement seemed related to differences in subspecialty of our expert panel. Theoretically, a vascular surgeon has a more invasive approach to treat UEDVT (thoracic outlet decompression surgery, percutaneous transluminal angioplasty, stenting, etc.) and needs to be informed on a possible underlying anatomical substrate for a patient's recurrent symptoms. The non-interventional approach of hematologists and vascular medicine specialists results in less invasive additional imaging. These preferences were reflected in the Delphi score as all vascular surgeons indicated to use some form of imaging in patients with suspected PTS and the majority was in favor of the standardized use of diagnostic imaging, in contrast to most internal medicine specialists.

This study has several limitations. There are some aspects of the current score that we either could not reach consensus on, or that could not be determined using the Delphi method. First, no consensus was reached on which functional disability score should be incorporated into a future UE-PTS score. Although the experts agreed on using a functional disability score, further research is needed to define which disability score is most suitable. Second, the Delphi method is not suitable to determine cut-off values for a clinical scoring method, in our case for the presence or absence of UE-PTS, grading of PTS severity, and the difference in arm width when measuring edema. This requires a clinical study that should

at least address the following issues: (1) Threshold values must be determined to indicate whether PTS is present or not and to indicate different severity grades. (2) A variety of functional disability scores must be compared to determine the most suitable scoring method for implementation in a definitive UE-PTS score. The low incidence of UEDVT will be the greatest pitfall of this study and we therefore recommend testing the herein proposed UE-PTS score in a large, preferably international patient cohort of UEDVT patients.

5 | CONCLUSION

We achieved consensus on what the most important clinical signs and symptoms of UE-PTS are and what aspects a clinical scoring method for diagnosing and measuring the severity of UE-PTS should encompass. Follow-up studies are required to test the clinical value of the proposed scoring method and to determine which functional disability score is most suitable for implementation in a future UE-PTS score, followed by a validation study in a large patient cohort.

AUTHOR CONTRIBUTION

R.J.C.M.F. de Kleijn: Concept and design of questionnaires, analysis and interpretation of data, monitoring of the Delphi process, and writing of manuscript. L. Schropp: Analysis, interpretation of data, and writing of manuscript. Eline S. van Hattum: Concept and design, interpretation of data between Delphi rounds, and monitoring of the Delphi process and revision of manuscript. Çagdas Ünlu: Interpretation of data between Delphi rounds and monitoring of the Delphi process and revision of manuscript. Saskia Middeldorp: Interpretation of data between Delphi rounds and monitoring of the Delphi process and revision of manuscript. Mathilde Nijkeuter: Concept and design, interpretation of data between Delphi rounds, and monitoring of the Delphi process and revision of manuscript. Jan Westerink: Concept and design, interpretation of data between Delphi rounds, and monitoring of the Delphi process and revision of manuscript. Bart-Jeroen Petri: Concept and design, interpretation of data between Delphi rounds, and monitoring of the Delphi process and revision of manuscript. Gert J. de Borst: Concept and design, interpretation of data between Delphi rounds and monitoring of the Delphi process, revision of manuscript, and final approval.

CONFLICT OF INTEREST

All authors declare to have no conflicts of interest.

INFORMED CONSENT

All authors have read and approved this article for submission and have provided informed consent for publication.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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