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ORIGINAL ARTICLE

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Post-thrombotic syndrome in children: Measurement properties of CAPTSure, a new diagnostic tool

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Abstract

Background: CAPTsure (Clinical Assessment of PTS) is a new tool for diagnosis and severity rating of pediatric postthrombotic syndrome (PTS). Our objective was to test the reliability, measurement error, and minimal detectable change of CAPTSure.

Methods: Children aged newborn to 18 years who sustained upper extremity or lower extremity deep vein thrombosis (DVT) were enrolled ≥ 6 months after DVT diagnosis. Patients were assessed by 2 raters to determine the reliability of the clinician assessment component (CC) of CAPTSure. Patients/proxies completed CAPTSure at baseline and approximately 2 weeks later to assess test-retest reliability of the symptoms component (SC).

Results: Of 148 patients enrolled in the study; 30 had sustained either bilateral or both upper and lower extremity DVT. Hence, 178 extremities were assessed for PTS signs (86 upper extremity, 92 lower extremity). Intraclass correlation coefficient (ICC) for the CC was 0.89 (95% confidence interval [CI], 0.84-0.93) for upper extremity and 0.88 (95% CI, 0.83-0.92) for lower extremity. Nonclinicians performed 59% of measurements. Ninety-eight patients completed the SC at baseline and follow-up, for a total of 60 upper extremity and 61 lower extremity assessments. ICC for the SC was 0.89 (95% CI, 0.84-0.93) for upper extremity and 0.92 (0.87-0.95) for lower extremity. ICC for CAPTSure was 0.92 (95% CI, 0.87-0.95) for upper extremity and 0.93 (95% CI, 0.88-0.95) for lower extremity assessment. Measurement error ranged between 1.7 and 4.3 of 100 points. A change of approximately 11 of 100 points in CAPTSure score would be required to be confident that there was a change in PTS severity.

Conclusion: CAPTSure has excellent reliability and a small measurement error, even when applied by nonhematologists.

KEYWORDS

child, infant, lower extremity, postthrombotic syndrome, reproducibility of results, surveys and questionnaires, upper extremity

Prior presentation of study data: Interim analysis of this work was presented at the XXVI Congress of the International Society on Thrombosis and Haemostasis, Berlin, Germany, July 8-13, 2017.

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Essentials

- CAPTSure (Clinical Assessment of PTS) is a tool for diagnosis and severity rating of pediatric postthrombotic syndrome (PTS).
- We tested its reliability, measurement error (ME), and minimal detectable change (MDC).
- CAPTSure showed excellent reliability and small ME, even when applied by nonhematologists.
- A change of 11 of 100 points would indicate that there was a change in PTS severity, as per the MDC.

1 | INTRODUCTION

Postthrombotic syndrome (PTS) is a long-term consequence of deep vein thrombosis (DVT), diagnosed by the presence of characteristic signs and symptoms.[1]

The index for the Clinical Assessment of PTS (CAPTSure) is a tool developed for the diagnosis and severity rating of PTS in children.[2,3] Whereas PTS signs are measured by the clinician using a clinician assessment component, PTS symptoms are reported by either the patient or their proxy, according to the age of the child being assessed, using a patient/proxy questionnaire component. The scores of signs and symptoms are combined to obtain a final score that ranges from 0 to 100 points, which are indicative of PTS severity of the upper or lower extremity; 100 points indicate the worst possible PTS. The scoring system takes into account the importance that health care providers and patient/parents assigned to each sign and symptom during the development of the tool.[3] Upper and lower extremities are assessed separately by means of specific subindexes. The items and responses of each subindex can be seen in Appendix S1.

CAPTSure was developed as a *formative* measure. Formative measurement models can be distinguished from the reflective models commonly used in psychology by a number of characteristics including correlation among items, direction of causality between the construct and its items, and nature of the construct.[4]

The study of test-retest reliability and interrater reliability is recommended for formative measures.[5,6] Reliability in this context can be related to the temporal stability of the index. The concept is similar to the "reliability/precision" aspect of reliability described in measurement in education and psychology,[7,8] and it is determined on the basis of obtaining consistent results when the testing is replicated. Importantly, the construct being measured would be expected to remain stable between replications.[8] Reliability is context specific and depends on the study sample.[9,10]

Variation in the results obtained through repeated testing reflect the presence of measurement error.[7,11] Measurement error of a tool is considered to be more stable than its reliability when the tool is applied to different samples,[10] and it provides information about the precision of the scores.[12]

In the context of PTS, the stability of scores over time obtained by assessment tools such as CAPTSure can be influenced not only by the reliability of the measurement instrument itself but also by changes in the individual applying the instrument and by true changes in PTS.[7,9] For example, scores of items that assess PTS symptoms can change due to oscillation of symptoms and differences within the subject between occasions not related to changes in the phenomenon[7]; test-retest reliability becomes relevant in this case. The variability in the scoring of items that assess PTS signs can be due to differences among clinical raters and differences in the measurement procedure; in view of such variability, interrater reliability is of interest.

Assessing the reliability of tools used in clinical practice is critical, as it allows clinicians to interpret why scores change over time and, therefore, be confident when making clinical decisions based on these tools.[8,13]

This study aimed to evaluate the reliability and measurement error of CAPTSure for the assessment of upper and lower extremity PTS as separate subindices. In addition, minimum detectable change (MDC) for each subindex was estimated.

2 | METHODS

This prospective study enrolled newborns to children aged up to 18 years old, who sustained upper and/or lower extremity DVT at least 6 months prior to study participation and were followed up at the Thrombosis Clinic in The Hospital for Sick Children, Toronto, Ontario, Canada.

Given an anticipated intraclass correlation coefficient (ICC) of 0.80, we estimated that the measurement of 60 upper and 60 lower extremities by either 2 raters or in 2 testing occasions, for a total of 120 upper and 120 lower extremity measurements overall, would provide an acceptable expected width of the 95% confidence interval (CI) of 0.2.[14] Assuming a 30% to 35% loss to follow up for test-retest and the fact that approximately 15% to 20% of patients were expected to have >1 extremity affected by DVT,[15] we estimated that a sample of 140 to 150 patients would allow us to reach the goal of obtaining measurements on 60 upper and 60 lower extremities.

At the time of study enrollment, 2 assessors measured PTS signs applying the clinician assessment component of CAPTSure, which includes the assessment of thigh and calf circumference difference and ulcers for the lower extremity and arm circumference difference and collaterals for the upper extremities (Appendix S1). Assessors took 3 measurements, as previously described,[2] and averaged the obtained values to determine limb circumference difference. In addition, the assessor evaluated pain intensity in children aged 4 to 9 years using the Faces Pain Scale–Revised (FPS-R).[16] Assessments were performed independently.

The assessors were trained to apply CAPTSure either in person or using online educational material[17] and were assigned to evaluate each patient from a pool of clinicians and research team members according to availability.

PTS symptoms were reported by patients or proxies, according to the age of the child (older or younger than 10 years), by completing the patient/proxy questionnaire component of CAPTSure. This questionnaire assesses the frequency of heaviness, tired limb sensation, swelling, skin redness, tightness, and paresthesia of the affected limb (Appendix S1). Children aged 10 years and older self-reported pain intensity using the FPS-R. An electronic version of the questionnaire developed using REDCap[18] was used in the study.

After study enrollment, patients or proxies were requested to complete the symptoms questionnaire at baseline and 14 days after the first assessment. It was expected that PTS would remain stable in this period of time, thus allowing the assessment of temporal stability of scores.[7]

Interrater reliability and 95% CI for the clinician assessment component of CAPTSure (ie, PTS sign measurement) and test-retest reliability and 95% CI for the patient/proxy questionnaire component of CAPTSure (ie, PTS symptom measurement) for each subindex were estimated using linear mixed models to take into account the nested nature of the data (ie, that some patients had more than one extremity assessed). Confidence intervals were calculated using a parametric bootstrap. To estimate the reliability of the final CAPTSure score of each subindex, the clinician and patient/proxy subscores of the first and second assessments were combined (ie, clinician assessment time 1 + patient/proxy report time 1 = final score time 1; clinician assessment time 2 + patient/proxy report time 2 = final score time 2).

Measurement error for each component of the index was calculated as the standard error of measurement, derived from the error variance (ie, the square root of the error variance). The standard error of measurement was, in turn, used to estimate the minimum detectable change or minimal difference between CAPTSure scores that would be needed to consider a real change in PTS severity, beyond measurement error.[12,19]

TABLE 1 Characteristics of patients

Characteristic	Frequency or median (n = 148)
Male sex, n (%)	76 (51)
Age at the time of study participation, median (25th-75th percentile)	8 years (4-12 years)
Underlying condition, n (%)	
Congenital heart disease	67 (45)
Infectious and inflammatory conditions	17 (11)
Prematurity	15 (10)
Surgical conditions	14 (9)
Organ transplant	7 (5)
Cancer	7 (5)
None	5 (3)
Central venous catheter-related DVT, n (%)	129 (87)

Abbreviation: DVT, deep vein thrombosis.

Statistical analysis was performed using R (R Core Team 2017, R Foundation for Statistical Computing, Vienna, Austria), using the lme4 package.[20]

Informed consent and assent, when applicable, were obtained prior to study participation. The study was approved by the hospital Research Ethics Board.

3 | RESULTS

In total, 148 patients were enrolled in the study between November 2016 and December 2017 at a median of 4.4 years after DVT diagnosis (range, 6.1 months to 17.7 years).

Characteristics of the included patients are shown in Table 1. Forty-five patients were toddlers and preschoolers (30%, 1-4 years of age), 60 were school-aged children (41%, 5-11 years of age), and 43 were teenagers (29%, 12-18 years of age). Median (range) PTS scores at the time of first assessment was 0 (0-82.5) for upper extremities and 3.6 (0-58.5) for lower extremities.

Forty-eight percent of the upper extremities and 57% of the lower extremities assessed had at least 1 sign or symptom of PTS (score > 0); 24% of the upper extremities and 32% of the lower extremities had a score > 10 of 100 possible points.

Nineteen of the 148 recruited patients (13%) had sustained a bilateral DVT, and 11 patients (7%) had sustained both an upper and a lower extremity DVT. Hence, 178 extremities were assessed for PTS signs (86 upper extremities, 92 lower extremities) using the clinical assessment component of CAPTSure. Reliability was high and measurement error was low for the clinician component of each subindex (Table 2). Nonclinicians performed more than half of the limb assessments (59%).

Ninety-eight patients (66%) completed the patient/proxy questionnaire component at baseline and follow-up, for a total of 121 unique extremities with full assessment (60 upper extremities, 61 lower extremities). The follow-up patient/proxy questionnaire was filled out at a median of 13 days after study enrollment (range, 7-34 days). Reliability was high and measurement error was low for the patient/proxy questionnaire component of each subindex (Table 2). Subanalysis of the patient vs. proxy responses showed an ICC of 0.92 (95% CI, 0.87-0.95) for self-report and an ICC of 0.61 (95% CI, 0.44-0.74) for proxy-reported symptoms.

Because early responses may increase reliability due to respondents recalling previous answers, we analyzed a subsample of retest responses provided <10 days from the first assessment. The analysis showed an ICC of 0.54 (95% CI, 0.16-0.77).

Reliability and measurement error of the CAPTSure subindexes for the assessment of upper and lower limbs are shown in Table 2.

According to the measurement error results, a minimal detectable change of 11.9 and of 10.5 of 100 points in CAPTSure scores would be required to convincingly indicate a change in PTS severity when assessing upper and lower extremities, respectively.

TABLE 2 Reliability and measurement error of CAPTSure and its components

Component	ICC (95% CI)	Measurement error (95% CI)
PTS symptoms (patient/proxy questionnaire component), upper extremity (n = 60)	0.89 (0.84-0.93)	4.3 (3.3-5.3)
PTS symptoms (patient/proxy questionnaire component), lower extremity (n = 61)	0.92 (0.87-0.95)	3.6 (2.8-4.4)
PTS signs (clinician assessment component), upper extremity (n = 86)	0.89 (0.84-0.93)	1.8 (1.5-2.2)
PTS signs (clinician assessment component), lower extremity (n = 92)	0.88 (0.83-0.92)	1.5 (1.2-1.8)
CAPTSure, upper extremity subindex (n = 60)	**0.92 (0.87-0.95)**	**4.3 (3.7- 5.2)**
CAPTSure, lower extremity subindex (n = 61)	**0.93 (0.88-0.95)**	**3.8 (3.2-4.6)**

Abbreviations: CI, confidence interval; ICC, intraclass correlation coefficient; PTS, postthrombotic syndrome.

4 | DISCUSSION

In the present study population, CAPTSure showed excellent reliability[13] in the assessment of PTS in the upper and lower extremities in children. Therefore, we can be confident of the level of agreement when applying CAPTSure, even when the tool is applied by nonhematologists.

In addition to CAPTSure, 2 other tools are available for the diagnosis of pediatric PTS: the Manco-Johnson Instrument[21] and the Modified Villalta Scale.[22] A recent study reported a fair to good interrater agreement for PTS status (present vs. absent PTS; kappa, 0.64 [95% CI, 0.18-0.81]) using the Modified Villalta Scale.[23] Assessments in the study were performed by medical students. Another pediatric study by Luceri et al[24] that enrolled children who underwent cardiac catheterization reported a kappa of 0.88 for the Manco-Johnson Instrument. However, the high frequency of children diagnosed with PTS observed in the study lead the authors to question whether the use of the Manco-Johnson Instrument by nonexperts could result in PTS overdiagnosis. A third study, available in abstract form, studied the reliability of the Modified Villalta Scale and the Manco Johnson Instrument, reporting an ICC higher than 0.92[25] for both tools. The level of expertise of the assessors in the third study was not reported.

We hypothesize that the level of expertise of assessors may be relevant when applying the Modified Villalta Scale or the Manco Johnson Instrument, and this could in turn explain the difference in results seen here compared to previous studies. In the present study, most raters for the clinical assessment component were nonclinicians, suggesting that CAPTSure scores can be replicated even when applied by nonhematologists. In fact, one of the strengths of CAPTSure is that it provides clear definitions for each item (ie, item operationalization) as well as a standardized procedure to measure them (ie, operational definitions), including an atlas for the assessment of collateral circulation and a training video. Clear operational definitions allow for consistency in the interpretation of the meaning and the measurement technique of items of an instrument, decreasing the need for personal judgment when applying the tool. Judgmental decisions are thought to be a prime source of variability when applying clinical indexes, thus affecting the reliability of the instrument.[26] This is particularly important when an instrument is applied by nonexperts.

Importantly, previous data have shown that children may show signs or symptoms of PTS several years after DVT.[27,28] Our findings indicate that CAPTSure can be used by trained pediatricians and nonhematologists to follow up and detect PTS in these patients over time.

In their study, Luceri et al[24] identified difficulties in the assessment of collateral circulation as a source of discrepancies. In CAPTSure, collaterals are assessed with the use of a modified scale that has shown good reliability, with a reported Krippendorff's alpha coefficient of 0.81 (95% CI, 0.62-0.93).[29]

CAPTSure includes the assessment of the symptoms pain, swelling, heaviness, paresthesia, and limited endurance for upper extremities and pain, swelling, paresthesia, tightness, heaviness, tired limb, change in skin color and limited endurance for the lower extremities. The Pediatric Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis has highlighted the problems in inquiring about symptoms in pediatrics.[30] However, PTS symptoms are a crucial component of the definition of the syndrome. In the present study, we have shown excellent reliability in the symptom domain of CAPTSure for the assessment of both upper and lower extremity PTS. Interestingly, subanalysis of this component showed much higher reliability of self-reported symptoms as compared to proxy-reported symptoms. This indicates that the assessment of symptoms is reliable in pediatric PTS.

Importantly, we estimated the minimal detectable change in CAPTSure scores. This measure, which indicates the smallest amount of change that is considered to be beyond measurement error,[31] is important for the application of CAPTSure in clinical practice as well as for the conduction of future responsiveness studies. A CAPTSure score of approximately 11 of 100 points would be considered to be above measurement error, a number that is similar to the CAPTSure scores that discriminate parents who feel neutral/satisfied vs. dissatisfied with the thrombotic condition of their child.[3] In addition, receiver

operating characteristic curve analysis of the same data showed that 10 points was the threshold score that would discriminate normal from below normal activity and participation scores, as measured by the Pediatric Outcomes Data Collection Instrument[32] (unpublished data).

Equal weighting and simple summation of items to obtain an overall score, as used in most PTS tools, result in a score that linearly represents disease severity.[33] This interpretation of the overall score can be problematic, particularly when adding ordinal subscales.[34] The approach to deriving item weights in CAPTSure allowed for the transformation of its ordinal items into an interval overall score,[35] which has sound mathematical properties that enable the estimation of a meaningful measurement error and minimal detectable change.

Our study should be interpreted in the light of potential limitations. One-third of patients enrolled in the study did not provide a second assessment in the evaluation of test-retest reliability, which could have led to a more homogeneous sample of patients and affected the reliability results (lower ICC). Of note, potential attrition was taken into account when designing the study sample size. In addition, in the assessment of test-retest reliability, it is considered that a short interval between administrations of a test can lead to increased reliability due to patients remembering their first responses.[10] However, subanalysis of responses provided <10 days or sooner did not show higher reliability of the sample.

In conclusion, CAPTSure is a newly developed tool for the assessment of pediatric PTS, which shows excellent reliability and small measurement error, even when applied by nonhematologists. Therefore, CAPTSure is an adequate instrument for use in clinical practice and research.

RELATIONSHIP DISCLOSURES

LRB, MLA, SW, EP, JV, CL, and MIM report nothing to disclose. BMF is a DSMB member for Pfizer, BMS, Novartis, Optum, and Abbvie outside the submitted work; these companies had no involvement with study design, conduction, analysis, or reporting. During the conduction of the study, LA received support from a Canadian Institutes of Health Research Post-doctoral Fellowship.

AUTHOR CONTRIBUTIONS

Study design: LA and LRB. Measurements: LA, LRB, JV, MM, CL, and SW. Data analysis and interpretation of results: LA, EP, and BMF. Manuscript writing: LA. Critically reviewed the manuscript: LRB, BF, JV, MIM, CL, SW, and EP. To obtain CAPTSure, please contact us at pts.research@sickkids.ca or ipc.requests@sickkids.ca. More information can be found at http://www.sickkids.ca/Thrombosis-Program/educational-materials-publications-captsure/index.html

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SUPPORTING INFORMATION

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

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