

Developing a Tool to Assess Placement of Central Venous Catheters in Pediatrics Patients

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ABSTRACT

Background Pediatric critical care medicine requires the acquisition of procedural skills, but to date no criteria exist for assessing trainee competence in central venous catheter (CVC) insertion.

Objective The goal of this study was to create and demonstrate validity evidence for a direct observation tool for assessing CVC insertion.

Methods Ten experts used the modified Delphi technique to create a 15-item direct observation tool to assess 5 scripted and filmed simulated scenarios of CVC placement. The scenarios were hosted on a dedicated website from March to May 2013, and respondents recruited by e-mail completed the observation tool in real time while watching the scenarios. The goal was to obtain 50 respondents and a total of 250 scenario ratings.

Results A total of 49 pediatrics intensive care faculty physicians (6.3% of 780 potential subjects) responded and generated 188 scenario observations. Of these, 150 (79.8%) were recorded from participants who scored 4 or more on the 5 scenarios. The tool correctly identified the expected reference standard in 96.8% of assessments with an interrater agreement kappa (standard error) = 0.94 (0.07) and receiver operating characteristic = 0.97 (95% CI 0.94–0.99).

Conclusions This direct observation assessment tool for central venous catheterization demonstrates excellent performance in identifying the reference standard with a high degree of interrater reliability. These assessments support a validity construct for a pediatric critical care medicine faculty member to assess a provider placing a CVC in a pediatrics patient.

Introduction

Pediatric critical care medicine (PCCM) fellows need to be skilled in performing bedside procedures, yet no criteria exist for determining competency in performing central venous catheter (CVC) insertion.¹ Assessment of learner proficiency usually is based on a global recall rating by supervising faculty, which is difficult to replicate and does not provide specific suggestions for performance improvement. Currently, no assessment tool with supporting evidence of validity exists for direct observational assessment of proficiency at CVC insertion in pediatric intensive care medicine.² Such tools have been developed for placement in adults, but applying these to the PCCM environment is difficult.^{3–8} In addition, existing tools typically focus on the technical aspect of procedural competence^{9–13} and rarely address the knowledge and communication elements of the procedure.¹⁴ Simple checklist assessment tools may not adequately iden-

tify global performance, and subjective recall ratings are difficult to standardize across a cohort of raters due to interrater variability in the definition of competency.¹⁵

Assessment of novel tools to address procedural competence in the clinical environment is time consuming and labor intensive. Gathering validity evidence using a direct observation tool in pediatric intensive care units across the United States would require the training of multiple expert raters, as well as obtaining consent from both the learners and the patients for the enrollment of actual CVC placements, many of which are urgent or emergent. One approach to simplify collection of validity evidence is through the use of simulation technology, which has emerged as an acceptable assessment environment in medical education.^{3–5,7,8,11,16–23} Simulation-based assessment of a tool allows for rapid accrual of study observations and the use of scripted reference standards for comparison.

Members of a large multicenter education collaborative—the education in pediatric intensive care investigators—convened to create a direct observation assessment tool for CVC insertion that evaluated

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both kinesthetic and cognitive abilities of learners. The goal was to create a direct observation assessment tool for CVC insertion among PCCM trainees and to demonstrate validity using the instrument in simulated scenarios.

Methods

Validity evidence obtained from observational assessments was measured using a 5-point construct that includes content, response process, internal structure (psychometrics), relationship to other variables, and consequences.^{24–26} No power calculation was generated for this study, but the research group set a target of 50 participants and 250 individual observations. We used standard summary statistics, including counts (percentages) and median (interquartile ranges), to describe categorical and continuous study variables. Their distribution, where appropriate, were compared using χ^2 , Fisher exact tests, or Wilcoxon rank sum tests. All statistical analyses were conducted using Stata version 13.1 (StataCorp LP, College Station, TX) and a *P* value < .05 was considered significant without adjustment for multiple comparisons.

Content

Ten members of the educational consortium created a 15-item checklist to encompass 3 phases of the CVC procedure. The final version of the tool was created through multiple iterations using the modified Delphi technique followed by a pilot study among a small group of participants. The tool encompasses 14 ratings for the specific steps in the procedure, along with 1 global rating. The individual items included 5 cognitive elements of medical decision making (analgesia, indications, site, risk, and verification) and 9 kinesthetic elements (time-out, position, landmarks, equipment, skin preparation, access vein, Seldinger technique, securing catheter, and document procedure) that require physical dexterity and communication and documentation, and these specific items were equally weighted (the tool is provided as online supplemental material).

To obtain assessments utilizing the instrument, 5 scripted scenarios of CVC placement were created and filmed using the FemoraLineMan System and CentraLineMan System (Simulab Corp, Seattle, WA). The scenarios included variation in the age of the child portrayed, indication for the procedure, site of line placement, and individual performing the task. To ensure that the checklist would reliably detect gradations of performance, the number of scripted errors was varied across scenarios. Of the 14 items in the tool, 12 had scripted errors in at least 1 of the

What was known and gap

Pediatric critical care medicine trainees are expected to become skilled in central venous catheter (CVC) insertion, but to date no criteria exist for assessing trainee competence.

What is new

Content experts developed a direct observation tool that was validated with pediatric critical care physicians using simulated scenarios.

Limitations

Use of simulated scenarios may reduce the ability to generalize to some real clinical situations.

Bottom line

The direct observation assessment showed validity evidence, including high interrater reliability, and has the potential of offering specific feedback on aspects of CVC placement.

scenarios (TABLE 1). For 2 elements (identifies indication for central venous line and positions patient), the content experts designing the tool felt that variability existed in acceptable practices to preclude identifying practice that would be seen universally as incorrect.

Each video clip was edited and scored in a pilot study, and the videos were further refined to ensure that the scenario was portrayed with minimal potential confounders. Final scenarios were edited to be 7 to 8 minutes in duration.

Response Process

The scenario and the scoring tool were presented online simultaneously on a split screen, and the assessment tool utilized REDCap for data capture.²⁷ Instructions for using the tool were provided on the website and included examples of appropriate responses for several elements (provided as online supplemental material). Data collection included deidentified demographic data about the observer, including type of practice, years since fellowship training, presence of residents and fellows in the pediatric intensive care unit, and self-reported comfort with assessment of learner competence.

We recruited PCCM attending physicians to participate in this study through an e-mail distributed via the mailing lists of the pediatric section of the Society of Critical Care Medicine and the critical care section of the American Academy of Pediatrics.

Internal Structure

We evaluated the interrater agreement of individual items, combination of items, and the summation of all items of the study tool across various provider categories. Kappa statistics were used to further quantify interrater agreement between the reference standard scenario and provider assessments.

TABLE 1

Simulated Central Venous Line Placement Scenario Characteristics

Scenario	Age of Patient	Site of Central Venous Line	No. of Errors	Specific Errors
1	7 yrs.	Internal jugular	0	None
2	13 yrs.	Internal jugular	0	None
3	16 mos.	Femoral	2	- Proceduralist let go of both the needle and guide wire during the insertion. - No sutures or adhesive dressing were applied to the central line.
4	15 yrs.	Subclavian	5	- No explanation of risks and benefits or potential complications of procedure during consent process. - No specific anatomic location of procedure during time-out. - No specific indication for procedure during time-out. - Skin preparation was incomplete with too brief a sterile scrub. - Incorrect landmarks were identified.
5	5 yrs.	Femoral	8	- No explanation of risks and benefits or potential complications of procedure provided during consent process. - Central line was too large for a child of this size; hence, the incorrect site/size was chosen. - No analgesia plan initiated despite the patient moaning and moving. - Proceduralist did not demonstrate adequate preparation of needed equipment. - Sterile field was contaminated during the procedure. - Rapid insertion and redirection of the needle was too fast, indicating lack of caution regarding injury to surrounding structures. - Pulsatile blood flow demonstrated that this was an artery, not a vein. - Pulsatile blood flow demonstrated that this was an artery, not a vein. - No verification of the line by x-ray or pressure monitoring, and the needle was in the artery at insertion, prompting documentation to be incorrect.

Relationship to Other Variables

The scripted scenario answer key was considered the reference standard for comparison. Standard test performance measures included sensitivity, specificity, negative predictive value, positive predictive value, and receiver operating characteristic (ROC) curve analysis.

Approval for study was obtained from the Duke University School of Medicine Institutional Review Board.

Results

A total of 49 PCCM attending physicians (6.3%) of a possible 780 individuals completed demographic data, a minimum of 1 scenario rating between March and May 2013, and provided a total of 188 observations. Of these, 150 ratings (79.8%) were from participants who scored 4 or more on the

scenarios. Nearly all respondents supervised residents and fellows and reported a high level of comfort with assessing procedural competence (TABLE 2).

A high degree of interrater agreement was observed among the 188 responses with kappa (standard error) = 0.94 (0.07), offering evidence of internal structure validity. Subgroup analysis demonstrated that this interrater agreement was not affected by the presence of fellows in the respondent's unit. Interrater agreement was higher among raters who scored 3 or more on the scenarios.

To demonstrate response process validity, we provided instructions alerting respondents that elements may be counted as "completed" if the video demonstrated the action or if the individual performing the procedure verbalized the action. It was evident that there were differences among experts in an acceptable Seldinger technique when compared with the other 12 *standard* checklist items, especially when

TABLE 2
Demographic Data for Respondents and Scenario Responses

Parameter	No. (%) or Median (IQR)
Respondents	49
Male	29 (59)
Comfort with rating procedural skills (scale 0–100)	90 (71–98)
PICU demographics of respondents	
Cardiac ICU	3 (6)
Medical/surgical ICU	20 (41)
Combined ICU	26 (53)
No. of ICU beds	25 (18–29)
PICU has fellows	
Yes	35 (71)
No	7 (5–10)
PICU residents	
Yes	45 (92)
No	4 (3–5.5)
Scenario responses	
Total observations	188
Scenario 1	46 (24.5)
Scenario 2	41 (21.8)
Scenario 3	33 (17.6)
Scenario 4	35 (18.6)
Scenario 5	33 (17.6)

Abbreviations: IQR, interquartile range; PICU, pediatric intensive care unit; ICU, intensive care unit.

technique to access the vein was poor. This finding is potentially related to the somewhat arbitrary separation of scoring for needle technique to access the vein and the Seldinger technique. Given the relationship between these 2 elements, they were ultimately combined into a single item for analysis with improvement of predictive performance with a ROC of 0.80 (TABLE 3).

The tool correctly identified the scenario reference standard in 96.8% of observations. Sensitivity and specificity were 94% and 100%, respectively, with a ROC of 0.97 (95% CI 0.94–0.99; TABLE 4). Analysis of the individual items comprising the checklist demonstrated strong agreement with the reference standard with ROC ranging from 0.80 to 1.0 (TABLE 3). The global rating item included in this tool correlated 90% of the time with the reference standard, and when augmented with the task item checklist, agreement improved to 97%, offering validity evidence pertaining to the relationship to other variables. Tool performance was not affected by simulated competence in line placement, and there

was 100% (87 of 87) identification of the reference standard in observed scenarios with no scripted errors and 94% (95 of 101) identification of the reference standard in scenarios containing errors.

Discussion

We created an assessment tool for direct observation of pediatric CVC placements by PCCM faculty. The tool demonstrated evidence of excellent content validity, interrater reliability, and the ability to identify the reference standard over the range of potential variability in level of knowledge and skill.

The instrument developed through this initiative differs from many others described in the literature. Most checklists focus on either the cognitive or kinesthetic aspect of a procedure, rather than combining these elements into a comprehensive assessment.^{9–14,28–30} In surgical specialties, observation tools have been created with criteria for each stage of the operation, but they risk becoming cumbersome if too many elements are included.^{28,29} In addition, the minute details of kinesthetic tasks do not tell the entire story of competency, and cognitive and communication elements must also be assessed.^{31,32}

The simulated scenarios used in this investigation enhanced the ability to evaluate the tool's performance by eliminating the anchor bias seen in live assessments. Anchor bias exists when assessments are influenced by prior knowledge of a trainee's performance and skills.³³ Using videos and individuals who are unknown to the raters minimizes this bias, as a rater can be more lenient or stringent in the evaluation depending on prior perceptions of the learner.

The final component of the validity construct is consideration of the consequences of utilizing this tool for CVC assessment. These data demonstrate that this tool can identify the minimal threshold of skill in CVC placement, and the global rating item identifies an individual who is able to perform the procedure independently. A second important consequence in the use of this tool is the detailed feedback regarding areas for improvement during skill development for the novice learner who has not yet achieved competence. Deliberate practice in this context allows for learners to integrate specific feedback on these components and focus on modification of techniques and repetition to develop expertise.³⁴ Because the individual was labeled only as a physician and not a trainee, an additional consequence is the broader applicability of this tool to other providers placing a CVC in pediatrics patients.

TABLE 3

Individual Item Tool Response Compared With Scenario Reference Standard

Item	ROC	Measured Agreement, %	Expected Agreement, %	Kappa (SE)	Z Score	Probability > Z
Analgesia	0.97	89.9	65.2	0.71 (0.07)	10.08	.00
Indications	^a	100	a	a	a	a
Site/catheter	0.94	87.2	65.5	0.63 (0.07)	8.91	.00
Risk/complications	0.98	94.2	52.5	0.88 (0.07)	12.08	.00
Consent	0.82	82.5	58.4	0.58 (0.07)	8.63	.00
Time-out	0.90	87.2	67.7	0.61 (0.07)	8.33	.00
Position	^a	100	a	a	a	a
Landmarks	^a	100	a	a	a	a
Equipment	0.93	84.6	52.5	0.68 (0.07)	9.31	.00
Skin preparation	0.95	83.5	61.7	0.57 (0.07)	8.42	.00
Access + Seldinger ^b	0.80	83.5	56.2	0.62 (0.07)	8.63	.00
Access vein	0.99	90.4	52.1	0.80 (0.07)	11.07	.00
Seldinger	0.62	70.7	68.6	0.07 (0.07)	0.93	.18
Secures line	1.00	97.9	70.4	0.93 (0.07)	12.74	.00
Verifies line	0.88	73.4	53.8	0.42 (0.06)	7.12	.00
Documents	0.88	76.6	57.9	0.44 (0.06)	6.94	.00
Global rating	0.90	90.4	50.5	0.81 (0.07)	11.08	.00

Abbreviation: ROC, receiver operating characteristic.

^a Indicates item with 100% agreement for which kappa statistics could not be calculated.^b Indicates a combination variable including both access vein and Seldinger technique.

This study has several limitations. First, it used simulation scenarios for assessment, and it is possible that the tool will perform differently in actual clinical situations. Second, we elected not to specifically mandate the *correct* way to perform some tasks given

variability in clinical practice for several elements of CVC placement. Third, using only PCCM faculty as raters limited the generalizability to practices outside of pediatrics without additional evaluation of the tool in the specific population of interest.

TABLE 4

Global Tool Performance in Identifying Scenario Reference Standard

Agreement	96.8%		
Kappa (SE)	0.94 (0.07)		
Z score	12.86		
Probability > Z	0.0000		
	Value (95% CI)		
Sensitivity	93.5 (87–97)		
Specificity	100 (96–100)		
Positive predictive value	100 (96–100)		
Negative predictive value	94 (88–98)		
Receiver operator curve	0.97 (0.94–0.99)		
Subgroup Analysis	No Fellows in ICU of Rater	Fellows in ICU of Rater	
Kappa (SE)	0.96 (0.15)	0.93 (0.08)	
Z score	6.42	11.15	
Probability > Z	0.00	0.00	
	3 Scenarios Scored	4 Scenarios Scored	5 Scenarios Scored
Kappa (SE)	0.70 (0.36)	0.68 (0.18)	0.86 (0.09)
Z score	1.93	3.78	9.42
Probability > Z	0.03	0.0001	0.0000

Abbreviation: ICU, intensive care unit.

While the tool was developed specifically for use in assessing CVC placement in pediatrics patients, the process used in our study is translatable to other specialties and procedures. Use of a group of content experts is key to content validity, and such a group can be formed from a single institution or multiple sites. An interdisciplinary approach also may be beneficial, depending on the competency being addressed. Finally, when simulation is used, inclusion of simulation experts is critical.

Conclusion

The instrument described in this study combines the power of a global rating with a checklist of kinesthetic and cognitive skills to provide guided, formative feedback to the learner. Next steps involve implementation in the clinical environment for assessment of PCCM fellows. Given the overall design and validity results, the checklist has potentially broader application to other practitioners who perform CVC placement in critically ill infants and children.

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