Review

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Cranial ultrasound performance assessment tool: development and validation

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Abstract

Aim: A standard assessment tool for direct evaluation of procedural skills to ensure proficiency of trainees is necessary for cranial ultrasound (US) in clinical practice. This study created and validated an assessment tool for cranial US performance by radiologists. **Material and methods**: An initial evaluation tool for cranial US using criteria was developed based on existing literature. The assessment form was modified using a three-round Delphi process by an expert panel, conducted between January 2021 and April 2021. Rubric scales for grading were added once consensus regarding generated items was reached. Experts confirmed the final assessment tool using a rubric scale. Two raters evaluated cranial US performance of 27 residents in video clips using the tool. Reliability and percent agreement were assessed. **Results**: Seventeen pediatric radiologists working in different settings participated in the expert panel. The content validation of the proposed evaluation tool was enabled by expert pediatric radiologists. Following three rounds of the Delphi process, the initial 14-item assessment form became a final 15-item form. A three-part rubric scale was used in the final form (preparation, US machine operation, and cranial US performance). Interrater reliability was evaluated with Cohen's Kappa. The Kappa value and percent interrater agreement for most items was moderate to almost perfect (0.42–0.93 and 77.8–100%, respectively). The Cronbach's alpha values for both raters were 0.856 and 0.891. **Conclusions**: This study produced the first validated cranial US assessment tool using a modified Delphi method. The final assessment form is a simple and reliable tool.

Keywords: cranial ultrasound; Delphi method; pediatric radiology; validation

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Introduction

The rapid evolution in obstetrics and neonatal care has increased the survival rate of premature babies. However, premature babies may present serious brain conditions, such as intraventricular hemorrhage and periventricular leukomalacia, the effects of which can range in severity from minor cognitive disorders to severe men-

tal retardation. Both abnormalities can be demonstrated clearly on cranial ultrasound (US) [1,2].

Cranial US is the standard method to evaluate brain pathology in neonates via a widened anterior fontanel. Nevertheless, cranial US experts are limited [2]. Moreover, cranial US training methods comprise predominantly workplace-based learning with unstandardized assessment methods using a logbook [3]. However, logbooks have limitations and are inappropriate for assessing competency due to their low reliability because of the self-assessment process involved and have low validity given the lack of guarantee of their accuracy [4]. Furthermore, only evaluating the number of procedures an individual has performed does not reflect performance and competency in those procedures [3-5].

Assessment methods based on competency are appropriate for evaluating skill performance, including the direct observation of procedural skills (DOPS) [6-10]. Using a standard and appropriate assessment tool is critical in the DOPS process. DOPS takes two forms: without and with criteria. Compared to DOPS without criteria, DOPS with criteria is better due to its excellent reliability [4]. The Delphi method is the proper method to develop a DOPS with criteria as an assessment tool. The Delphi method is a consensus development process recommended when creating lists or items in an assessment tool. It has many advantages, such as the inclusion of a large number of participants, the use of the email questionnaire method, low cost, and the avoidance of abusive dominance [11-13]. Several previous studies have used the Delphi method to develop an assessment tool for evaluating US competency in various organs [14-17].

The development of a standard and appropriate assessment tool to apply the DOPS method with criteria allowing proficient trainees to develop an independent cranial US practice is necessary. This study aimed to develop an assessment tool for cranial US skill performance. The reliability of the developed tool was also assessed.

Materials and methods

Phase 1. Assessment tool development

Settings and participants

We used the modified Delphi method to establish a new cranial US performance assessment tool [15,18]. From January 2021 to April 2021, three steps of the procedure were conducted, including the development of the initial cranial US evaluation form, selecting a group of experts for the expert panel, and shaping and verifying the final assessment form using the modified Delphi method.

Generating items for the initial assessment tool

After reviewing the literature related to US assessment forms to determine the performance required for a US user, the primary researcher developed an initial assessment form as part of the modified Delphi method [14,15,19]. The literature review was conducted by searching PubMed for articles published from 2011 to 2020 using the keywords "ultrasound," "skill," "assessment," and "tool." Overall, 300 related articles were identified: 265 were excluded due to them being unrelated or repetitive articles and 35 articles were reviewed [19-53]. All items regarding general US skills that were significantly correlated with the cranial US were pooled in the initial assessment form.

Selecting a group of experts for the expert panel

The specialists invited to the expert panel had to be practicing pediatric radiologists with at least 3 years of cranial US experience. Each expert had to complete a Google Form to participate in this study while maintaining anonymity.

Delphi process

After the primary researcher developed the initial assessment tool following the literature review, it was sent to the participating experts as a Google Form via email during the first round of the Delphi process. The participating experts were requested to score each item using a 5-point rating scale, with scores ranging from 1 to 5, where 1 meant that the item was not relevant, 2 was defined as the item being relevant but not important, 3–5 meant that the items were relevant and important, and 5 was equivalent to the item being "most important" (3 = "a little important," 4 = "moderately important," and 5 = "absolutely important"). The experts were also asked to provide comments or opinions to eliminate items, add other items, or modify the initial items. The experts returned the responses to the researcher and the mean scores and their distribution were evaluated. All items with mean scores equal to or more than 4 were retained, and those with lower mean scores were eliminated. In each round, we allotted a total response time of 1 month, with email reminders sent to non-responders after 2 weeks.

During the second and third rounds of the Delphi process, the cranial US assessment tool, with the items with lower mean scores eliminated and new items added based on expert opinions, was sent again to all experts and the mean scores and distribution were re-evaluated. The experts were requested to re-rank their agreements and provide opinions, with an opportunity to change their scores after viewing the group's reply to the previous round. These repeated processes were stopped after

the third round due to consensus being achieved with no further suggestions.

After completing the items to identify performance criteria for cranial US, the next step was setting the performance levels. Four performance levels were chosen: distinguished, proficient, emergent, and insufficient. We chose these four levels for formative and summative decision-making with greater reliability in scoring performance than that of fewer levels. Rubrics were used to develop performance descriptions for each level of each performance criterion; they provide information to guide rater judgements. Finally, all items in the third round of the Delphi process were divided into three parts: the preparation phase, US machine operation, and cranial US performance, with their summation as the overall performance score. The final cranial US skill assessment tool with a rubric scale was sent to all experts for verification [54-57].

Phase 2. Assessment tool performance

The reliability of the final cranial US skill assessment tool was determined. The tool was used to evaluate cranial US skill performance of radiology residents recorded in video footage by two raters who were pediatric radiologists. The video footages of cranial US procedure were recorded after the information and objective of the study was given to radiology residents, and the neonate's parents participated in the study after providing written informed consent. Two raters were assigned to use the assessment tool and completed the form after standardization with the instruction sheets. All radiology residents had different levels of experience with cranial US lectures and skills.

The video footage was recorded using two mobile video cameras. The first device recorded the hand movements of the US performers during cranial US and the second device recorded the US screen monitor and the ability to use the US console. Two video recorded footages of the same neonate were merged into one footage, synchronously, with high definition (HD) resolution.

Two raters completed all three parts of the cranial US assessment tool and determined the overall performance of the US performer. Inter-rater reliability was measured using Cohen's kappa. Total percent agreement was also calculated.

Statistical analysis

The characteristics of experts were reported as percentage values. During the Delphi process, the mean score of each item was evaluated. Reliability of each item in the assessment tool were calculated using Cohen's Kappa. Cronbach alpha coefficients were calculated using individual item scores completed by both raters. Percent agreement between two raters was also measured. All data were analyzed using R software version 3.6.1.

Ethical statement

The study protocol was approved by the local Ethics Committee. This study was performed based on the ethical principles of the Declaration of Helsinki and The International Conference on Harmonization in Good Clinical Practice.

Results

Phase 1. Assessment tool development

Overall, 28 pediatric radiologists were invited to participate as expert panelists in this study. Invitation forms were sent via an online group of pediatric radiologists. Seventeen (60.71%) pediatric radiologists agreed to join in the Delphi process. The characteristics of the experts are shown in Table I.

Three rounds of the Delphi process progressed as described below. The response rates of experts to round 1 and rounds 2–3 were 17 of 28 (60.71%) and 13 of 17 (76.47%), respectively.

Round 1 of the Delphi process

After the primary researcher conducted the literature review, 14 relevant items were created and inserted into the initial assessment form. This form was sent to all participating experts in Delphi round 1. Before sending the results back to the researcher, all experts were asked to provide the relevant score for each item and add, eliminate, or modify the items, as necessary. Table II presents the initial items with the mean scores and their distributions from Delphi round 1. The suggested new items from experts in round 1 included "additional US by using linear probe" and "identified patient."

Table I. Characteristics of experts in the expert panel

Characteristic	Number (%)
Sex	
Male	3 (17.65)
Female	14 (82.35)
Position	
Instructor	9 (52.94)
Assistant Professor	3 (17.65)
Associate Professor	3 (17.65)
Professor	2 (11.76)
Workplace	
University Hospital	12 (70.59)
Pediatric Hospital	2 (11.76)
General Hospital	2 (11.76)
Other	1 (5.88)
Experience in cranial ultrasound	
3–5 years	8 (47.06)
5–10 years	4 (23.53)
>10 years	5 (29.41)

Round 2 of the Delphi process

The revised assessment form, including all initial items that had a mean score more than 4 and the newly added suggested items, was resent to the experts in Delphi round 2 as part of the iterative process. The comment "additional US by using linear probe" was proposed to be included in the rubric scale for the item "selected appropriate probe." In round 2, there were no additional suggested or modified items, and all items had a mean score more than 4, as shown in Table III.

Round 3 of the Delphi process

All 15 finalized items with a mean score more than 4 on the rubric scale were accepted. Subsequently, the components were divided into four levels. The rubric scale in the assessment form was developed by the primary researcher according to the properties for each item. The

Table II. Initial items with mean scores and distributions in round 1 of the Delphi process

Items	Distribution (n = 17)					Mean score
	5	4	3	2	1	
1. Positioned the US machine appropriately	7	9	1	0	0	4.35
2. Selected the appropriate probe	16	1	0	0	0	4.94
3. Corrected probe handing	14	3	0	0	0	4.82
4. Applied gel on the probe	10	7	0	0	0	4.59
5. Used proper functions of the US machine	13	4	0	0	0	4.76
6. Adjusted appropriate gain and frequency	12	5	0	0	0	4.71
7. Adjusted depth and focus to include the whole brain and appropriate area of focus	17	0	0	0	0	5
8. Cleansed the probe after use	8	8	1	0	0	4.41
9. Corrected placement of probe at anterior fontanel to start US	15	2	0	0	0	4.88
10. Corrected probe orientation	16	1	0	0	0	4.94
11. Displayed cranial US approach systematically	11	6	0	0	0	4.65
12. Presented the relevant brain structures according to standard protocol	13	4	0	0	0	4.76
13. Identified positive findings (e.g., IVH, PVL, hydrocephalus, and anomaly)	17	0	0	0	0	5
14. Overall performance	13	4	0	0	0	4.76

IVH, intraventricular hemorrhage; PVL, periventricular leukomalacia; US, ultrasound

Table III. Initial items with mean scores and distributions in round 2 of the Delphi process

Items	Distribution (n = 13)					Mean score
	5	4	3	2	1	
1. Positioned the US machine appropriately	5	7	1	0	0	4.31
2. Selected the appropriate probe	12	1	0	0	0	4.92
3. Corrected probe handing	11	2	0	0	0	4.85
4. Applied gel on the probe	10	3	0	0	0	4.77
5. Used proper functions of the US machine	10	3	0	0	0	4.77
6. Adjusted the appropriate gain and frequency	11	2	0	0	0	4.85
7. Adjusted the depth and focus to include the whole brain and appropriate area of focus	11	2	0	0	0	4.85
8. Cleansed the probe after use	7	5	1	0	0	4.46
9. Correctly placed the probe at the anterior fontanel to start US	10	3	0	0	0	4.77
10. Corrected probe orientation	13	0	0	0	0	5
11. Displayed cranial US approach systematically	8	4	1	0	0	4.53
12. Presented the relevant brain structures according to standard protocol	9	4	0	0	0	4.69
13. Identified positive findings (e.g., IVH, PVL, hydrocephalus, and anomaly)	13	0	0	0	0	5
14. Overall performance	8	5	0	0	0	4.62
15. Identified the patient	10	3	0	0	0	4.77
16. Additional US using a linear probe	7	5	1	0	0	4.46

IVH, intraventricular hemorrhage; PVL, periventricular leukomalacia; US, ultrasound

Table IV. Final cranial US performance assessment form with rubric

Cranial US performance assessment form with rubric				
	4 (Distinguished)	**3 (Proficient)**	**2 (Emergent)**	**1 (Insufficient)**
I. Preparation phase				
1. Identified the patient	Done and confirmed	Done	Not done	Wrong patient
2. Properly positioned the US machine	Located to the right, close to the patient	Located to the right of the patient	Any side but tries to do with the dominant hand	Any side and operates with the non-dominant hand
II. US machine operation				
1. Selected the appropriate probe	Small curvilinear 8-5 MHz probe	Linear high-frequency probe	Large curvilinear low-frequency probe	Hockey stick probe
2. Corrected probe handling	Complete	Inadequate	Improper	Incorrect
3. Applied warm gel onto the probe	Applied the optimal amount of gel onto the probe	Applied the gel onto the probe	Applied the gel on the patient's head	Did not use gel
4. Used proper buttons on the US machine	Familiar with operating	Operated with experience but was inconsistent	Operated with inexperience	Unable to operate
5. Adjusted gain and frequency correctly	Appropriate	Inappropriate	Incorrect	Unable to operate
6. Adjusted the depth and focus to include the whole brain and appropriate area of focus	Optimum field of view, depth, and focus	Included the whole brain but with inappropriate depth and focus	Included partial brain	Unable to operate
7. Cleansed the probe after use	Done			Not done
III. Cranial US performance				
1. Corrected placement of the probe at the anterior fontanel	Placed on the anterior fontanel with good contact	Placed on the anterior fontanel with poor contact	Place on another fontanel	Placed on other areas
2. Confirmed the side of brain orientation	Correct side with confidence	Confirmed several times	Not done	Wrong side
3. Displayed cranial US approach systematically	Consistently systematic display	Some systematic display	Unsystematic display	Could not display
4. Presented the relevant brain structures according to standard protocol	Followed standard protocol	Inconsistent	Presence of some images	Could not do
5. Identified positive findings	Completely identified positive findings	Identified some findings	Missed positive findings	Could not do
Overall performance	Excellent	Good	Borderline	Poor

final assessment form, including the 15 adjusted items and the four levels of competence assigned to each cell of the rubric scale, was divided into three sections: the preparation phase, US machine operation, and cranial US performance. The form is user-friendly and is shown in Table IV. The final assessment form with the rubric scale was sent to the experts for approval. In round 3, consensus and verification by experts were achieved.

Phase 2. Assessment tool performance

Validity

Content validity of a tool refers to whether the tool that can accurately measure all aspects of content.

All experts in the Delphi panel were pediatric radiologists who were content experts in cranial US. Good content validity was confirmed during the Delphi process.

Reliability

The Kappa value for each item in the assessment tool ranged from 0.15 to 0.93 and "NA". "NA" indicated that the Kappa value could not be calculated due to lack of variation in the data. The percent agreement of all items ranged from 37–100%. The internal consistency of the assessment tool was assessed using Cronbach's alpha, which were 0.856 and 0.891 for both raters (table V).

Discussion

Cranial US is a supporting assessment required in the field of neonatal care. A standardized assessment process to determine individual proficiency in clinical practice is required. Thus, new and valid cranial US assessment forms need to be developed.

The cranial US assessment form developed in this study should be considered a quality assessment tool because it was developed by a panel of 17 experts in cranial US. It reflects the content validity of the assessment form developed using the Delphi process. The rubric scale in each cell provides the details of the rater's assessment [58]. The information provided by the rubric scale allows the rater to assess competency confidently, precisely, and reliably [58].

All experts in this study were anonymized to prevent group guidance due to authority or reputation. Therefore, experts could comment and make decisions independently [59]. Nevertheless, the anonymization of participants prevented the responses from being associated with professional experience, which is a limitation of this study. Moreover, each cycle of the Delphi process was associated with a reduction in the participant response rate, which caused the responses from fewer participants to be overemphasized.

After evaluating the reliability of the assessment tool, all items had moderate to almost perfect agreement (Kappa = 0.42-0.93 and NA), except only two items, "adjusted gain and frequency correctly" and "displayed cranial US approach systematically." Although the item "displayed cranial US approach systematically" had a Kappa value of 0.27, the percent agreement was slightly higher at 63%. The item "adjusted gain and frequency correctly" had lower values for both Kappa and percent agreement, 0.15 and 37%, respectively. The low Kappa and percent agreement of this item was likely owing to subjective nature of the evaluation due to the widely variable acceptance of bright color contrast of US images between raters. Moreover, the internal consistency of the assessment tool was good, as indicated by the Cronbach's alpha values of 0.856 and 0.891 for the two raters.

A limitation of this study was that all cranial US performers evaluated were radiology residents with some experience in general US and familiarity with the US machine due to the vulnerability of the neonatal population in the study. This limitation led to a complicated analysis, skill homogeneity, and lack of high variability of US performers. An inexperienced individual was not eligible as

Table V. Interrater reliability of the assessment tool

Items	Kappa (95% CI)	% Agreement
1. Identification of the patient	NA	100
2. Properly positioned the US machine	0.93 (0.80–1)	96.3
3. Selected appropriate probe	NA	100
4. Corrected probe handing	0.69 (0.45–0.92)	81.5
5. Applied warm gel onto the probe	0.42 (0.03–0.81)	77.8
6. Used proper buttons on the US machine	0.44 (0.14–0.74)	70.4
7. Adjusted gain and frequency correctly	0.15 (-0.003–0.3)	37.0
8. Adjusted the depth and focus to include the whole brain and appropriate area of focus	0.55 (0.26–0.84)	77.8
9. Cleansed the probe after use	NA	100
10. Corrected placement of the probe at the anterior fontanel	0.55 (0.21–0.89)	81.5
11. Confirmed the side of brain orientation	0.57 (0.29–0.86)	77.8
12. Displayed cranial US approach systematically	0.27 (-0.002–0.55)	63.0
13. Presented the relevant brain structures according to standard protocol	0.82 (0.64–1)	88.9
14. Identified positive findings (e.g., IVH, PVL, hydrocephalus, and anomaly)	0.65 (0.38–0.93)	85.2
15. Overall performance	0.84 (0.66–1)	88.9

IVH, intraventricular hemorrhage; PVL, periventricular leukomalacia; US, ultrasound; CI, confident interval; NA, Kappa could not be measured due to lack of variation in the data.

a cranial US performer in this study for ethical reasons and this contributed to the limited range in cranial US ability evaluated in this study.

Conclusion

The cranial US assessment form and rubric scale developed in this study is straightforward to use, and it aligns all raters to the same standard of evaluation. It was confirmed to have a good preliminary validity and reliability.

Conflict of interest: none

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