Neonatal Umbilical Catheter Pathway Simulator

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Study Background and Rationale

Currently, training for umbilical catheter placement in neonates is primarily focused on inserting the catheter into the umbilical vein. However, no models to date allow real-time ultrasound assessment of catheter tip navigation and final positioning during the procedure. This study introduces the first training simulator designed specifically to address this need, enabling operators to practice not only the insertion but also the ultrasonographic localization of the catheter tip during the placement process.

Study Objectives

Primary Objective

To design and construct a realistic educational simulator for the placement of umbilical venous catheters in neonates.

Secondary Objectives

1. To assess the simulator's durability after 100 hours of training use.
2. To collect expert feedback on the simulator's realism and ease of use.
3. To evaluate the reliability and safety of the simulator after extended use, verifying structural resistance and suitability for training purposes.
4. To assess whether the use of the simulator leads to increase in vivo use of ultrasound during actual umbilical catheter insertions.

Study Endpoints

Primary Endpoint

Assessment of simulator usability and practicality, measured via user satisfaction questionnaires.

Secondary Endpoints

- Accuracy of the simulator in reproducing neonatal hepatic venous anatomy.
- Improvement in participants' practical skills, assessed via pre- and post-training tests.
- Evaluation of simulator durability and safety under training conditions.

Study Design

This is an interventional, non-drug, non-device study focused on procedural simulation. It aims to develop and validate a training tool to enhance clinical competencies in neonatal catheterization.

Participants

A total of 25 individuals will participate:

- **5 experienced neonatal ultrasound practitioners**, who will test and validate the simulator.
- **20 less-experienced healthcare professionals or medical trainees**, who will participate in the training sessions.
- **1 neonatal patient** whose abdominal CT scan will be used (with parental consent) for vascular 3D reconstruction purposes.

Inclusion Criteria

- Experts must have at least 3 years of experience in neonatal abdominal ultrasound or central line placement.
- Trainees must be medical residents in their 3rd year or beyond.
- Written informed consent is required from all participants and from the legal guardians of the neonate providing imaging data.

Exclusion Criteria

- Less than 3 years of relevant experience for expert participants.
- Less than 3rd year of specialty training for trainee participants.

Study Duration

The entire study will be conducted over 12 months.

Study Procedures

1. **Simulator Construction:** A 3D ultrasound-compatible model of the umbilical and hepatic venous system will be created from an abdominal CT scan of a neonate obtained for clinical reasons.
2. **Expert Evaluation:** Neonatal ultrasound experts will assess the anatomical and procedural realism of the simulator.
3. **Training Phase:** Once validated, training sessions will be conducted with medical trainees to enhance their procedural skills and ultrasound competence.
4. **Satisfaction Assessment:** A feedback questionnaire will be administered to all participants to assess user experience.

Statistical Analysis

Sample Size:

25 participants (5 experts and 20 trainees) are planned for enrollment.

Analysis Methods:

- Demographic and baseline characteristics will be described using descriptive statistics.
- Quantitative variables will be reported as medians and interquartile ranges.
- Qualitative variables will be presented as absolute and relative frequencies.
- User satisfaction will be evaluated through questionnaire analysis.
- Skill improvement will be analyzed using the paired Student's t-test or Wilcoxon test, with p-values < 0.05 considered statistically significant.

Statistical analysis will be performed using R software (R, CRAN).

Safety and Adverse Events

No specific risks or adverse event monitoring procedures are defined, as the study involves simulation and not clinical interventions.

References

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