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Scoring instrument for breathing tube insertion in newborn babies

Submission date
29/11/2019

Recruitment status
No longer recruiting

Registration date
03/12/2019

Overall study status
Completed

Last Edited
03/09/2021

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Neonatal intubation is a complex life-saving skill to treat respiratory failure that is not used often but clinicians need to be sufficiently skilled to perform it well. Many professionals are insufficiently skilled and may inflict harm while performing the procedure. Frequent training and clinical exposure are necessary to maintain neonatal intubation competence and to ensure greater success, shorter duration, and less complications. The researchers have previously developed a reliable and practical instrument for video-based assessment of neonatal intubations. The instrument's construct validity and real-time applicability remained to be determined. Therefore, this study's objectives were to
1. Establish the construct validity of our scoring instrument, using an extreme groups approach and the hypothesis that targeted feedback leads to improved intubation skills
2. Determine whether our tool can be reliably employed for real-time assessment of neonatal intubation skills

Who can participate?
Healthcare professionals, affiliated with Lucile Packard Children's Hospital and frequently involved in neonatal intubation, participated as 'experts'. First to fourth-year medical students from Stanford University School of Medicine, lacking (neonatal) intubation experience, participated as 'novices'

What does the study involve?
Participants had to perform two intubations on a newborn manikin. All subjects were divided over two groups: one that received feedback on their performance in between the two intubations and one that did not receive feedback. The scoring instrument was used to rate the intubation, both in real time and on video.
If the scoring instrument is valid, the feedback group will have a higher score after feedback. Also, the experienced clinicians would have higher scores than the students. If the scoring instrument is reliable across real time and video assessment, then the scores will be similar in both domains.

What are the possible benefits and risks of participating?
There were no particular risks associated with participation in this study. A potential advantage

might be that subjects had the opportunity for extra training in neonatal intubation in a simulated setting. Especially the subjects in the intervention group may have benefited from the feedback they received on their intubation performance.

Where is the study run from?
The study was conducted at the Center for Advanced Pediatric and Perinatal Education (CAPE), Stanford University, Palo Alto, USA

When is the study starting and how long is it expected to run for?
January 2018 to April 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Validation of an instrument for real-time assessment of neonatal intubation skills: a randomised controlled simulation study

Study objectives

The construct validity of a previously developed neonatal intubation scoring instrument can be established by showing that more experienced clinicians have higher scores than medical students and by demonstrating that structured feedback improves intubation scores. We also try to prove the reliability of real-time assessment with our assessment instrument.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2018, Institutional review board of Stanford University (1705 El Camino Real, Palo Alto, CA 94306, USA; irbeducation@stanford.edu; +1 (650) 724-7141), ref: 44321

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Simulation-based skills training

Interventions
Clinicians and medical students are randomly assigned to either the intervention group, receiving feedback before they perform a second simulated neonatal intubation or the control group, receiving no feedback between first and second intubation. The correlation between intubation experience and intubation score is determined. Also, the interrater reliability of real-time assessment compared with assessment on video is determined.

Subjects in the intervention group received a form with predefined feedback regarding every item of the scoring instrument, which was structured in accordance with performance metrics taken from The Textbook of Neonatal Resuscitation, 7th Edition. Feedback specific to the errors made during the first intubation was highlighted on the form. The principal investigator gave this feedback form to the subjects.

All subjects provided their background characteristics, including four characteristics that indicated their neonatal intubation experience: NICU experience (years), number of previous successful neonatal intubations, number of previous simulated neonatal intubations, and most recent successful neonatal intubation. Each characteristic was assigned 0 to 5 points. Composite experience scores were calculated for all subjects by the principal investigator. Zero points represented no experience, twenty points represented high experience. We were unable to identify another useful, validated measure of neonatal intubation experience in the literature. Therefore, we used this experience score, which was based on consensus among various neonatal intubation experts, and also used in the prequel of this study.

Intubation score was measured by the principal investigator using the neonatal intubation scoring instrument (NISI) (i.e. the instrument being validated in this study)

Randomisation:
Simple, stratified, computer based randomisation.

Intervention Type
Behavioural

Primary outcome(s)
1. Construct validity was assessed by:
1.1. Determining the correlation, analysed with Spearman's rank-order correlation test, between intubation experience and intubation score, measured with the scoring systems mentioned above. Intubation experience was measured just prior to the simulation, intubation score was measured during the simulated intubation
1.2. Evaluating the effect of feedback on intubation performance; to this end, we compared the intervention group to the control group regarding the difference in intubation scores between the first and second intubation.
2. Reliability of real-time assessment assessed by: the intra-rater reliability, expressed as Intraclass correlation coefficient, of the intubation scores obtained using real-time assessment and the intubation scores obtained using video-based assessment.

Key secondary outcome(s))
None.

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Clinicians experienced in neonatal intubation
2. Medical students lacking intubation experience

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
35

Key exclusion criteria
Clinicians with intermediate intubation experience

Date of first enrolment

26/01/2018

Date of final enrolment
30/03/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Stanford University
Center for advanced pediatric and perinatal education
Palo alto
United States of America
CA 94304

Sponsor information

Organisation
Radboud University Medical Center

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/09/2020	03/09/2021	Yes	No