

Scoring instrument for breathing tube insertion in newborn babies

Submission date 29/11/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/12/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/09/2021	Condition category Other	<input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

None.

Overall study start date

01/09/2017

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

Age group

Adult

Sex

Both

Target number of participants

36

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

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Sponsor information

Organisation

Radboud University Medical Center

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

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ROR

<https://ror.org/05wg1m734>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Publication in peer reviewed medical journal on pediatrics/neonatology.

Intention to publish date

01/01/2020

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