Impact of personal protective equipment on neonatal resuscitation procedures: a randomised, cross-over, simulation study

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ABSTRACT

Background and objective Healthcare providers should use personal protective equipment (PPE) when performing aerosol-generating medical procedures during highly infectious respiratory pandemics. We aimed to compare the timing of neonatal resuscitation procedures in a manikin model with or without PPE for prevention of SARS-COVID-19 transmission.

Methods A randomised controlled cross-over (AB/BA) trial of resuscitation with or without PPE in a neonatal resuscitation scenario. Forty-eight participants were divided in 12 consultant–nurse teams and 12 resident–nurse teams. The primary outcome measure was the time of positive pressure ventilation (PPV) initiation. The secondary outcome measures were duration of tracheal intubation procedure, time of initiation of chest compressions, correct use of PPE and discomfort/limitations using PPE.

Results There were significant differences in timing of PPV initiation (consultant–nurse teams: mean difference (MD) 6.0 s, 95% CI 1.1 to 10.9 s; resident–nurse teams: MD 11.0 s, 95% CI 1.9 to 20.0 s), duration of tracheal intubation (consultant–nurse teams: MD 22.0 s, 95% CI 7.0 to 36.9 s; resident–nurse teams: MD 9.1 s, 95% CI 0.1 to 18.1 s) and chest compressions (consultant–nurse teams: MD 32.3 s, 95% CI 14.4 to 50.1 s; resident–nurse teams: MD 9.1 s, 95% CI 0.1 to 18.1 s). Twelve participants completed the dressing after entering the delivery room. PPE was associated with visual limitations (43/48 participants), discomfort in movements (42/48), limitations in communication (32/48) and thermal discomfort (29/48).

Conclusions In a manikin model, using PPE delayed neonatal resuscitation procedures with potential clinical impact. Healthcare workers reported limitations and discomfort when wearing PPE.

Trial registration number NCT04666233.

What is already known on this topic?

- Healthcare providers should use personal protective equipment (PPE) when performing aerosol-generating medical procedures during highly infectious respiratory pandemics.
- Protocols including the use of PPE may affect the timing of the neonatal resuscitation interventions.

What this study adds?

- In a manikin model, using PPE delayed neonatal resuscitation procedures with potential clinical impact.
- Healthcare workers reported limitations and discomfort when wearing PPE.

INTRODUCTION

The 2019-novel coronavirus, officially named SARS-CoV-2, has caused an unprecedented and escalating global pandemic with more than 119 million cases and 2 642 612 deaths.[1–4] Transmission occurs through close contact via respiratory droplets and fomites, which is increased during aerosol-generating medical procedures.[5] Thus, healthcare providers should be advised to use personal protective equipment (PPE) when performing such procedures during highly infectious respiratory pandemics.[6 7]

There has been an increasing number of SARS-CoV-2 infections in pregnant women and neonates, although evidence to date with either SARS-CoV-2 nucleic acid testing or antibodies within the first few days of life suggests that neonatal infection is most likely horizontal.[8–10] Neonatal resuscitation interventions including open airway, suctioning, positive pressure ventilation, non-invasive respiratory support, tracheal intubation and endotracheal drug administration are among the aerosol-generating medical procedures which may increase the risk of transmission to the unprotected healthcare providers.[6] Hence, during postnatal management of a newborn born to a mother with suspected or confirmed SARS-CoV-2 infection, healthcare providers should follow specific protocols focused on PPE and its correct use.[8 11] In emergency situations, it is reasonable to speculate that protocols including the use of PPE may affect the timing of the neonatal resuscitation interventions. However, information on occurrence and magnitude of such effect is not available.

The present study aimed to compare the timing of neonatal resuscitation procedures in a manikin model with or without PPE for prevention of SARS-COVID-19 transmission.

METHODS

Study design

This was a randomised controlled cross-over (AB/BA) trial of resuscitation with or without PPE for prevention of SARS-CoV-2 infection in a manikin model simulating a neonate needing resuscitation at birth (clinicaltrial.gov). The AB/BA scheme is

uniform within sequences and periods, thus removing any period and sequence effects.[12]

Setting

This simulation study was conducted at the University Hospital of Padova (Italy) and the General Hospital of Bolzano (Italy) between 16 and 23 March 2021. The University Hospital of Padova is a tertiary referral centre with around 2800 births and 450 neonatal intensive care unit (NICU) admissions per year, and the clinical staff also includes residents and fellows of the University. The General Hospital of Bolzano is a tertiary referral centre with around 1750 births and 350 NICU admissions per year. In both centres, COVID-19-related neonatal resuscitation guidelines were implemented,[11] and training sessions on the use of PPE for COVID-19-related neonatal resuscitation were mandatory to all perinatal staff at the beginning of the pandemic and to newly employed staff at recruitment.

The scenario consisted of an asphyxiated term infant needing PPV with face mask and endotracheal tube and chest compressions (neonatal simulator manikin: SimBaby, Laerdal Medical Corporation, USA; Laerdal, Stavanger, Norway). Briefly, heart rate, respiratory rate and breath sounds were controlled remotely and could be assessed by auscultation of the thorax and observation of chest movements. Oxygen saturation via pulse oximetry (SpO_2) was displayed on the bedside monitor about 40 s after the positioning of the pulse oximeter sensor. Heart rate was assessed by using a 3-lead ECG. The external observer provided verbal feedback during the scenario only if specifically required by the resuscitation team and not provided by the manikin (eg, the presence of secretions). A bedside Apgar timer was available for the resuscitation team.

Participants

Level III NICU consultants (Bolzano), paediatric residents (Padova) and nurses (Padova, Bolzano) were eligible to participate in the study. Participants were divided into teams including a consultant and a nurse (in Bolzano), or a resident and a nurse (in Padova) during the simulation. Refusal to participate was the only exclusion criteria.

Randomisation

All teams were randomly assigned to AB or BA arms in a 1:1 ratio. Allocation was stratified for consultant–nurse teams and resident–nurse teams. Randomisation was performed using a computer-generated random assignment list. Arm assignments were placed in sequentially numbered, sealed, opaque envelopes.

Procedures

Teams in AB arm were assigned to perform the procedure with PPE, followed by the procedure without PPE. PPE included gown, FP2 mask, gloves, hat, eye protection, shoe covers. The PPE was the same at each unit. Teams in BA arm were assigned to the reverse sequence. A washout period of 6 hours (one procedure in the morning and one in the afternoon) was included to reduce any carryover effect.

In the scenario, participants were alerted 2 min before the birth of a newborn with fetal distress. Participants spent this time in donning, preparing the equipment and briefing. At 2 min from alert, the neonatal manikin was put under the infant warmer and participants started the resuscitation procedures. These were based on the Neonatal Resuscitation Programme and the American Heart Association neonatal resuscitation algorithm,[13 14] and included initial steps (prevention of thermal losses, stimulation, suctioning, assessment), ventilation (face mask and tracheal tube) and chest compressions.

During each simulation, an external observer recorded the time of PPV initiation, the duration of the intubation procedure and the time of initiation of chest compressions. The observer started the stopwatch when the manikin was put under the infant warmer. The duration of intubation was calculated as the sum of the times from insertion to removal of the laryngoscope of each intubation attempt until reestablishment of ventilation. During the simulation with PPE, the observer also recorded whether the participants wore all PPE correctly and whether the dressing was completed before entering the delivery room. At the end of the simulation with PPE, participants were asked to grade the discomfort using PPE (none; some limitations/discomfort; relevant limitation/high discomfort) regarding four aspects (visual limitations, discomfort in movements, limitations in communication, thermal discomfort). All procedures were video-recorded.

Outcome measures

The primary outcome measure was time of PPV initiation. The secondary outcome measures were the duration of tracheal intubation procedure, the time of initiation of chest compressions, the correct use of PPE and participant's opinion on discomfort/limitations using PPE.

Data collection

Randomisation sequence, time of PPV initiation, duration of tracheal intubation procedure, time of initiation of chest compressions, correct use of PPE and participant's opinion on discomfort/limitations using PPE were collected by an observer who was not involved in the simulation. Data were recorded on a data sheet designed for the study and stored in a password-protected computer to protect confidentiality before, during and after the trial.

Masking

The characteristics of the intervention did not allow the masking of participants and outcome assessors. The statistician who performed data analysis was masked to treatment allocation.

Sample size

A minimum of 12 teams (6 in AB arm and 6 in BA arm) were required to have a 90% chance of detecting, as significant at the 5% level, a standardised effect size of 1 in a cross-over design. The final sample size included 12 consultant–nurse teams in Bolzano and 12 resident–nurse teams in Padova (48 participants overall). Sample size calculation was performed using R V.4.0 (R Foundation for Statistical Computing, Vienna, Austria).

Statistical analysis

Continuous data were summarised as mean and SD. The study included a washout period that was chosen to reasonably prevent carryover effects. Timing of PPV initiation, duration of tracheal intubation procedure and timing of initiation of chest compressions were compared between procedures (with vs without PPE) using a paired Student's t-test. Period effects were tested using a two-sample Student's t-test applied to the differences between procedures.[15] Following the paired analysis in consultant–nurse teams and resident–nurse teams separately, the differences between procedures (with vs without PPE) were compared in consultant–nurse teams versus resident–nurse teams using a two-sample Student's t-test. Effect sizes were expressed as mean differences (MDs) with 95% CIs.

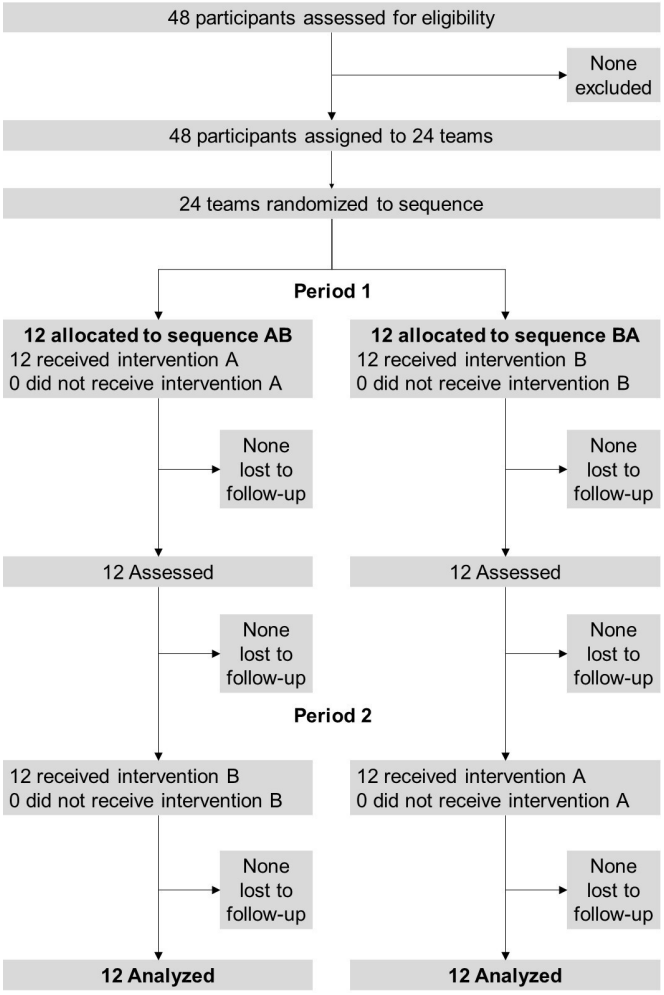

Figure 1 CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

The correct use of PPE and participant's opinion on discomfort/limitations using PPE were summarised as number and percentage with descriptive purpose. In addition, participant's opinion on discomfort/limitations was compared between team leader and assistant using Fisher's exact test. All tests were two sided, and a p value less than 0.05 was considered statistically significant. Statistical analysis was performed using R V.4.0 (R Foundation for Statistical Computing).[16]

RESULTS

The trial included 48 participants (12 level III NICU consultants in Bolzano, 12 paediatric residents in Padova and 24 nurses in Bolzano and Padova) who were divided into teams including a consultant and a nurse (in Bolzano), or a resident and a nurse (in Padova) during the simulation (figure 1). Experience in intubation was >10 intubations in seven residents, 5–10 intubations in two residents and <5 intubations in three residents. All consultants had high experience in intubation. Successful intubation required two attempts in two cases, while one attempt in the remaining cases.

PPV was started later with versus without PPE in consultant–nurse teams (MD 6.0 s, 95% CI 1.1 to 10.9 s; p=0.02) and in resident–nurse teams (MD 11.0 s, 95% CI 1.9 to 20.0 s; p=0.02) (table 1). No period effect was found in consultant–nurse teams (p=0.53) or resident–nurse teams (p=0.91). The difference in timing of PPV initiation with versus without PPE was not statistically significant between consultant–nurse teams and resident–nurse teams (MD −5.0 s, 95% CI −14.9 to 4.9 s; p=0.30). Overall, all participants started PPV within 1 min as indicated the Neonatal Resuscitation Programme and the American Heart Association neonatal resuscitation algorithm.[13 14] Duration of tracheal intubation procedure was longer with versus without PPE in consultant–nurse teams (MD 22.0 s, 95% CI 7.0 to 36.9 s; p=0.008) and in resident–nurse teams (MD 9.1 s, 95% CI 0.1 to 18.1 s; p=0.04) (table 1). No period effect was found in consultant–nurse teams (p=0.11) or resident–nurse teams (p=0.28). The difference in duration of tracheal intubation procedure with versus without PPE was not statistically significant between consultant–nurse teams and resident–nurse teams (MD 12.9 s, 95% CI −3.8 to 29.6 s; p=0.12).

Chest compressions were started later with versus without PPE in consultant–nurse teams (MD 32.3 s, 95% CI 14.4 to 50.1 s; p=0.002) and in resident–nurse teams (MD 9.1 s, 95% CI 0.1 to 18.1 s; p=0.04) (table 1). No period effect was found in consultant–nurse teams (p=0.48) or resident–nurse teams (p=0.42). The difference in timing of initiation of chest compressions with versus without PPE was not statistically significant between consultant–nurse teams and resident–nurse teams (MD 4.8 s, 95% CI −26.4 to 35.9 s; p=0.75).

In the simulation of a neonate born to mother with confirmed COVID-19, all participants wore PPE (48/48, 100%), but some (12/48, 25%) breached the dressing protocol by completing it after entering the delivery room (hat in five, gloves in four, gown in two, eye protection in one).

During the procedures with PPE, 43 out of 48 participants reported visual limitations (18 some limitations, 25 relevant limitations); 42 out of 48 participants reported discomfort in movements (28 some discomfort, 14 high discomfort); 32 out of 48 participants reported limitations in communication (26 some limitations, 6 relevant limitations); 29 out of 48 participants reported thermal discomfort (22 some discomfort, 7 high

Table 1 Timing of PPV initiation, duration of tracheal intubation procedure and initiation of chest compressions

Outcome measure	Team	Procedure with PPE: mean (SD)	Procedure without PPE: mean (SD)	Comparison of with PPE vs without PPE		P value (consultant–nurse team vs resident–nurse team)
				Mean difference (95% CI)	P value	
PPV initiation (s)	Consultant– nurse	26.2 (6.7)	20.2 (3.5)	6.0 (1.1 to 10.9)	0.02	0.30
	Resident–nurse	38.6 (16.8)	27.7 (9.6)	11.0 (1.9 to 20.0)	0.02	
Duration of tracheal intubation procedure (s)	Consultant– nurse	53.0 (24.4)	31.0 (8.0)	22.0 (7.0 to 36.9)	0.008	0.12
	Resident–nurse	36.0 (23.6)	27.1 (17.8)	9.1 (0.1 to 18.1)	0.04	
Initiation of chest compressions (s)	Consultant– nurse	168.8 (24.6)	136.6 (21.2)	32.3 (14.4 to 50.1)	0.002	0.75
	Resident–nurse	200.7 (55.7)	173.3 (42.9)	27.5 (0.1 to 54.9)	0.04	

PPE, personal protective equipment; PPV, positive pressure ventilation.

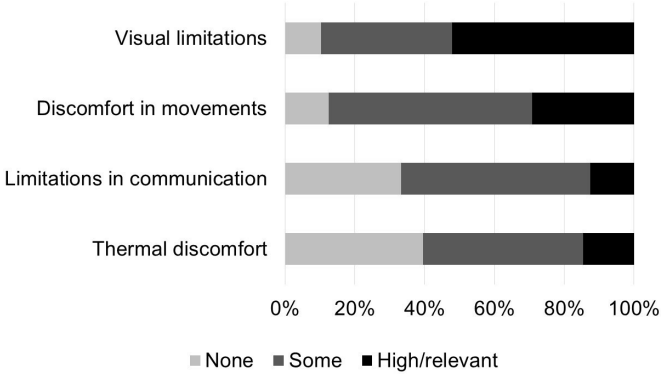

Figure 2 Participant's opinion on discomfort/limitations using personal protective equipment.

discomfort) (figure 2). The comparison of discomfort using PPE between team leader and assistant did not provide any statistically significant result (online supplemental table 1).

DISCUSSION

In our trial, the use of PPE increased the time of PPV initiation, the duration of tracheal intubation procedure and the initiation of chest compressions. In the simulation, all participants wore PPE (with some breaches of the dressing protocol) and more than half reported some PPE-related limitations or discomfort.

To our knowledge, this is the first study comparing time of neonatal resuscitation procedures with versus without PPE in a manikin. The strengths of the study include the use of a high-fidelity manikin and the videorecording, the participation of both inexperienced and experienced healthcare providers, and the cross-over design. These findings can be used to inform the healthcare providers about the importance of optimising resuscitation procedures when the situation involves a neonate with highly infectious respiratory disease. However, the reader should be aware of some limitations of the study. The simulation using a manikin implied that the procedures were performed under safe and secure conditions in a lower stress environment, although the trial simulated the exposure to a highly contagious neonate. In addition, the participation of consultant–nurse teams and resident–nurse teams may limit the generalisability of the findings in settings with different resuscitation teams. Of note, healthcare staff with lower familiarity with donning/using PPE (ie, at the beginning of the pandemic and for newly employed staff during the pandemic) and lower exposure to simulation activities may lead to longer delay and duration of procedures.

In the last two decades, global concerns about respiratory infectious diseases have gathered attention on the use of PPE for healthcare workers caring for patient with confirmed or suspected infection.[17] Following the last SARS-CoV-2 outbreak, new PPE guidelines were established for protecting healthcare workers from transmission during aerosol-generating medical procedures.[6 8 18] However, it is reasonable to speculate that using PPE may affect performing medical procedures. After the 2002 SARS-CoV outbreak, Watson *et al* showed that wearing standard gowns significantly delayed chest compressions and ventilations (potentially increasing patient morbidity and mortality) by firefighters in a simulated cardiac arrest scenario.[19] Similarly, we found that using PPE caused some delays in PPV, intubation and chest compressions in a simulated asphyxiated infant. However, the magnitude was heterogeneous, as the timings of the procedures could have been potentially harmful for a real neonate in some teams, while other teams performed the procedures without clinically relevant delays. Of note, the effects of PPE on resuscitation timings were not statistically different between consultant–nurse and resident–nurse teams, likely because of the high level of proficiency of the residents and the simulation being a lower stress environment compared with real-life situation.

A dressing protocol including PPE may affect the time spent in donning. In 2006, Abrahamson *et al* reported a donning time from 1 1/2 to 5 1/2 min in a simulated scenario of cardiac arrest resuscitation in an 'at risk of contamination situation'.[20] In our simulation, 25% of participants completed the donning only after entering the delivery room, despite being alerted 2 min before the birth of a newborn with fetal distress. Of note, the magnitude of the delay in resuscitation procedures due to donning would be larger in emergency situations where the team cannot be alerted with adequate anticipation. Previous simulation studies also described discomfort in terms of mobility, communication and dexterity in healthcare providers wearing PPE.[21 22] In our study, more than half of the participants reported some PPE-related limitations or discomfort, with high occurrence of visual limitations and discomfort in movements. Of note, the choice of eye protection among the range of available models can differently impact the visual limitations.

In the context of a respiratory infectious disease, healthcare providers should always wear PPE for aerosol-generating procedures during resuscitation.[6] Although specific measurements were not undertaken during the trial, we can speculate that the delay in starting PPV may be mainly due to the time spent in donning PPE before the resuscitation, while the longer duration of intubation and the delay in chest compressions may also be influenced by PPE-associated visual limitations and discomfort in movements. Given the drawbacks/limitations associated with the use of PPE during medical procedures, simulation and training of healthcare providers could play an important role in overcoming such difficulties and improving patient care.[23] In this scenario, earlier warning from the obstetric team and modifications of routines to allow advance preparation of equipment may help in reducing latencies in resuscitation procedures. In addition, further research should focus on optimising the use of available PPE[19] and/or comparing different alternatives,[21] in order to identify the best device and the best combination in the context of the emergency.

CONCLUSIONS

In a manikin model, using PPE delayed neonatal resuscitation procedures with potential clinical impact. Healthcare workers reported limitations and discomfort when wearing PPE. Simulation and training of healthcare providers, as well as further research on available and new PPE, could improve both patient care and user comfort. Since simulation is performed under safe and secure conditions in a lower stress environment, further studies in a clinical setting are warranted.

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Competing interests None declared.

Patient consent for publication Not required.

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Data availability statement Data are available upon reasonable request.

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