NeoLISA - A New Method of Less Invasive Surfactant Administration Developed based on in Situ Simulation

Dr. Shilpa Kalane (DNB)[1], Dr Arti Rajhans (MD)[2]

[1, 2]Consultant Neonatology, Deenanath Mangeshkar Hospital, Pune 04, India
Corresponding author email id: *drshilpakalane[at]gmail.com*

Short title: *Less Invasive Surfactant Administration*

Abstract: ***Background**: Respiratory distress syndrome (RDS) caused by surfactant deficiency is the major cause of respiratory distress in preterm neonates. Exogenous surfactant therapy is effective in reducing RDS-related mortality and morbidity. Due to the complications of surfactant administration, minimal or less invasive administration techniques have been developed and appear promising. **Objective**: To address the knowledge gaps in less invasive surfactant administration techniques at the level of the health care worker (HCW). **Methodology**: Four simulation-training sessions were conducted in April 2020, two before and two after the NeoLISA technique was developed. The neonatal clinical team consisted of neonatology specialists and neonatal nurses. **Results**: Each simulation session lasted for approximately 30 minutes, including debriefing. The learnings during this process were discussed, and the new technique of NeoLISA was developed. The key change was the development of method to confirm the catheter position so as to minimize the surfactant wastage. **Conclusion**: A new method for surfactant administration was developed. An innovative bedside clinical method confirming catheter position into the trachea has been developed.*

Keywords: Preterm, LISA, surfactant, RDS, neonate

1. Introduction

The technique of intubation, surfactant administration and extubation (INSURE) has been widely practiced. The difficulties and limitations of the INSURE technique have led to less invasive modes of delivering surfactant to preterm infants with RDS. Some techniques involve the use of instrumentation to aid passage of the catheter tip through the vocal cords (e.g., Magill forceps), yet others use no internal guide and rely on the skill of the clinician to direct the catheter into the trachea (1). Beyond these original reports, a wide range of different catheters has now been used for surfactant delivery, including umbilical, suction, and urethral catheters, inserted by both oral and nasal routes (2,3). However, for a bedside clinician, many procedure-related issues remain unaddressed. Hence, we decided to address the knowledge gaps in the technique of less invasive surfactant administration.

2. Methods and Materials

We expected the new technique to fulfil the objective of ensuring surfactant administration below the vocal cords. To reach this goal, we developed a novel simulation session consisting of a preterm neonate with RDS on continuous positive airway pressure (CPAP) requiring surfactant replacement therapy. A convenience sample of neonatology consultants, residents and nurses consented to participate. The 15-minute simulation session was run with two learners, an embedded simulation nurse and a low-fidelity mannequin in a neonatal intensive care unit (NICU) setting. The "newborn" was a low fidelity simulator (Laerdal Medical, Stavanger, Norway). After each scenario, a debriefing was performed, and feedback was sought from all involved as to what actions needed to change (Table 2). Based on this, the second scenario was written down and conducted. This iterative process was continued for a total of two scenarios. The difficulties encountered by the learners during initial simulation sessions were addressed, and a new technique of surfactant administration called NeoLISA was developed (table 1).

A series of lectures were taken, and learners were educated in the NeoLISA method of surfactant administration. The same simulation case scenario was again run with the same learner group. Following the completion of the final simulation sessions, the checklist of critical actions focusing on the skills important for the HCW performing NeoLISA was developed (Table 2). We conducted this process during the second lockdown phase and felt the need to publish as valuable information was obtained. Our institution's ethics committee's regular meetings were discontinued, and a formal ethical approval process was not possible. However, we state that we have followed all ethical processes possible as laid down in the National Ethical Guidelines for Biomedical and Health Research involving Human Participants published by the ICMR in 2017.

3. Results

We completed four simulation sessions. At baseline, all participants (n = 8) demonstrated a knowledge deficit in measures to ensure surfactant delivery. Post-final simulation, all said the new technique was helpful in terms of ease of administration and ensuring the feeding tube position. In Table 1, we have presented detailed results-based learning with reasoning that helped develop the new technique NeoLISA.

NeoLISA method of surfactant administration: A five Fre feeding tube was used for tracheal catheterization. The catheter is cut at a 30 cm mark to have a smaller length for ease of administration. The tube depth of insertion is determined by the nasal-tragus length (NTL) + 1 cm formula (4). The position at which the tube is to be fixed at the upper lip is marked using sterile tape. With the CPAP (with short binasal prongs) and orogastric tube (OGT) in situ, tracheal catheterization is performed under all asep-tic precautions, and the tube tip below the vocal cord is confirmed on direct laryngos-copy by the bedside clinician. No equipment was used to catheterize the trachea. Sur-factant is administered as a single bolus as quickly as possible by the neonatal nurse. The catheter position during the procedure is being monitored by the pediatric resident by auscultation of crackling sound over both lung fields and continuous aspiration of gastric contents. The absence of cracking sound from the stomach is considered cathe-ter dislodgment. After surfactant administration, the catheter is removed, and bubble CPAP is continued. Throughout the procedure, the baby's vital parameters are moni-tored.

4. Discussion

This new technique shows a feasible way to intubate the trachea with a soft flexible feeding tube, confirm its position and handle the crisis during the procedure. Similar toKanmaz et al., we used a soft 5 Fr feeding tube for endotracheal insertion (1). Bedside clinician skill was relied upon to direct the feeding tube into the trachea. While the original reports mention details of catheter insertion and method of insertion, we inno-vated following clinical skills to confirm the tube position in the trachea: 1. Depth of insertion equal to NTL+1, 2. Crackling sound in the left axillary and infra axillary are-as while surfactant is being administered, 3. Absence of surfactant on aspiration oro-gastric tube, 4. Change in quality of cry. The presence of the first 2 criteria with or without the other two confirms catheter position below the vocal cords and above the trachea. We have also addressed likely complications during the LISA procedure.

While attempting to address a major knowledge gap in confirming catheter position during the procedure, we developed a new technique of NeoLISA. We propose that sur-factant administration by a skilled neonatologist using NeoLISA is feasible with no wastage of surfactant from the marginal error of feeding tube displacement.

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Authors contribution

- Dr. Shilpa Kalane - participated in conceptualization, literature search, drafting the article, and approval of the final manuscript.
- Dr Arti Rajhans – Participated in data collection and drafting of the manuscript

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Table 1: Knowledge gaps raised during simulation sessions and addressed.

Delta	Knowledge gaps addressed
Inclusion Criteria	Neonates at all gestation age with CPAP >= 6 cm H2O with FiO2 >=0.3 to maintain SpO2 in local target range.
Exclusion Criteria	Neonates at all gestation age with severe respiratory distress, requiring CPAP >=7 and FiO2 >= 0.6. Alternative cause for respiratory distress. Maxillofacial, tracheal or bronchopulmonary malformation. No experienced personnel available.
Preparation before the procedure	As mentioned in table 3
Minimization of discomfort	Nonpharmacologic means of enhancing tolerance of the tracheal catheterization procedure include swaddling, tactile stimulation, and administration of 1 drop of own mother's milk or donor human milk.
Maintenance of respiration and avoidance of bradycardia	• Pre procedure Caffeine
	• If the neonate if on bubble CPAP ensure bubbling
Which catheter to be used?	5 Fr feeding tube
How to deal with the flexibility of the catheter?	• Select the feeding tube which is straight from the hub to the number 30.
	• Perform good oropharyngeal suction with 8 or 10 Fr suction catheter before the procedure
Time and attempts for tracheal catheterization?	• Tracheal catheterization should not take >30 seconds.
	• No more than two attempts in case of failure of catheterization.
Depth of insertion	• Use the formula NTL+1 to decide the depth of insertion. Tape the marking at which the catheter should

	be fixed at upper lip using the formula.
	• Also confirm the position by direct laryngoscopy during catheterization.
Ensuring surfactant delivery below vocal cords	• Catheter positioning is confirmed by auscultating cracking sound in axillary and infra axillary areas of the left lung throughout the instillation process.
	• Pushing 0.1 ml air through the tube at the end of the procedure, confirms the catheter position as well as minimizes the wastage of surfactant.
	• Change in baby's cry quality is another indirect marker of catheter position below vocal cord level.
	• Absence of surfactant on aspiration of OGT during the procedure.
Catheter displacement during the procedure	Diagnosis - Absence of crackling sound over left lung field and or presence of surfactant on OGT aspiration.
	Steps to be taken - Confirm the position with direct laryngoscopy.
	To re catheterize or intubate for INSURE will be the bedside neonatologist's decision.
Apnea during the procedure	The entire process of NeoLISA should not take >1 minute.
	Early identification of apnea and prompt intervention is the key to prevent failure of LISA.
	If the baby is apneic during the procedure, stimulate the baby and increase CPAP. if the baby does not respond, abandon the procedure and follow the resuscitation protocol (5).
Postprocedure care	Wean CPAP based on the clinical response and SpO2.

Table 2: Checklist for the procedure of NeoLISA

	The checklist for NeoLISA	Tick if yes
1	Obtains consent	
2	Checks the inclusion & exclusion criteria for NeoLISA	
3	Performs equipment check	
4	Performs role allocation	
5	Administers Inj Caffeine	
6	Selects the feeding tube and determines it's depth of insertion	
7	Performs interventions to minimize discomfort during the procedure	
8	Follows aseptic precautions	
9	Performs tracheal catheterisation with CPAP in situ	
10	Evaluates catheter position during and after surfactant administration	
11	Adequately evaluates respiration and HR during and after the procedure	

Table 3: Preparation of NeoLISA - equipment / supplies

1	Continuous cardiovascular monitoring equipment
2	Surfactant
3	Size 5 Fr feeding tube
4	Surfactant
5	5ml or 10ml syringe (dose dependent)
6	Large gauge needle (18g, 19g or 20g)
7	Alcohol swab 70%
8	Sterile towel or drape (2)
9	Sterile tapes
10	Sterile scissors or blade
11	Emergency equipment: T piece resuscitator and mask, suction, AMBU, Endotracheal tube.