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Lisa vs Insure in the Treatment of Respiratory Distress Syndrome in Preterm Infants

Jaweia Lodhi, Ayesha Shuaib, Rabia Tabassum, Hina Khan, Almas Mushtaq, Sohail Aslam

ABSTRACT

Objectives: To compare the outcome of Less Invasive Surfactant Administration (LISA) versus Intubation–Surfactant–Extubation (INSURE) for treatment of respiratory distress syndrome in preterm infants

Study design and Setting: Randomized controlled trial, Department of Pediatric, Fauji Foundation Hospital Rawalpindi. March 27, 2022 till September 26, 2022 Subjects: Total 70 neonates aged 1 to 24 hours of life having gestational age of 32-36 weeks of either gender having respiratory distress syndrome were enrolled using non- probability consecutive sampling technique.

Methodology: Study was conducted after approval of hospital ethical committee and written informed consent of parents. Neonates were enrolled in LISA group A and INSURE group B using lottery method. In LISA group surfactant was given using 6Fr nasogastric tube and in INSURE group neonates were intubated and surfactant was given. Frequency of need for mechanical ventilation in both groups was noted. Data was entered and analyzed using SPSS 21.

Results: In our study total 70 patients were enrolled, 35 patients in each group. Mean age was 7.8±6.6 hours in group A and 6.6±5.9 in group B. There were 40% males in group A and 57.1% in group B. females were 60% in group A and 42.9% in group B. In LISA group 28.6% needed mechanical ventilation while in INSURE group 60% needed mechanical ventilation, p-value 0.008

Conclusion: LISA is more effective in preventing need for mechanical ventilation after surfactant administration in preterm neonates.

Keywords: Intubate-surfactant-extubate: Less invasive surfactant administration: Preterm: Respiratory distress syndrome: Surfactant.

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INTRODUCTION:

Respiratory pathology is considered the most common complication of preterm birth, often presenting as respiratory distress syndrome, which results from structural immaturity of the lungs and early surfactant deficiency.[1] Out of 10 babies are born premature with the rate growing up in the majority of countries in the world.[2,3]

Respiratory distress syndrome is known to be one of the most popular causes of high morbidity and mortality in infants.[4] The survival of respiratory distress syndrome was diagnosed to be secondary to primary surfactant deficiency some 7 decades and continuous positive airway pressure was implemented, almost 5 decades ago. Since, some period lapsed and a lot happened in neonatology as well: we have known a lot but still there is more that remains disputable.[5]

The process of non-invasive ventilating and in particular that that is known by the usage of the continuous positive airway pressure (CPAP) has become commonplace in the treatment of the respiratory problems of the premature infant. However, failure of CPAP may occur in the situations of respiratory distress syndrome, i.e. failure of the surfactants. Less invasive surfactant administration (LISA) is a method

that aims at providing the amount of surfactant that is enough when the baby is breathing on his/her own without relying on positive pressure ventilator to help him/her breathe. Included in the application of the thin catheter to deliver the surfactant is the possibility of the babies being able to continue with the normal functionality of the glottis and spontaneous respirations as opposed to the conventional INSURE procedure that is linked to the sedation/analgesia, routine intubation, and a (short) duration of positive pressure ventilation.[6]

At the current stage LISA is the most suitable way of administering a surfactant and it should be the most widespread due to the benefits it brings to respiratory morbidities in preterm children with respiratory distress syndrome.[7] In a study by Cao et al., it was indicated that mechanical ventilation was investigated in 30 percent of LISA cases and 60 percent of INSURE cases in the treatment of respiratory distress syndrome in newborns ($p<0.05$).[8] Permall et al., conducted another study and reported that mechanical ventilation within 72 hours was required in 13.2% in LISA group vs.27.5% in INSURE group in preterm neonates ($P<0.05$).[9]

A study conducted in Poland which reveals that the need of mechanical ventilation was observed in 42.2 percent with LISA and 32.6 percent with INSURE in the treatment of respiratory distress syndrome in preterm infants ($p>0.05$).[10]

Another study was done in India in which there was no difference in the need of intubation and mechanical ventilation within 72 h of birth between within the two groups namely [InSurE, 30 percent and LISA, 30 percent, relative risk.[11]

The rationale of this study is to make a comparison between the outcome concerning LISA and INSURE in the treatment of respiratory distress syndrome in pre term babies. As stated in the literature, LISA was superior regarding rapid recovery of the respirations and decreased utilization of the mechanical ventilation. But in the literature, contradictory evidence has been provided and also it needs to conduct a study in the local setting so as to come up with magnitudes in the local setting. It follows therefore, that on the basis of this study we would like to have the current evidence to us such that we can manage to implement the findings of this study locally and that we shall also have the means of proposing which approach of managing the pre-term neonates with respect to respiratory distress syndrome is more acceptable. It would also help us to improve our performance and working style of the superior way of taking care of high-risk neonates.

METHODOLOGY:

The study was carried out in Fauji Foundation Hospital Rawalpindi between March 27, 2022 and September 26, 2022. Using the WHO calculator, it has been calculated 35 in each group and with sample size of 70 cases keeping 80 per cent power of study, 5 per cent level of significance and percentage of need of mechanical ventilation i.e. 30 per cent with LISA and 60 per cent with INSURE as the mode of delivering the need of the respiratory distress syndrome in pre-terminal infants through Non-Probability and in series sampling technique. Neonates aged 1–24 hours, irrespective of gender, born at a gestational age of 32–36 weeks (as determined from antenatal records), and diagnosed with respiratory distress syndrome (based on the operational definition) were included in the study. Neonates with severe congenital malformations and those requiring intubation during resuscitation at birth were excluded from the study.

Following approval from the hospital's ethical committee, a total of 70 neonates who met the inclusion criteria were enrolled in the study from the emergency department of the Department of Pediatrics at Fauji Foundation Hospital.

One also did a capture of demographic data that entailed name, age, sex, birth weight, gestational age at birth, Apgar scores and mode of delivery, after getting consent of the parents of the participating child. It involved the routine admission of neonates to the neonatology ward and their ongoing management.

Thereafter baby neonates were randomly divided into two and it was done through the use of lotteries. Group A consisted of introducing LISA treatment to the group of neonates by giving the dose of 100 mg/Kg Survanta using the help of 6 Fr size nasogastric tube. In the INSURE group B, the neonates were administered with the INSURE 2-3 aliquots using the endotracheal tube that bore the same dose as the LISA group and received the regulated positive pressure previously ventilated by the use of the T- piece resuscitaire. The endotracheal was removed after a short lease with the positive pressure ventilation of 15-20 minutes and the infants was subjected to the nCPAP. Respiratory and CPAP were administered using the initial pressure of 5 to 7 cm of water and FiO2 0.3. Follow up of neonates was done in between 6-24hr. Other than this, when the oxygen level was not maintained and when FiO2 has not gone down, the mechanical ventilation was supplemented and reported (as per the operational definition).

RESULTS:

In our study total 70 patients were enrolled, 35 patients in each group. Mean age was 7.8 ± 6.6 hours in group A and 6.6 ± 5.9 in group B. Mean gestational age was 33.8 ± 1.2 weeks in group A and 33.7±1.2 weeks in group B. Mean birth weight was 2 ± 0.1 in group A and 2 ± 0.17 in group B. (Table 1). There were 40% males in group A and 57.1% in group B. females were 60% in group A and 42.9% in group B. (Table 2), In group A 54.3% neonates delivered by vaginal delivery and in group B 42.9% delivered by vaginal delivery. (Table 3). In LISA group 28.6% needed mechanical ventilation while in INSURE group 60% needed mechanical ventilation, p-value 0.008. (Table 4)

Table 1: Mean values of Age, Birth weight and AGPAR group

Variable	Group	N	Mean ± Std. Deviation	p-value
Age (hours)	LISA	35	7.83 ± 6.697	0.452
	INSURE	35	6.69 ± 5.905	0.452
Gestational age	LISA	35	33.89 ± 1.207	0.694
	INSURE	35	33.77 ± 1.215	0.694
Birth weight (kg)	LISA	35	2.0486 ± 0.19610	0.949
	INSURE	35	2.0514 ± 0.17552	0.949
AGPAR group	LISA	35	7.46 ± 1.197	0.927
	INSURE	35	7.43 ± 1.399	0.927

Table 2: Gender Distribution

		Gender		Total	p-value
		Male	Female		
LISA	Count	14	21	35	0.151
	% within Group	40.0%	60.0%	100.0%	
INSURE	Count	20	15	35	
	% within Group	57.1%	42.9%	100.0%	

Table 3: Mode of delivery

		Mode of delivery		Total	p-value
		Vaginal	Cesarean		
LISA	Count	19	16	35	0.339
	% within Group	54.3%	45.7%	100.0%	
INSURE	Count	15	20	35	
	% within Group	42.9%	57.1%	100.0%	

Table 4: Comparison of need for mechanical ventilation in both groups

		Need for mechanical ventilation		Total	p-value
		Yes	No		
LISA	Count	10	25	35	0.008
	% within Group	28.6%	71.4%	100.0%	
INSURE	Count	21	14	35	
	% within Group	60.0%	40.0%	100.0%	

DISCUSSION:

The current form of the Respiratory Distress Syndrome (RDS) is a top cause of morbidity and mortality in premature infants with high usage of surfactant deficiency which predisposes this complication.[12] The predisposing factor in the condition is surfactant deficiency, a condition that emerges with inability of a baby to exchange gases that causes production of alveoli of small size along with decreased ingredients in improved delivery of the surfactant.[2]

Historically, endotracheal intubation and mechanical ventilation (MV) were performed to administer the surfactant replacement therapy.[13] Although this method has proven to be efficient in delivering the surfactant and in enhancing gas exchange, it also resulted in a number of sequelae including ventilator-induced lung injury (VILI), barotrauma, volutrauma and a higher risk of bronchopulmonary dysplasia (BPD).[4,5] To eliminate these adversities, less invasive ways of introducing the system, including INSURE (This would be to shorten the period of positive pressure ventilation and maintain spontaneous breathing, a condition that would eventually limit the chances of iatrogenic lung injury.[6]

The INSURE method proposed during the 1990s involves only brief intubation to install only surfactant and then extubate immediately to nCPAP.[7] The LISA technique instead has the ability to deliver the surfactant through a thin catheter passed through the vocal cords as a neonate breathes on his or her own on nCPAP, never to experience positive pressure ventilation.[14] This approach was later developed but became scarcely followed until it was revisited again and standardized in the early 2000s.[6,7]

Our study can be considered to contribute to this growing body of literature as it is a direct comparison of LISA versus INSURE outcome in a cohort of preterm neonates with RDS. The first one considered the need of mechanical ventilation within the first 72 hours after birth. The results indicated that there was a statistically significant decrease in chances of mechanical ventilation in LISA group (28.6%) at a relative percentage of surgery compared to INSURE group (60%) of 0.008. These findings agree with the hypothesis that uses of LISA will be better than that of INSURE in decreasing the need of invasive respiratory support among preterm neonates. The observation is in line with the results presented by Permall et al. (2024), who used a retrospective study to examine infants that received LISA. The study revealed that the LISA group had a lower need of mechanical ventilation and incident rates of moderate and severe BPD. But the study is retrospective and therefore cannot prove a causality. Moreover, the research study did not give significant details of the standardization of process, and possibility of procedures that were specific to centers and clinicians could have impacted the reliability of the results. However, the big sample size would lend merit to their conclusions and corroborate our findings of efficacy of LISA.[9]

The same tendency was seen in another research study by Cao et al. (2020). According to the study findings, only 30% of babies in its LISA group received mechanical ventilation as opposed to 60% in its INSURE group.[8] Also, the mechanical ventilation time, as well as the duration of FiO2 necessity, was greatly reduced in the LISA group. But the sample of their study was small in number, and the design was single center. The team of scientists cannot provide the details of LISA technique and give no information about training of the medical staff which undertakes the procedures. This standardization is not standard, which may affect the results and narrow reproducibility. Nonetheless, these restrictions do not cancel out our outcomes since they support our results and regard the feasibility of LISA in South Asian environments.

The study by Buyuktiryaki et al. (2019) was another study that supported the same results as it was a five-year retrospective study aimed at comparing LISA with INSURE.[7] The results have shown better respiratory outcomes with fewer cases of BPD and shorter ventilation periods among infants treated with LISA. Despite the fact that the longitudinal nature of the research contributes to the insights regarding the long-term trends, there is an inherent limitation due to the absence of randomization and control of the confounders. Besides, this study was not controlled over learning curve of LISA administration. Since physician skills also improved as the LISA technique progressed during the five years, the results being obtained may have been biased to show some positivity to LISA during the latter years.[15]

In contrast to most of the literature addressing LISA, Mansouri (2024) found no significant difference in the outcomes between the two methods.10 It included 129 preterm infants who were recruited and compared in terms of their intubation rates, the time spent mechanically ventilated, and the overall use of respiratory assistance. In their study, they established similar findings in both population groups, except that it had a number of limitations. First, the sample size was fair and the uneven distribution of the sample among the two groups (LISA: 83: INSURE: 46) had limited the statistical power. Second, LISA methodology was introduced rather recently in their hospital (2014-2016), so physicians did not have experience to teach them yet. It is expected that such an initial step of implementation influenced procedural efficacy and obscured the possible benefits of LISA. What is more, there are no specific records made of sedation procedures and type of surfactant which, again, reduces the interpretability. These constraints affect the findings of the researchers since we found that LISA and INSURE due to various reasons such as timings, use of sedative and post-surgical outcome.[16]

The study of Chakraborty and Course (2020) in Wales during the audit revealed the existence of highly variable practices when LISA is applied in various NICUs.[3] Focused to describe the processes but not clinical outcomes, the study emphasized the necessity of coordinated procedures and frequent training to provide consistency in LISA implementation. The audit method gave a great hinge into practical problems that one encounters when carrying out LISA especially in a system where there exists a lot diversity of provider expertise and in resources that an institute possesses. Their results bear out the belief that unstructured training without clarity in the process will result in the failure of the advantages of LISA to be exploited in practice. It is necessary to emphasize the advantages of LISA with the reference to clinical practices with the purpose of giving support to the patients concerning the management of respiratory distress syndrome.[17]

In favor of LISA, Bhayat et al. (2020) scanned the benefits and the risks that LISA might encounter.[6] The authors noted its ability to diminish cases of invasive ventilation and lung harm, mentioning its need of technical skills. Other issues of placement of the catheter correctly, alternate spontaneous gear during laryngoscopy as well as use of sedation were all established with regard to success limitations. This review observed that overall, the outcomes of LISA cannot be generalized due to a lack of standardization in catheter size, speed of instillation and sedation methods among other things across centers.[18] This review provides credence to our observations and is cautious on the idea that the benefits found in a controlled setting automatically apply in the environment where such procedures occur in a widespread manner.

Pareek et al. (2021) performed a pilot randomized controlled trial examining LISA vs INSURE efficacy.[12] As they indicate, the trial yielded results in support of LISA as more feasible and safer, though due to the small study sample size (n = 60) and insufficient statistical power, their results could not be statistically significant in relation to an outcome like BPD or mortality. However, random allocation of the study and prospective research design makes it internally sound. But the small sample size and brief follow-up as well as the single center study design points out to the need of having larger and multicentric trials backing up their initial results.

Huo et al. (2020) merged data of multiple clinical trials comparing LISA and INSURE (2020).[19] The combined evidence associated LISA with a reduction in the necessity of mechanical ventilation and respiratory outcomes. Nevertheless, the authors admitted that there has been a significant heterogeneity between the studies, which include variation in the gestational age of the study groups, a type of surfactant, use of sedation methods and LISA procedures. Such a variance reduces the generalizability and the accuracy of the results in the meta-analysis. In addition, the majority of the analyzed studies were short term, and not many long-term consequences on the respiratory system or neurodevelopmental outcomes were covered.

Kanmaz et al. (2013) undertook one of the first randomized controlled trials of LISA compared with INSURE that demonstrated much-reduced need to support with mechanical ventilation, and shorter nCPAP time, in the LISA group.[20] These results are the solid arguments in the effectiveness of the technique. Nevertheless, the study failure to include extremely sick neonates is likely to restrict the applicability to the sicker groups. Also, there are no long-term outcomes data to limit the knowledge on the overall clinical advantages of LISA.

Compiling the results of different studies, it is visible that LISA is to show numerous benefits compared to INSURE in the case of preterm infants having RDS.[21] LISA will require less mechanical ventilation, less risk of ventilator-associated events, and less time spent on respiratory support. The spontaneous breathing is also supported by LISA and it would have a more physiological respiratory mechanics

and would help in providing a superior pulmonary outcome. Although the evidence base is increasing, the success of the technique is by no means universal and is strongly dependent on such factors as physician training, institutional procedures, and patient selection.

Although our study supports many of these findings, it is not without limitations. To begin with, the sample size was small (n=70), which limits the possibility of generalizing the results and limiting the power of them. Second, this research was done in one center, which possibly represents institution-specific practice and experience of operators that cannot be transferred to other places. Third, the other confounding variables (e.g., timing of administration of surfactant, antenatal steroid exposure, and maternal health condition) were not taken into account, although there were similarities in the demographic variable (e.g., gestational age, birth weight, APGAR scores) in the different groups. Moreover, the short-term respiratory results that we studied did not have a follow-up, at least, to assess the long-term effect of LISA on BPD, neurological development, and survival. The results indicate that in order to use LISA in institutions that aspire to implement it, it is essential to spend money on the systematic training, practice using simulation, and continuous evaluation of competency.[22] Although the process is conceptually simple, it requires a high level of technical accuracy and planning, especially during laryngoscopy and the insertion of catheters. Another possible strategy would involve the development of standardized procedures concerning the type of surfactants, type of catheters, and sedation rules to reduce the variability.[23] Our paper shows, LISA will have significant results in reducing the invasive mechanical ventilation infants with RDS when compared with INSURE. This is coupled with an emerging number of national and international studies that support LISA as safe and effective surfactant delivery technique.[24] The success of the technique is very sensitive to the trained personnel, consistency, and institutional preparedness. Multicentric, randomized controlled trials with large samples, long-term outcome, and stratified data should be used in the future to replicate and perfect the role of LISA in the contemporary neonatal practice.[25]

CONCLUSION:

Finally, one could conclude that use of LISA technique in the replacement of surfactant can not only minimize the requirement of mechanical ventilation but also minimize long-term risk of mechanical ventilation in case of neonates with RDS but have spontaneous respirations and do not necessarily require mechanically assisted ventilation by endotracheal intubation at the time.

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Authors Contribution:
Jaweria Lodhi: Concept and design of study, literature review, final approval of manuscript
Ayesha Shuaib: Concept of study, critical appraisal of final version
Rabia Tabassum: Data analysis and interpretations, final approval of manuscript
Hina Khan: Literature review, drafting of manuscript, final approval of manuscript
Almas Mushtaq: Data collection and validation, literature review, final approval of manuscript
Sohail Aslam: Concept of study, critical appraisal of final version

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