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ORIGINAL ARTICLE

Comparison of Surfactant Administration through Laryngeal Mask and Through a Thin Tracheal Catheter in Treatment of Neonatal Respiratory Distress Syndrome

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ABSTRACT

Background: Respiratory distress syndrome (RDS) is considered a major problem in preterm infants. Surfactant deficiency is the main cause of RDS as it is necessary for lung functions. The treatment of surfactant in neonatology reduced mortality and improved the prognosis of RDS.

Aim and objectives: To compare between efficacies of surfactant administration by laryngeal mask technique and minimally invasive surfactant therapy (MIST).

Patients and methods : A randomized clinical trial study was carried out at the Neonatal Intensive Care Unit (NICU), Zagazig University Hospitals, on 24 patients who were divided into two groups, all patients received (poractant 120 mg/1.5 mL) and the same dose (200 mg/kg) for surfactant preparation, with close monitoring of the infants.

Results: There was no statistically significant difference between both groups as regard FiO2 before intervention while there was a highly significant decrease in FiO2 at 6, 12 and 24 hours in thin tracheal catheter group, on the other hand, each group showed a highly significant decrease in FiO over time after intervention. Also, there was a statistically significant decrease in nasal continuous positive airway pressure (NCPAP) and duration of O2 therapy in thin tracheal catheter group and there was no statistically significant difference between them as regard need for mechanical ventilation or occurrence of death during hospital stay.

Conclusion: The endotracheal method is prior to the laryngeal mask method for surfactant alternative therapy.

Keywords: surfactant, RDS, NICU.

INTRODUCTION

Respiratory distress syndrome (RDS) is considered a major problem in preterm infants. Surfactant deficiency is the main cause of RDS as it is necessary for lung functions **[1].** The treatment of surfactant in neonatology reduces mortality and improves the prognosis of the RDS **[2].**Surfactant was given by endotracheal tube (ETT), although superimposed lung injury from facemask-bag or ETT-bag positive pressure ventilation (PPV) which followed by mechanical ventilation (MV) could decrease surfactant function and cause inflammatory response in the lung, which lead to bronchopulmonary dysplasia (BPD) **[3].** The laryngeal mask airway (LMA) which is a supraglottic airway device used to maintain a seal around the laryngeal inlet to deliver PPV in the case of difficult airway administration or anesthesia practice **[4].**For newborns, LMA has a high potential in many circumstances, especially in neonatal resuscitation and administration of drugs **[5].**A few studies have discussed the administration of surfactant through LMA, but there was no published prospective randomized controlled trial (RCT) comparing the surfactant administration by LMA versus ETT and MV **[3].**Recently, a new technique was used for surfactant administration which is "less invasive surfactant administration" (LISA). According to this technique, neonates receive noninvasive continuous positive airway pressure (CPAP) treatment while endotracheal surfactant was given through a feeding tube with or without Magill forceps **[6].**

AIM OF THE WORK

To compare between efficacies of surfactant administration by laryngeal mask technique and minimally invasive surfactant therapy (MIST)

SUBJECTS AND METHOD

A randomized clinical trial was carried out at the Neonatal Intensive Care Unit (NICU), Zagazig University Hospitals, on 24 patients who were divided into two groups. All patients received (poractant 120 mg/1.5 mL) and the same dose (200 mg/kg) for surfactant preparation, with close monitoring of the infants.

All participants were subdivided into 2 groups:

Group I (n=12): Patients who were treated with surfactant administration by LISA.

Group II (n=12): Patients who were treated by administration of surfactant by laryngeal mask airway.**Inclusion criteria**

-Preterm males and females infants with gestational age (GA) between 28-36 weeks at birth and birth weight ≥1 kg and <8 h of age.

-Silverman-Anderson (SA) score greater than four and/or respiratory frequency >60 bpm and/or fraction of inspired oxygen (FiO2) ≥ 0.40 for maintaining oxygen saturation (SpO2) between 91 to 95%. **[7].**

-Clinical diagnosis of RDS; included cyanosis, grunting, nasal flaring, tachypnea (more than 60 breaths/minute) and poor feeding and may be a retractions in the intercostal, subcostal or suprasternal spaces. These typical symptoms mostly occur in premature infant immediately after birth.

-Typical RDS chest X-ray.

Exclusion criteria

Refusal of patients or their legal guardians to give informed consent, GA > 36 weeks, previous ETT, Apgar score <3 at 5 min, chorioamnionitis, congenital anomalies, and fever.

The sample size was taken as a comprehensive sample due to attendance of preterm neonates who need surfactant (4/month) so the sample size was 24 (12 in each group). The participants were chosen by systematic random sampling from patients admitted at the NICU, Zagazig University Hospitals.The MIST had included administration of exogenous surfactant by intrapharyngeal instillation, nebulization, a laryngeal mask, and a thin catheter. All patients received the same surfactant preparation (poractant-, 120 mg/1.5 mL) and the same dose (200 mg/kg), with close monitoring of the infants. **All cases had undergone (interference):** Patients were randomized to one of two treatment arms using a table of random numbers, before data collection. Eligible patients were identified according to the inclusion and exclusion criteria after clinical evaluation, chest X-ray, assignment of surfactant treatment, arterial blood gases analysis, and umbilical vein catheterization.

The researcher checked the sequential randomization and performed the laryngeal mask or less invasive surfactant insertion, and all patients were followed for six hours.

Follow up: The diagnosis of interventricular hypertrophy (IVH) was performed by cranial ultrasound examination on the days 5 to 7 of birth. Patent ductus arteriosus (PDA) was diagnosed according to clinical signs and confirmed by echocardiography. Chest x-ray was done for all infants before and 6 hours after surfactant therapy and the severity of RDS was determined by pediatric radiologist. Parameters of arterial blood gases were recorded at admission and 3 hours after administration of surfactant. The severity of RDS was evaluated by Downs RDS scoring system in the patients. Variables like RDS score, oxygen need before and after surfactant administration, need for reintubation or frequent use of the surfactant, radiological evidence of recovery of RDS, and other complications during hospitalization were recorded. The Downs RDS scoring system **[8]** checks for respiratory distress in pediatric patients based on pulmonary function parameters such as respiratory rate. This health tool allows clinicians to evaluate infant respiratory function and to check for impending respiratory failure. The Downes score calculator consists of five respiratory parameters:

Respiratory rate – measured in breaths per minute. The normal rate for infants (newborn to 6 months) is 30 to 60. After 6 months, it decreases to 24 to 30 breaths per minute. This is one of the pediatric vital signs, along with heart rate, blood pressure and temperature. Cyanosis – defined as a bluish discoloration of the skin and mucous membranes, usually caused by low air entry – evaluated by the intensity and loudness of the breathing sounds.

Grunt – defined as the expiratory noise produced by air pressing through the partially closed glottis during respiratory distress.

Retraction – defined as the sucking of the skin around and inward towards the chest bones during inspiration in respiratory distress.

Each of the five parameters is awarded a number of points ranging from 0 which means normal function, 1 point meaning moderate impairment and 2 points which means severe impairment in the function. The Downes score is often represented as in **Table (1)** Written informed consent was taken from all participants' guardian and the current study was carried according to the research ethical committee of Faculty of Medicine, Zagazig University. This study has been performed according to the Ethical Code of the World Medical Association (Declaration of Helsinki) for studies involving humans.

STATISTICAL ANALYSIS

Data were analyzed by the Statistical Package for

Social Science (IBM SPSS) version 20. Chi-square test was used for comparing two groups with qualitative data. t test was used to compare means of two groups. Nonparametric test (Mann Whitney) was used for comparison of means. ANOVA test was used for normally distributed data and Friedman test was used for abnormally distributed data. ROC curve analysis was used to evaluate the best cutoff of studied parameters. The level of statistical significance was considered at $P<0.05$.

RESULTS

There was no statistically significant difference between the studied groups regarding gender or age, GA, or birth weight. There was no statistically significant difference between the studied groups as regard their history including (mode of delivery, history of premature rupture of membranes (PROM)>8 hours, maternal use of antenatal steroid, and APGAR score at 5 minutes) Table (2). There was no statistically significant difference between the studied groups as regard PH before or after intervention, on the other hand, each group showed significant increase in PH over time after intervention. There was no statistically significant difference between the studied groups as regard PO2 before intervention while there was significant increase in PO2 after intervention and (significantly increase in PO2 thin tracheal catheter group), on the other hand, only thin tracheal group showed significant increase in PO2 over time. There was no statistically significant difference between the studied groups as regard PCO2 before intervention while there was significant decrease in PCO2 after intervention and decrease in PCO2 in thin tracheal catheter group, on the other hand, each group showed significant decrease in PCO2 over time Table (3). There was a statistically significant difference between the studied groups regarding fluctuation in their heart rate (HR) (highly significant decrease in HR fluctuation in thin tracheal catheter group), and there was no significant difference between the two groups regarding mean blood pressure fluctuation Table (4). There was no statistically significant difference between the studied groups as regard FiO2 before intervention while there was a highly significant decrease in FiO2 at 6, 12 and 24 hours in thin tracheal catheter group, on the other hand, each group showed highly significant decrease in FiO over time after intervention Table (5). There was a statistically significant decrease in nasal continuous positive airway pressure (NCPAP) and duration of O2 therapy in thin tracheal catheter group, similarly there was a significant decrease in hospitalization stay and ventilation days in thin tracheal group Table (6). There was no statistically significant difference between them as regard need for MV or occurrence of death during hospital stay (both were lower among thin tracheal catheter group but non-significant) Table (7)

Table (1): Downes RDS score

Item / Score	0 points	1 point	2 points
Respiratory rate (breaths/min)	<60	60 - 80	>80
Cyanosis	Nil	In room air	In ≥40%
Air entry	Normal	Mild decrease	Marked decrease
Grunt	None	Audible with stethoscope	Audible with naked ear
Retraction	Nil	Mild	Moderate

Table (2) Demographic and clinical characteristics of studied group:

Demographic characteristics	Thin tracheal catheter group		Laryngeal mask group		X2	P
	N (12)%		N(12) %			
Gender: **Male** **Female**	 8 (66.7) 4 (33.3)		 7 (58.3) 5 (41.7)		Fisher	1
	Mean ± SD	Median	Mean ± SD	Median	Z	p
Age (hours)	4.75 ± 0.87	6.5	6.08 ± 3.58	3	-0.058	0.954
	Mean ± SD		Mean ± SD		t	p
Gestational age (weeks)	30.58 ± 2.02		32.58 ± 0.79		-1.735	0.103
Birth weight (g)	1460 ± 240		1684.17 ± 143.62		-1.979	0.06
					X2	p
Mode of delivery: **NVD** **CS**	 3 (25) 9 (75)		 3 (25) 9 (75)		0	1
Antenatal steroid:						

Demographic characteristics	Thin tracheal catheter group	Laryngeal mask group	X2	P
No	6 (50)	5 (41.7)	0.168	0.682
Yes	6 (50)	7 (58.3)		
PROM>8 hours:				
No	10 (83.3)	9 (75)	Fisher	1
Yes	2 (16.7)	3 (25)		
	Mean ± SD	**Mean ± SD**	**t**	**p**
APGAR score at 5 minutes	8 ± 0.6	8.42 ± 0.51	-1.82	0.082

Z: Mann Whitney test - t: independent sample t test - X^2 :Chi-square test - NVD :normal vaginal delivery - CS: cesarean section - PROM : premature rupture of membranes

Table (3): results of ABG of the studied groups before and after intervention:

PH	Thin tracheal catheter group	Laryngeal mask group	T	P
	Mean ± SD	**Mean ± SD**		
arterial PH before	7.28 ± 0.06	7.27 ± 0.03	0.562	0.582
arterial PH after 3 hours	7.31 ± 0.03	7.31 ± 0.02	0.686	0.502
P (paired t)	0.009*	<0.001**		
PO2 before	**58.08 ± 10.09**	**52.58 ± 6.01**	**1.622**	**0.119**
PO2 after 3 hours	**67.23 ± 17.66**	**55.75 ± 2.96**	**2.222**	**0.047***
p (paired t)	**0.023***	**0.152**		
PCO_2 before	44.23 ± 6.27	45 ± 3.91	-0.359	0.723
PCO_2 after 3 hours	37.23 ± 3.62	42.33 ± 5.66	-2.633	0.017*
p	0.001**	0.006*		

t : independent sample t test - p (paired t): p value for paired sample t test - *p<0.05 is statistically significant - **p≤0.001 is statistically highly significant

Table (4): Distribution of the studied groups according to their hemodynamic fluctuation:

	Thin tracheal catheter group		Laryngeal mask group		Z	P
	Mean ± SD	**Median**	**Mean ± SD**	**Median**		
Heart rate fluctuation	6 ± 2.22	5	18.08 ± 12.32	16	-3.482	<0.001**
Mean blood pressure fluctuation	5.42 ± 4.46	5.5	6.75 ± 4.49	8	-0.947	0.344

Z : mann whitney test -*p<0.05 is statistically significant -**p≤0.001 is statistically highly significant

Table (5): Distribution of the studied groups according to change in NCPAP FiO2 value over time:

	Thin tracheal catheter group	Laryngeal mask group	T	P
NCPAP FiO2	**Mean ± SD**	**Mean ± SD**		
Baseline	57.5 ± 3.99	58.75 ± 3.77	-0.789	0.438
After 6 hours	47.92 ± 3.96	52.92 ± 2.57	-3.664	0.001**
After 12 hours	39.17 ± 4.69	44.17 ± 3.59	-2.934	0.008*
After 24 hours	31.25 ± 3.77	39.17 ± 6.69	-3.574	0.002*
P (F)	<0.001**	<0.001**		

t: independent sample t test - p (F): p value for repeated measure ANOVA test -*p<0.05 is statistically significant - **p≤0.001 is statistically highly significant

Table (6): Distribution of the studied groups according to methods and duration of O2 therapy and hospital stay value over time:

	Thin tracheal catheter group	Laryngeal mask group	T	P
	Mean ± SD	**Mean ± SD**		
NCPAP	45.75 ± 6.36	50.75 ± 5.21	-2.398	0.047*

	Thin tracheal catheter group		Laryngeal mask group		T	P
	Mean ± SD		Mean ± SD			
Duration of therapy	130 ± 31.33		157.58 ± 24.63		-2.398	0.025*
	Mean ± SD	**Median**	**Mean ± SD**	**Median**	**Z**	**p**
Hospital days	11.42 ± 4.56	10	13 ± 3.36	13	-0.968	0.343
Ventilation days	3 ± 1.41	3	3.2 ± 2.05	3	-0.123	0.907

t: independent sample t test Z: Mann Whitney test
*p<0.05 is statistically significant - **p≤0.001 is statistically highly significant

Table (7): Distribution of the studied groups according to their outcome:

	Thin tracheal catheter group	Laryngeal mask group	X2	p
	N (12) %	N (12) %		
Need for ventilation:				
No	10 (83.3)	8 (66.7)	Fisher	0.64
Yes	2 (16.7)	4 (33.3)		
Death:				
No	11 (91.7)	9 (75)	Fisher	0.59
Yes	1 (8.3)	3 (25)		

DISCUSSION

Exogenous surfactant administration is the established treatment of RDS. Many studies showed that early (prophylactic) administration of surfactant was more useful than late (rescue) therapy **[9].** It is a standard technique, where premature babies at risk of RDS mostly receive prophylactic surfactant immediately after birth. But this technique is invasive, because it requires endotracheal intubation for surfactant administration. The most common complications of surfactant administration include hypotension, hypoxia, and bradycardia **[10].**Supraglottic device is used to maintain a seal around the laryngeal inlet to deliver PPV in the case of difficult airway administration or anesthesia practice. The LMA which is a supraglottic airway device consisting of curved plastic tube and an elliptical inflatable mask which is inserted blindly into the posterior pharynx of the infant. The mask could be inflated in the hypopharynx to create an airtight seal around the upper esophagus. It has the ability of rapidly establishment of effective ventilation and access to the airway without tracheal intubation **[11]**.This study showed that there was a statistically significant difference between the studied groups as regard fluctuation in their HR (highly significant decrease in HR fluctuation in thin tracheal catheter group). While, there was no statistically significant difference between the two groups regarding mean blood pressure fluctuation. On the contradict, **Roberts [12]** observed progressive increase in HR in treatment with LMA because of use a greater number of cases.Also, we observed no statistically significant difference between the studied groups as regard FiO_2 before intervention while there was a highly significant decrease in FiO2 at 6, 12 and 24 hours in thin tracheal catheter group. On the other hand, each group showed a highly significant decrease in FiO over time after intervention**. Waal et al., [13]** agreed with our study as FiO2 was significant, rapid, with persistent decrease following MIST ($p < 0.001$).Our study showed that there was no statistically significant difference between the studied groups as regard PH before or after intervention. On the other hand, each group showed significant increase in PH over time after intervention**.** Also, we found that there was no statistically significant difference between the studied groups as regard PO2 before intervention while there was a significant increase in pO2 after intervention and (significant increase in pO2 thin tracheal catheter group). On the other hand, only thin tracheal group showed significant increase in PO_2overtimeIn current study, there was no statistically significant difference between the studied groups as regard PCO_2 before intervention while there was a significant decrease in PCO_2 after intervention and decrease of PCO_2 in thin tracheal catheter group. On the other hand, each group showed a significant decrease in PCO_2 over time. **Mirnia et al., [14]** found that Po2 increased after surfactant administration in both groups. Pco2 decreased in both groups 2 hrs after surfactant administration but the slope of this decrease was steeper in InsurE (p<0.08). Hco3 increased 2 hrs after surfactant administration in TEC group and was statistically significant (p<0.05).PH increased in both groups 2 hrs after surfactant administration but there was no difference statistically.In our

study there was statistically significant decrease in NCPAP and duration of O2 therapy in thin tracheal catheter group. Similarly, there was a significant decrease in hospitalization stay and ventilation days in thin tracheal group, which is in agreement with the study of **Lopez-Gil et al., [15]** who concluded the successful use of LMA for surfactant administration in 2 preterm neonates with birth weight of 1.36 and 3.2 kg. They reported an improvement in respiratory function between 3 to 6 hours**.** In the current study there was no statistically significant difference between them regarding need for MV or occurrence of death during hospital stay (both were lower among thin tracheal catheter group but non-significant), which is in agreement with the study of **Berneau et al., [16]** who found that infants who received LISA technique had lower duration of MV and lower incidence in the required oxygen on the day 28.

On the contrary, **Lista et al., [10]** demonstrated that main concern of LISA technique including the side effects like apnea, bradycardia, hypotension, and desaturation. Also, adverse effects like coughing, choking, sneezing, gagging, and surfactant reflux were noted in association with the maneuver.

Limits of the study: The small size of sample, and the comparison of physiological indicators (e.g. FiO2) which have different meanings in ventilated and non-ventilated patients. Also, the estimation of surfactant delivery to the lung (administered volume minus aspirated gastric fluid volume) was of questionable value and not validated.

Conclusions: The endotracheal method is prior to the laryngeal mask method for surfactant alternative therapy.

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