

Surfactant Therapy Using INSURE Method (Intubation- SURfactant- Extubation) In Management of Respiratory Distress Syndrome and Risk Factors Contributing to Failure of This Method

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Abstract

Background: The INSURE method (Intubation- SURfactant- Extubation) is increasingly being used to treat the respiratory distress syndrome in preterm infants and associated with declining the necessity for mechanical ventilation and reducing it is associated adverse events.

Objectives: To evaluate the effectiveness of surfactant therapy using INSURE method in the management of respiratory distress syndrome and to identify the risk factors associated with its failure.

Patients and methods: A retrospective descriptive cross sectional study was conducted in neonatal intensive care unit in Al- Yarmook Teaching Hospital, Baghdad, Iraq from April through October 2014. All preterm neonates (Gestational age 24- 34 weeks) with clinical signs and chest X- ray findings suggestive of respiratory distress syndrome and received surfactant by INSURE method were enrolled in this study and allocated into INSURE success and INSURE failure group depending whether they need re- intubation and mechanical ventilation or not.

Results: The total number of neonates enrolled in this study was one hundred five; of whom number of males was 60 patients (57.1%) compared with 45 females (42.9%). The INSURE method was successful in 71 neonates (67.6%). The mean birth weight and gestational age in the failure group were 1135(\pm 296) grams and 28.47(\pm 2.402) weeks respectively, and were significantly lower than the success group (1426(\pm 327) grams and 30.5(\pm 1.969) weeks respectively. This study also showed that the INSURE method was successful in 36 among 42 (85.7%) neonates with gestational age > 30 weeks while succeed in 35 among 63(55.6 %) neonates with gestational age \leq 30 weeks. The Apgar scores at 5 min were significantly lower in the failure group up in comparison with success group (the Apgar score between 4- 6 was present in 31.4% of success group where as 68.6% of failure group). Severe respiratory distress syndrome was significantly more common in the failure group (75.7%) than in the success group (24.3%).

Severe radiological finding on CXR was significantly more common in the failure group than in success group (83.9% vs. 16.1%). The need for second dose of surfactant was significantly more common in failure group than in success group (81.1% vs. 18.9%). This study showed that the more prolonged CPAP (continuous positive airway pressure)

treatment after surfactant administration, the more the INSURE method failed. Sepsis, recurrent apnea and pneumothorax were significantly more common in the failure group.

Conclusion: INSURE method is very effective method in the management of respiratory distress syndrome. It is associated with decrease the need for mechanical ventilation and decline in the neonatal mortality rate. There is an increased risk of failure of this method among those preterm neonates with low birth weight, lower gestational age, lower Apgar score, severe respiratory distress syndrome with severe radiological findings on CXR and with prolonged CPAP treatment duration after surfactant administration. Complications during the course of treatment such as Sepsis, recurrent apnea and pneumothorax may adversely affect the INSURE method success.

Introduction: Respiratory distress syndrome (RDS) is one of the most common causes of mortality and morbidity among preterm infants ^(1, 2). The definite pathogenesis is the deficiency of surfactant due to prematurity of alveolar cells in the lung. Therefore, exogenous surfactant therapy is the main stay of treatment ^(3, 4). A reduction in the mortality rate of 40% among neonates has been observed with application of exogenous surfactant through endotracheal tube ⁽⁵⁾. A major issue in surfactant therapy is the time and the method of prescription. Surfactant is usually prescribed via naso/ oro tracheal tube while it is necessary for the neonates to be intubated for this method ^(4, 6). on the other hand tracheal intubation is one of the important risk factor for pneumonia, bronchopulmonary dysplasia and it can increase the duration of hospitalization ⁽⁷⁾. In addition pneumothorax, Bronchopulmonary fistula and nosocomial infection were reported in intubated neonates for long time ⁽⁸⁾. INSURE protocol which includes Intubation, **SURfactant** prescription and Extubation followed by nasal continues positive airway pressure (NCPAP) ⁽⁹⁾. This protocol makes the neonates less exposed to the complications of intubation versus the routine protocol which includes intubation, surfactant prescription and mechanical ventilation ⁽¹⁰⁾. The treatment is initiated as soon as possible in the hours after birth ⁽¹¹⁾. The optimal dose of surfactant is from 100mg/kg to 200 mg/kg and repeated doses may be needed for patients who show relapse ⁽¹²⁾.

We conducted this work for the evaluation of INSURE method (Intubation- SURfactant-Extubation) in the management of respiratory distress syndrome among Iraqi preterm neonates and to identify the risk factors that are associated with failure of this method.

Patients and methods: A retrospective cross sectional study was performed on all preterm neonates who were admitted to the neonatal intensive care unit at Al Yarmook Teaching Hospital, Baghdad, Iraq; from April through October 2014 with clinical and radiological signs of respiratory distress syndrome. Those preterm infants (gestational age between 24-34weeks) who had spontaneous breathing and were given surfactant replacement therapy by INSURE method were enrolled in this study. Other preterm neonates with other clinical conditions as (no spontaneous breathing and on mechanical ventilation, no clinical or radiological evidence of RDS, transient tachypnea of newborn, congenital pneumonia, meconium aspiration, diaphragmatic hernia, congenital heart disease, birth asphyxia, Apgar score less than 4 at 5 min and major malformation or chromosomal anomalies) had

been excluded from the study. The total number included in this study was 105 patients. Neonatal variables (gender, birth weight, gestational age, respiratory distress syndrome severity and the severity of respiratory distress syndrome on the initial chest X ray) had been evaluated before INSURE method. The neonatal variables after INSURE method which include the need for 2nd dose of surfactant, duration of CPAP treatment after surfactant therapy and complication during the course of respiratory distress syndrome has been evaluated as well. Following the initial steps of resuscitation 3 different approaches are available for management of RDS:

1. Respiratory support: no sign of increase work of breathing and not require any supplemental oxygen within 6 hrs of resuscitation; these neonates monitored for the development of any signs of respiratory distress then INSURE method will be initiated.
2. INSURE method: for those infants with signs of moderate to severe respiratory distress and confirmed by radiological findings at 30 min or later and their oxygen saturation(SpO_2) <85% in room air, they were intubated electively and given surfactant(dose 100mg /kg)then immediately assessed for Extubation if they have good respiratory drive and clinically stable. Then put on CPAP.
3. Mechanical ventilation: for those with poor respiratory drive following surfactant delivery or clinically unstable following resuscitation.

INSURE method considered to be successful if the baby clinical condition improved (decrease in respiratory distress, $SpO_2 >90\%$ on $FiO_2 <30\%$ and $PEEP <4$ cm water) then the neonate can be weaned off CPAP and put on oxygen. If not improved or oxygen saturation <85% within 4- 6 hrs increase PEEP to 6cm water and adjust FiO_2 40-60%, if still no improvement within 12- 24 hrs a 2nd dose of surfactant given. If there is no improvement then put on mechanical ventilation. So the criteria for **INSURE failure** include (hypoxic; $SpO_2 <85\%$ despite $FiO_2 >60\%$ and $PEEP >6$ cm water, had recurrent apnea more than 4/hr and severe metabolic acidosis or shock).

Results: A total number 105 neonates were enrolled within this study; 60 males (57.1%) vs.45 females (42.8%) as shown in **table 1**.

Among those neonates INSURE method was successful in 71 (67.6%) while failure occurs in 34 neonates (32.4%) as show in **figure 1**.

A **mean gestational age** of 30.56(± 1.969) weeks found in preterm infants of whom INSURE method succeeded in comparison with 28.47(± 2.405) weeks in INSURE method failure (**table 2**). Regarding the **birth weight**, a mean weight of 1426(± 327) grams found in success group whereas a mean weight of 1135(± 296) grams found in method failure group (**table 2**). A mean **duration of CPAP treatment** was 38(± 15.312) hrs was found in success group vs. 56(± 13.576) hrs in failure group as shown in **table 2**. This study shows that the INSURE method was successful in 36 among 42 (85.7%) neonates with gestational age >30 weeks while succeed in 35 among 63(55.6) neonates with gestational age <30 weeks as shown in **table 3**.

The association between **Apgar score at 5 minutes** and the response of the INSURE method shown in **table 4**. In 35 neonates among 105, the Apgar score was between 4-6, 11 of them (31.4%) the INSURE method succeed while in 24 neonates (68.6%) the INSURE method failed. **Severe respiratory distress syndrome** was present in 37 neonates among 105, the INSURE method was successful in 9 of them(24.3%) while failed in 28(75.7%) as shown in **table 4**. **Severe radiological finding in CXR** defined as white out lungs with loss of cardiac borders found in 31 neonates among 105, the INSURE method succeed in 5 of them (16.1%) while it failed in 26 (83.9%) as in **table 4**. **2nd dose of surfactant** was needed in 37of total 105 neonates (35.2%), 7 neonates in success group (18.9%) & 30 neonates in failure group (81.1%) as shown in **table 4**.

The complications that occurred during the course of the RDS treatment which were associated with INSURE failure were shown in **table 5**. **Sepsis** occurred in 15 neonates within the total sample (14.3%), 3of them were in success group (20%) and 12 in failure group (80%). **Pneumothorax** occurred in 13 (12.4%), 5 of them in success group (38.5 %) and 8 in failure group (61.5%). **Recurrent apnea** occurred in 12 neonates within the total sample (11.4%), all of them occur in failure group.

The mortality rate in this study was 32 among 105 (30.5%) Mortality in INSURE failure group occurred in 25 neonates among 34 (73.5%), while in the INSURE success group occurred in 7 neonates among 71 (9.9%) as shown in **table 6**.

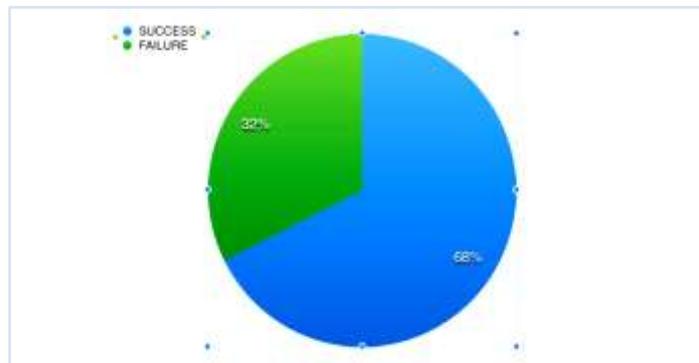


Figure 1 shows the percentage of response to INSURE method

Table 1 shows distribution of neonate according to gender

Variable	Number	Percentage %
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male	60	57.1%
female	45	42.9%
Total	105	100%

Table 2 shows the INSURE method association with neonatal variable

variables	Success no. 71	Success no 71	Failure no.34	Failure no. 34	Statistics
	mean	± SD	mean	± SD	
Gestational age in weeks	30.56	1.969	28.47	2.402	t= 4.738 p<0.001*
Birth weight in grams	1426	327	1135	296	t=4.392 p<0.001*
Duration of CPAP treatment in hours	38	15.312	56	13.576	t=5.526 p<0.001*

SD= Standard deviation, * statistically significant at a confident level of 95

Table 3 shows comparison between successful and failure groups according to their birth weight

Gestational age	Total number	INSURE success	Success %	INSURE failure	Failure %	P value
≤ 30 weeks	63	35	55.6%	28	44.4%	0.01

>30 weeks	42	36	85.7%	6	14.3%	0.01
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Table 4 shows the relationship between the INSURE method and the clinical characteristics of the neonate

(Response to INSURE method)

variable	Success		Failure		Total		statistics	
	f	%	f	%	f	%		
Apgar score at 5 min	4- 6	11	31.4	24	68.6	35	100	P<0.001* X ² =31.404
	7- 10	60	85.7	10	14.3	70	100	
RDS severity	moderate	62	91.2	6	8.8	68	100	P<0.001* X ² =48.910
	severe	9	24.3	28	75.7	37	100	
CXR severity	moderate	66	89.2	8	10.8	74	100	P<0.001* X ² =35.261
	severe	5	16.1	26	83.9	31	100	
Need 2 nd dose surfactant	yes	7	18.9	30	81.1	37	100	P<0.001* X ² =61.885
	no	64	94.1	4	5.9	68	100	

(Significant at a level of 95%, X² chi square)

Table 5 the relationship between the INSURE method and the complication occurred during the course of management which associated with INSURE failure

(Response to INSURE method)

variable		Success		Failure		Total		
		f	%	f	%	f	%	
Recurrent apnea	yes	0	0	12	100	12	100	P<0.001* X ² =28.292
	no	71	76.3	22	23.7	93	100	
sepsis	yes	3	20	12	80	15	100	P<0.001* X ² =18.123
	no	68	75.6	22	24.4	90	100	
pneumonia	yes	5	38.5	8	61.5	13	100	P<0.016 X ² =5.761
	no	66	71.5	26	28.3	92	100	

(*Statistically significant at a confidence level of 95%) (X² chi square)

Table 6 shows the mortality rate in the INSURE success and failure groups

outcome	Total number	%	INSURE success	Success %	INSURE failure	Failure %
survived	73	69.5%	64	90.1%	9	26.5%
dead	32	30.5%	7	9.9%	25	73.5%

Discussion: The best respiratory management for preterm infants remains a controversial issue. Due to adverse effects of mechanical ventilation, there is an increasing trend of avoiding the use of mechanical ventilation^(13, 14). This study shows INSURE **success** occurred in 71 neonates among 105 (67.6%), while failure occurred in 34 neonates (32.4%), which is approximately similar to Gharehbaghi *et al*⁽¹⁵⁾ study that showed of the 147 neonates, 45 (30.6%) required intubation within the first 72 hours of intratracheal surfactant administration and, therefore, were included in the failure group. Cherif *et al*⁽¹⁶⁾ study showed a INSURE failure was registered in 26 infants among 70 neonates (37.1 %) ,this small difference may be due to different sample size, different criteria of INSURE failure or the use of pre-intubation medication, Morphine which is a long-acting drug that may increase the risk of INSURE failure and the need for mechanical ventilation.

Gharehbaghi *et al.* and Najafian *et al*⁽¹⁷⁾. showed that **gestational age** and **birth weight** were significantly lower in the INSURE failure group, which is the same result in this study, while Cherif *et al.* and Dani *et al.* showed the same result concerning birth weight but not the gestational age due to different gestational age groups enrolled within these studies (27–34 weeks 'gestation and below 30 weeks' gestation, respectively). This study showed a high statistically significant association between the gestational age and birth weight with the response to INSURE method. In the fact of increasing in the probability of the INSURE method failure when there is a decrease in the **gestational age & birth weight**. The likely reason for failure appears to be the immaturity of lungs in neonates with lower gestational age and birth weight.

Concerning the **Apgar score**, Gharehbaghi *et al.* showed that Apgar score were significantly lower in the INSURE failure group, which is the same result in this study. Similar to this study, Gharehbaghi *et al.* showed that **severe RDS & severe radiological finding on the chest X-ray** (defined as white out lungs with loss of cardiac borders) was an important predictor of CPAP failure. But this is different from what was found by Cherif *et al.* which may be due to different study sample, difference in percentage of severe cases & different criteria for INSURE failure. In this study, **the need of 2nd dose of surfactant** was more common and not beneficial in neonates with INSURE failure which is the same finding in Gharehbaghi *et al.*, while in another study by Dani *et al*⁽¹⁸⁾ they postulated that instituting INSURE multiple times may decrease the failure rate and prevent need for

mechanical ventilation. This may be related to different study populations, study design, strategies for mechanical ventilation or different criteria for intubation. Gharehbaghi *et al.* showed that **prolonged duration of CPAP treatment** was more common in INSURE failure group which is the same finding in this study, the prolonged duration of treatment may associated with increase complication of CPAP such as pneumothorax which inversely affect the response of INSURE method. So the variables associated with failure of INSURE method were:

- 1) Lower birth weight.
- 2) Lower gestational age.
- 3) Severe RDS.
- 4) Whiteout on the chest X-ray (radiological signs of severe RDS).
- 5) Low APGAR score at 5 minute.
- 6) Prolonged duration of CPAP treatment after surfactant administration.

Sepsis cause multi organ failure including respiratory failure, pulmonary surfactant is altered in sepsis, and these changes contribute to the predisposition of septic lungs to subsequent insults, ultimately leading to acute lung injury. Specifically, the total amount of surfactant is lower in sepsis, mainly due to decreased small aggregate surfactant pools. The amount of large aggregate surfactant is not altered⁽¹⁹⁾. These factors select multi-resistant microorganisms and lead to a rapid spread of infection and affect the response to INSURE method. **Pneumothorax** occurs following over distention of the lungs caused by inappropriately high pressures. They tend to occur when the lung compliance starts improving and the oxygen requirements also show a reduction so it may lead to INSURE method failure⁽²⁰⁾. This is not similar to what was found in Cherif *et al.* & Najafian *et al.* this may be due to availability of more diagnostic & treatment facilities in the centers of these studies. **In this study recurrent apnea** was more common in the neonates of failure group. **Recurrent apnea** is one of the contraindication of CPAP, Poor respiratory drive (frequent apnea and bradycardia) will not improve by CPAP and need mechanical ventilation so it is associated with INSURE method failure⁽²⁰⁾.

The mortality rate in this study was 30.5% while in Cherif *et al.* was (34.2%). This small difference may be due to different sample size (105 vs. 70) cases. Mortality rate in the INSURE failure group was 73.5% while in the INSURE success group was 9.9%, while in Najafian *et al.*, The mortality in success group was 0% & in failure group 31.2%. This difference may be due to small number of premature neonates treated by INSURE method in Najafian *et al.* (45 cases vs. 105 cases in this study). But both of these studies show that the INSURE method associated with decreased mortality rate and decreased the need for mechanical ventilation and hence avoiding it complication.

As a conclusion INSURE method is very good method in management of Respiratory Distress Syndrome that associated with decreased need for mechanical ventilation &

decreased neonatal mortality rate. This study shows that preterm neonates with lower birth weight, lower gestational age, lower Apgar score at 5 minutes, with severe RDS & severe radiological finding on CXR & with prolonged CPAP treatment duration after surfactant administration have increased risk for INSURE method failure. Sepsis, recurrent apnea and pneumothorax are the main complications during the course of treatment which may adversely affect the INSURE method success.

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العلاج بمادة السيرفكتنت باستخدام (طريقة التنبيب، زرق السيرفكتنت، اخراج الانبوب الرغامي) في علاج متلازمة عسر التنفس الولادي وتشخيص العوامل التي تؤدي الى فشل هذه الطريقة

الخلاصة

خلفية الدراسة: العلاج بمادة السيرفكتنت بطريقة (التنبيب، زرق مادة السيرفكتنت، ازالة الانبوب الرغامي) طريقة يتزايد استخدامها في علاج متلازمة عسر التنفس الولادي في الاطفال الخدج وهي طريقة فعالة في تقليل الاحتياج الى التهوية الميكانيكية وتقليل اثارها الجانبية.

اهداف البحث: تقييم فعالية العلاج بمادة السيرفكتنت بطريقة (التنبيب، زرق مادة السيرفكتنت، ازالة الانبوب الرغامي) في علاج متلازمة العسر التنفسي الولادي وتحديد العوامل التي قد تؤدي الى فشل هذه الطريقة.

العينة: دراسة وصفية استرجاعية اجريت في وحدة الخدج وحديثي الولادة في مستشفى اليرموك جميع الاطفال الخدج من التعليمي، بغداد، العراق للفترة بين شهر ابريل الى شهر اكتوبر لعام ٢٠١٤ حديثي الولادة ما بين ٢٤-٣٤ اسبوع جنيني وكانوا يعانون من العلامات السريرية وعلامات الاشعة السينية لمتلازمة العسر التنفسي الولادي وتم معالجتهم بمادة السيرفكتنت بطريقة (التنبيب، زرق مادة السيرفكتنت، ازالة الانبوب الرغامي) قد ضمنوا ضمن هذه الدراسة وقسموا الى مجموعتين، مجموعة نجحت معهم طريقة العلاج ومجموعة لم تنجح اعتمادا على احتياجهم الى التهوية الميكانيكية من عدمه.

النتائج: شمل ١٠٥ خديج في هذه الدراسة. وكان العدد الكلي الذكور ٦٠ (٥٧,١%) وللاناث ٤٥ (٤٢,٨%). العلاج بمادة السيرفكتنت بطريقة (التنبيب، زرق مادة السيرفكتنت، ازالة الانبوب معدل الوزن الولادي والاسبوع الرغامي) كانت ناجحة في ٧١ حالة (٦٧,٦% من عينة الدراسة). الجنيني في المجموعة التي فشلت معها طريقة العلاج كان ١١٣٥ (٢٩٦ ±) غم و ٢٨, ٤٧ (±) ٢, ٤٠٢) اسبوع على التوالي، وهو اقل بدرجة كبيره من المجموعة التي نجحت معها طريق العلاج {١٤٢٦ (±) ٣٢٧} غم و ٣٠, ٥٦ (±) ١.٩٦٩) اسبوع على التوالي. مقياس ابغار عند الدقيقة الخامسة بعد الولادة كان اقل بدرجة كبيره في المجموعة التي فشلت معها طريقة العلاج (مقياس ابغار ٤-٦) وجد في ٣١, ٤% في المجموعة التي نجحت معها طريقة العلاج و ٦٨, ٦% في مجموعة التي فشل بيها العلاج. عسر التنفس الشديد قد وجد في المجموعة التي فشلت معها طريقة العلاج بصورة اكبر من

الجموعه التي نجحت معها طريقة العلاج {٧٥,٧٪ مقابل ٢٤,٣٪} على التوالي كذلك علامات الاشعة التشخيصية الشديده لمتلازمة عسر التنفس ايضا وجدت في المجموعه التي فشلت معها طريقة العلاج بصورة اكبر من المجموعه التي نجحت معها طريقة العلاج { ٨٣,٩٪ مقابل ١٦,١٪} على التوالي.الاحتياج الى جرعه اخرى من ماده السيرفكتانت في المجموعه التي فشلت معها طريقة العلاج كانت اكثر بدرجه كبيره من المجموعه التي نجحت معها طريقة العلاج (٨١.١٪مقابل كلما زادت فشل العلاج بمادة CPAP ١٨٠٩٪)علي التوالي. وجد ان كلما زادت فترة العلاج بجهاز السيرفكتنت بالطريقة المدروسة.المضاعفات التي حصلت اثناء فترة علاج متلازمة عسر التنفس وادت الى فشل طريقة العلاج هي: تسمم الدم الجرثومي وتوقف التنفس واسترواح الصدر

الاستنتاجات: العلاج بمادة السيرفكتنت بطريقة (التنبيب، زرق مادة السيرفكتنت، ازالة الانبوب الرغامى) طريقة جيدة جداً في علاج لمتلازمة عسر التنفس الولادي التي ترتبط بتقليل الاحتياج للتهويه الميكانيكيه وتقليل معدل وفيات حديثي الولادة الخديجين الذين يعانون من الانخفاض الشديد لوزن الخديج وقلة عمر الخديج الرحمي وقلة مقياس ابغار وشدة متلازمة عسر التنفس الولادي وعلامات متلازمة عسر التنفس الشديده في صورة الاشعه السينيه وطول مدة بقاء الخديج تحت تاثير جهاز الضغط الايجابي المستمر للهواء في المجاري التنفسيه , لديهم نسبة اكبر من احتمالية عدم استجابتهم للعلاج بالطريقة المذكوره اعلاه. تسمم الدم الجرثومي و توقف التنفس واسترواح الصدر يعتبرون من اهم مضاعفات التي تحدث خلال فترة العلاج والتي تؤثر بصورة سلبيه على نجاح العلاج.