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Assessment of the Early Predictors of Failure of Continuous Positive Airway Pressure in Preterm Neonates with Respiratory Distress Syndrome

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Abstract

Background: The most frequent disorders of admission in neonatal intensive care unit is respiratory distress syndrome. Continuous positive airway pressure (CPAP) is essential to maintains functional residual capacity. Many predictors of CPAP failure have been reported in studies

Aim of Study: This study aimed to evaluate the early predictors of the failed continuous positive airway pressure (CPAP) in preterm babies with respiratory distress syndrome (RDS).

Patients and Methods: All born preterm neonates with gestational age (GA) 36 weeks or less from December 2020 to October 2022, in whom CPAP was initiated within the first 72 hours after birth and FIO2 level was determined in the first 2 hours of life, were enrolled in the study.

Results: Of the 207 neonates 36 weeks gestation or less in the study, 7 neonates were excluded from the analysis, so 200 neonates were included. In the vast majority of neonates with CPAP failure, the following factors were highly significant explaining CPAP failure as birth weight and FiO2 level at the first & second hours of life compared to CPAP success patients. In ROC analysis, FiO2 - 1st hr. at cut off point >0.38 and FiO2 - 2nd hr. at cut off point >0.33 achieved significance for predicting CPAP failure with sensitivity of (72%, 87%) and specificity of (66.7%, 70.2%), with PPV (68%, 79%) and NPV (70%, 82%), respectively.

Conclusion: FiO2 - 1st hr> 0.38 and FiO2 - 2nd hr. >0.33 predict CPAP failure in preterm neonates.

Key Words: *Preterm neonates – Respiratory distress syndrome – Continuous positive airway pressure.*

Introduction

IN preterm newborns, respiratory distress syndrome (RDS) is the most frequently encountered disorder leading to admission to the neonatal intensive care unit (NICU) and has a major contribution to morbidity and mortality. It has been demonstrated that continuous positive airway pressure (CPAP) maintains functional residual capacity, prevents collapse of lungs and upper airway, decreases demand to oxygen, breathing effort, apnea periods, and reduces risk of reintubation in neonates subjected to mechanical ventilation, hospital stay length, and referral to tertiary hospitals. It should be noted that infants who underwent CPAP failure are more risky for morbidity, such as likely to die and experience negative consequences such as intra ventricular hemorrhage (IVH), broncho pulmonary dysplasia (BPD), and pneumothorax, and mortality **[1]**.

Since surfactant deficiency has been identified as the primary factor in CPAP failure, it is crucial from a therapeutic standpoint to identify newborns who are surfactant deficient momentarily and administer early rescue surfactant therapy. In the literature, a number of predictors of treatment failure have been put out, but the maximal percentage of inspired oxygen (FiO2) shortly after birth has received the most attention **[2,3]**.

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Abbreviation:

CPAP : Continuous Positive Airway Pressure.
RDS : Respiratory Distress Syndrome.
GA : Gestational Age.
NICU : Neonatal Intensive Care Unit.
BPD : Broncho-Pulmonary Dysplasia.
IVH : Intraventricular Hemorrhage.
ROC : Receiver Operating Characteristic.
AUC : Area under Curve.
PIH : Pregnancy Induced Hypertension.
DM : Diabetes Mellitus.
HTN : Hypertension.
ROP : Retinopathy of Prematurity.

The aim of this study was to identify the factors predicting failure of CPAP in preterm neonates with respiratory distress syndrome.

Patients and Methods

Study population:

The present study was performed at the neonatal care unit of Benha University Hospitals and NICU of Benha Children Hospital. Preterminfants with gestational age of 36 weeks or less who were admitted to NICU with RDS and indicated CPAP were consecutively recruited to the study. RDS was diagnosed by the presence of **[4]**:

1- Respiratory distress during the first 24 hour of life,

2- Typical findings in chest x-ray of lung ultrasound **[5]**.

3- Complete, persistent, and immediate improvement of oxygenation with surfactant replacement or notable improvement while using CPAP, which precluded the need to administer surfactant.

Neonates with congenital lung disorder, life-threatening congenital anomalies, congenital infections causing hypoxemia, septic shock/severe sepsis **[6]**, transient tachypnea of the neonate **[5]**, meconium aspiration syndrome **[7]**, blood aspiration syndrome **[8]**, pulmonary hemorrhage **[9]**, or any type of neonatal ARDS, neonatal hemolytic disease, newbornsunder steroid treatment, and those of preeclamptic or diabetic mothers were excluded.

Study design:

This was a prospective, pragmatic, observational cohort study conducted from December 2020 to October 2022, enrolled all preterm neonates with gestational age 36 weeks or less, in whom CPAP wasinitiated within the first 72 hours after birth and FIO2 level was determined in the first 2 hours of life, were eligible in the study.

Definition of CPAP failure:

CPAP failure was defined as neonates requiring invasive ventilation within the first 72 hours of life based on the Polish Neonatal Society criteria **[10]**:

- Low arterial blood oxygen tension (PaO2 <50mmHg) or Oxygen saturation less than 87% with FiO2 >0.6.
- Pathological apnea.
- Excessive work of breathing despite non-invasive respiratory support.

Surfactant was administered for newborns with gestational age ≤ or >28 weeks' if FiO2 was above 0.3 or 0.4, respectively **[11]**.

Data collection:

Each patient included in this study were subjected to:

- *Thorough history taking:* Including date of birth, sex, gestational age, type of feeding, mode of delivery, history of birth trauma, intra partum fever, history of premature rupture of membranes, history of maternal illness, drugs, history of previous siblings with neonatal distress, symptoms suggestive of respiratory distress in the form of (poor suckling, lethargy, tachypnea, tachycardia), date of onset of symptoms suggestive of respiratory distress.
- *Careful clinical examination:* Including assessment of anthropometric parameters, neonatal reflexes, and neurological examination, in addition to chest, cardiac and abdominal examination.

Ethical consideration:

This present study was executed per the Helsinki declarationand approved by the Ethics Committee in the Faculty of Medicine, Benha University, NoMS 16-11-2020. This is an observational study involved the collection of data from the hospital records without direct interventional procedure. Informed consent was retrieved from all neonates'parents/care givers.

Statistics:

The neonates' data were retrieved and analyzed using the statistical software SPSS 22.0 for windows (SPSS Inc., Chicago, IL, USA). Normality testing was performed. Categorical variables were expressed as number and percentage and compared using Chi square (χ^2) or Fisher exact test. Numerical variables were presented as mean ± standard deviation or median and range and compared by student-tor Mann Whitney test according to the normality testing. The factory potentially predicting the CPAP failure were determined by binary logistic regression test using the stepwise method. Receiver operating characteristic (ROC) curve was established to assess the performance of different diagnostic tests. Areaunder a ROC curve (AUC) was interpreted as excellent performance if it ranged from 0.90 to 1, good performance if it ranged from 0.80 to 0.90, fair performance if it ranged from 0.70 to 0.80, poor performance if it ranged from 0.60 to 0.70, and failed performance if it ranged from 0.50 to 0.60. The performed statistical comparisons were two tailed. *p*-values of ≤0.05 were indicators of statistical significance.

Results

We enrolled 207 neonates 36 weeks gestation or less in the present study. Seven neonates were transferred to another hospital during the first 24 hours of life, and their data were excluded. So the final analysis included 200 neonates with the proportion of male was (57.5%) and female was (42.5%). The mean gestational age was 32.19 weeks (±2.65SD). The mean values of neonates' birth weight was 1.84±0.338kg. The mean Apgar score at 1st & 5th minute was 5.49±2.26 & 7.81± 2.73 respectively. Cesarean section was the mode of delivery in 167 neonates (83.5%). The majority of the subjects with preterm delivery and maternal risk factor of pregnancy induced hypertension (PIH), Diabetes Mellitus (DM) & Hypertension (HTN) was 35%, 17% & 8% respectively.

Predictors of CPAP failure:

Overall, CPAP failure occurred in 56 neonates (28%), with highly significant difference between tem and CPAP success regarding perinatal factors as maternal age, parity and PIH.

In the vast majority of neonates with CPAP failure, the following factors were highly significant explaining CPAP failure as gestationalage, birth weight, PaO2, PaCo2, FiO2 level , both at the first & second hours of life compared to CPAP success patients as shown in Table (1).

Table (1): Perinatal & neonatal data among RDS group according to CPAP outcome.

	CPAP success (n=144) (72%)	CPAP failure (n=56) (28%)	T / χ^2	*p*
Maternal age (years): Mean ± SD	29.11±4.12	31.56±4.73	3.62	.001
Parity: Mean ± SD	1.55±1.02	2.21±1.14	3.97	.000
Antenatal steroids, n (%)	109 (75.7%)	51 (91.1%)	5.96	.015
PIH, n (%)	40 (27.8%)	32 (57.1%)	15.1	.000
GA (weeks): Mean ± SD	31.62±2.81	29.12±2.3	5.93	.000
Birth weight (kg): Mean ± SD	1.74±.387	1.21±.485	8.08	.000
Apgar at 1min: Mean ± SD	5.96±2.17	5.27±2.43	1.95	.052
Apgar at 5min: Mean ± SD	8.21±2.18	7.57±2.68	1.74	.083
Gender, n (%): Male Female	81 (56.2%) 63 (43.8%)	34 (60.7%) 22 (39.3%)	.329	.566
FiO2 - 1st hour of life: Mean ± SD	0.326±0.118	0.517±0.192	251	.000
FiO2 - 2nd hour of life: Mean ± SD	0.308±0.096	0.388±0.174	185	.000
FiO2 before surfactant: Mean ± SD	0.426±0.073	0.485±0.087	164	.000
Age at surfactant: Mean ± SD	1.46±1.05	1.72±1.13	89	.154
pH: Mean ± SD	7.307±0.034	7.293±0.031	2.68	.008
PaO2: Mean ± SD	92.09±5.24	87.15±6.38	5.62	.000
PaCO2: Mean ± SD	38.29±4.67	42.98±5.48	6.07	.000
HCO3: Mean ± SD	25.34±2.24	24.71±1.96	1.85	.066

CPAP Results and Clinical Outcome:

CPAP failure was associated with significantly highly increased mortality andair leak syndrome. Also there is significant increase in the risk of BPD & ventilator associated pneumonia in neonates with CPAP failure as shown in Table (2).

Table (2): Clinical outcomes among RDS group according to CPAP outcome.

	CPAP success (n=144)		CPAP failure (n=56)		χ^2	*p*
	N	%	N	%		
Death	1	0.69	33	58.9	19.4	.000
Retinopathy of Prematurity (ROP)	25	17.4	10	17.9	.136	.712
Air-leak syndrome	1	0.7	8	14.3	14.1	.000
Ventilator-associated pneumonia	2	1.3	46	82.1	.507	.024
BPD	0	0	19	28.5	3.54	.059

In the multivariate logistic regression analysis, birth weight (with OR1.930 & 95% CI 1.388 - 2.111) and FiO2 level, in the first and second hours of life (Wit OR 1.929 & 95% CI 1.098 - 2.376), (wit OR 1.320 & 95% CI 1.021 - 1.990) respectively, were the possible predictors of CPAP failure in preterm neonates wit RDS as shown in Table (3).

Table (3): Multivariate logistic regression analysis to determine the possible predictors of CPAP failure in RDS neonates.

	OR	S.E.	Sig.	95% CI
GA	1.215	.019	.273	.139 - 2.679
Male gender	3.725	.085	.456	.117 - 8.321
Birth weight	1.930	.070	.007*	1.388 - 2.111
Apgar at 1 min	.803	.034	.075	.310 - 1.050
Apgar at 5 min	.399	.034	.105	.020 - .160
FiO2 - 1st h of life	1.929	.066	.006*	1.098 - 2.376
FiO2 - 2nd h of life	1.320	.019	.001*	1.021 - 1.990

In ROC analysis, FiO2 - 1st hr. at cut off point >0.38 and FiO2 - 2nd hr. at cut off point >0.33 achieved significance for predicting CPAP failure with sensitivity of (72%, 87%) and specificity of (66.7%, 70.2%), with PPV (68%, 79%) and NPV (70%, 82%), respectively as shown in Fig. (1).

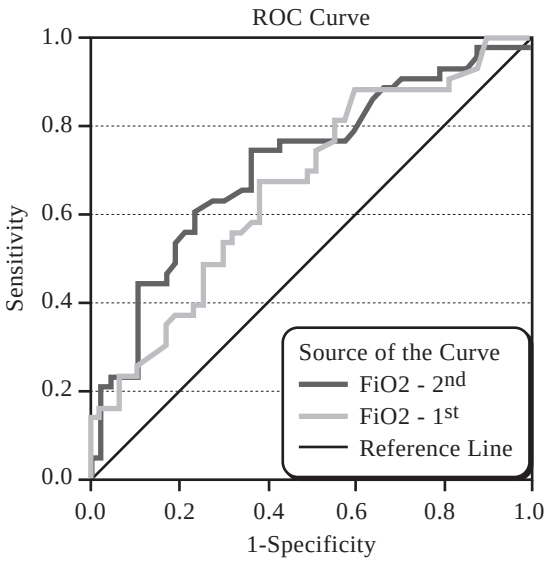

Fig. (1): ROC curve of fraction of FiO2 as a predictor of CPAP failure.

Discussion

Identification of CPAP failure predictors is crucial for selecting the appropriate strategy for respiratory support and constructing a properly justified surfactant therapy.

In this two center study, two-hundred neonates with gestational age 36 weeks or less who were treated with early nasal CPAP were prospectively followed. 72% of the studied group had CPAP success and 28% of them had failed CPAP.

The present study showed significant difference between CPAP success and failure rate regarding maternal age, parity, antenatal steroids and PIH. Our results are in keeping with Kakkilaya et al., **[12]** who reported lower percentage of mothers receiving antenatal steroids and higher percentage of mothers with pregnancy induced hypertension and Cesarean section in the group with failed CPAP than the group with CPAP success. Our study differs from Gulczyńska et al., **[13]** who reported no significant difference in the method of delivery, using antenatal steroids, or multiple pregnancy.

Statistically, ABG findings in our study, regarding pH, PaO2 and PaCO2,was significantly associated with CPAP failure rate which differs from **[12]** who reported non-significant difference regarding ABG findings on CPAP failure rate.

As expected, and similar to previous reports, this study demonstrated higher CPAP failure rates was associated with lower gestational age. The preterm neonates of gestational ages less than 36 weeks showed a CPAP failure rate of 28%. Our

results were supported by study of **[13]** as they revealed that neonates with gestational ages less than 30 weeks showed CPAP failure rate of 27.8%. Also, other studies by Rocha et al., **[14]** and De Jaegere et al., **[15]** showed failure rates of 20.6% -34% in neonates with gestational age less than 36 weeks. Fernandez-Gonzalez SM et al., **[16]** reported in their study a CPAP failure rate of 64% in preterm neonates of gestational age less than 28 weeks compared to a rate of 8.5% in neonates with gestational age above 28 weeks. In accordance, low gestational age seems to be the most critical risk factor of CPAP failure **[17,18]**.

This study showed statistically significant correlation between incidence rate of CPAP failure and birth weight. Birth weight among CPAP success group was 1.74±.387 while among CPAP failure group was 1.21±.485 with p value .000. The smaller the baby's birth weight, the success rate of using CPAP is also getting lower. This is in concordance with the findings of Permatahati et al., **[1]**, De Jaegere et al., **[15]** and Gulczyńska et al., **[13]** who reported that the smaller birth weight, the high risk to have CPAP failure.

The current work demonstrated that birth weight and FiO2 in the first 2 hours of life were the independent predictors of failed CPAP.In consistency with our findings, De Jaegere et al., **[15]** found that birth weight of ≤800g was associated with the highest risk of CPAP failure. A considerably higher value was described by Gulczyńska **[13]** (1,010g) who highlighted the impact of unequal experience from multiple centers of treatment. In addition, the diversity in perinatal care among the study centers may have an impact on the study findings.

These results were different from the study conducted by Darnifayanti et al., **[19]** that are gestational age and antenatal steroid administration were the risk factors affecting the CPAP success, with Chi-square test $p<0.05$. On the other hand, sex, birth weight, and mode of delivery did not influence the CPAP success (p-value >0.05).

Our study used CPAP level of 7cm H_2O at FiO2 of 0.3-0.5. Logistic regression analysis using the stepwise method was used in our study, to determine the multivariate potential factors predicting failure of CPAP those were birth weight (OR 1.320 & 95% CI 1.021 - 1.990) and FiO2 in the first and second hours of life (OR1.929 & 95% CI 1.098 - 2.376). In ROC curve analysis for FiO2 cutoff level that indicated CPAP failure showed that FiO2 - 1st hr. at cut off point > 0.38 and FiO2 - 2nd hr. at cut off point >0.33 achieved significance for predicting CPAP failure with sensitivity of (72%, 87%) and specificity of (66.7%, 70.2%), with PPV (68%, 79%) and NPV (70%, 82%), respectively.

Our result was similar to Gulczyńska et al., **[13]** who found a FiO2 cutoff value of 0.29 in the first 2 hours of life best recognized CPAP failure. De Jaegere et al., **[15]** reported an FiO2 cutoff value of 0.25 in the group of neonates with gestational ages between 25 and 28 weeks. In turn, Dargaville et al., **[18]** study used CPAP level of 8cm H_2O in the group of neonates born at 29-32 weeks GA reported an FiO2 cutoff value of about 0.3. Kakkilaya et al., **[12]** used CPAP level of 5-7 at FiO2 of 0.45-0.5 showed that a FiO2 >0.30 within two hours of life predicts CPAP failure in a group of neonates born <30 weeks.

Interestingly, as opposed to a threshold of 0.6 FiO2 at CPAP level of 8cm H_2O, Fuchs et al., **[2]** shown that targeting 0.35-0.45 FiO2 can reduce the time to intubation without noticeably raising the risk of unnecessary intubation. Even though the thresholds used varied between trials, this might account for the similar CPAP failure rates.

In our study, we found that the CPAP failure group had noticeably increased probabilities of preterm problems, such as high mortality, air leakage syndrome, and BPD that needed treatment. Our study's findings are consistent with those of **[13]** who also stated that, after risk adjustment, the ORs were significantly higher for severe morbidity, such as grade III/IV IVH, air leaks, and PDA requiring treatment. Our findings concur with those of other studies **[18-20]**, which also note a startling difference in the incidences of problems in newborns with CPAP failure.

The small sample size that limitedly represent the study's most immature neonates are limitations of our analysis. Furthermore, there are no comparable data on the clinical outcomes of newborns initiated on nasal CPAP.

Conclusion:

This study shows that the efficacy of nasal CPAP in preterm newborns permits its utilization as a primary respiratory support. The failure rate in infants <36 weeks GA was 28% with the ultimate prognostic factors being FiO2 - 1st hr. at cut off point >0.38 and FiO2 - 2nd hr. at cut off point >0.33 for predicting CPAP failure. This threshold requires further evaluation in multicenter study including larger cohort of neonates cared for in different settings. Such a threshold enables targeting early interventions to reduce the requirement of mechanical ventilation.

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التنبؤات المبكرة لفشل ضغط مجرى الهواء الإيجابى المستمر عند الأطفال الخدج المصابين بمتلازمة الضائقة التنفسية

الخلفية : يوجد العديد من العوامل التى تؤدى إلى فشل العلاج بضغط مجرى الهواء الإيجابى المستمر الانفى وكان من أهمها هو إعطاء الخدج الجزء الأقصى من الأكسجين الاستنشاقى فى الساعات الأولى من الحياة.

الهدف من الدراسة : تقييم العوامل النذرية التى تنبئ بفشل العلاج ضغط مجرى الهواء الإيجابى المستمر.

المرضى والأساليب : أجريت هذه الدراسة المقطعية المستعرضة من ديسمبر ٢٠٢٠ إلى أكتوبر ٢٠٢٢.

وشملت ٢٠٠ من عند الأطفال الخدج المصابين بمتلازمة الضاءقة التنفسية الذين تم حجزهم وحدة عناية الأطفال حديثى الولادة بمستشفى بنها الجامعى ومستشفى الأطفال التخصصى ببنها وتتراوح أعمارهم ٣٥ أسبوع أو أقل من الذكور والاناث جميع المرضى سوف تخضع للآتى أخذ تاريخ شامل : بما فى ذلك تاريخ الميلاد والجنس و عمر الحمل ونوع التغذية وطريقة الولادة وتاريخ حدوث أذى أثناء الولادة والحمى أثناء الولادة وتاريخ تمزق الأغشية قبل الوان وتاريخ أمراض الأمهات والمخدرات والتاريخ السابق لألشقاء المصابون بالضيق الوليدى، والأعراض التى توحى بضائقة التنفس، خمول، عدم انتظام دقات القلب، عدم انتظام دقات القلب. كما سيتك أخضاعهم لتحديد العمر الرحمى باستخدام مقياس بالرد

النتائج : أظهرت الدراسة فروق إحصائية بين المجموعات التى استجابت للعلاج بضغط مجرى الهواء الايجابى المستمر والتى فشل فيها العلاج به فى تر كيز الأكسجين المستنشق خلال السا عة الأولى والثانية بعد الولادة

الخلاصة : يعد تركيز الأكسجين المستنشق فالساعة الأولى والثانية بعد الولادة كعامل تنبؤى لفشل العالج بضغط مجرى الهواء الإيجابى المستمر عند الرضع المصابين بمتلازمة الضائقة التنفسية.