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Original Article

The Newborn Outcomes Following HFNCO in Term Parturients Undergoing Caesarean Section: A Prospective Randomized Study

Hatice Durmuş,[1] Mehmet Yılmaz,[2] Emine Yurt,[2] Ayse Zeynep Turan Cıvraz,[2] Ayten Saracoglu,[3] Bedirhan Günel,[2] Kemal Tolga Saracoglu[3]

[1]Department of Anesthesiology and Reanimation, Pursaklar State Hospital, Ankara, Türkiye
[2]Department of Anesthesiology and Reanimation, University of Health Sciences Kocaeli City Hospital, Kocaeli, Türkiye
[3]Department of Anesthesiology, University of Florida UF Health College of Medicine, Jacksonville, USA

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Correspondence: Bedirhan Günel, Department of Anesthesiology and Reanimation, University of Health Sciences Kocaeli City Hospital, Kocaeli, Türkiye
E-mail: bedirhangunel71@gmail.com

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ABSTRACT

Objective: High-flow nasal oxygenation (HFNO) is a well-established preoxygenation technique in non-pregnant patients. However, its efficacy in term parturients remains uncertain, with some studies reporting suboptimal results. Moreover, data on neonatal outcomes in this population are limited. To evaluate the effects of HFNO on neonatal outcomes in parturients undergoing cesarean section under general anesthesia, focusing on Apgar scores as the primary outcome and umbilical cord venous blood gas parameters as the secondary outcome.

Methods: Following Ethics Committee approval and clinical trial registration (NCT03903003), 102 term parturients were randomized into two groups: HFNO (n=50) and conventional face mask preoxygenation (n=52). The HFNO group received oxygen at 60 L/min, while the conventional group received 100% oxygen at 10 L/min. Induction was initiated once end-tidal oxygen (etO_2) reached 90%, and oxygenation continued during intubation. Neonatal Apgar scores at 1 and 5 minutes, umbilical cord venous blood gas values, and maternal hemodynamic parameters were recorded.

Results: The HFNO group showed significantly higher Apgar scores at both 1 minute (9 (3-10) vs. 8 (3-10); p<0.001) and 5 minutes (10 (7-10) vs. 10 (4-10); p<0.001) compared to the conventional group. Cord venous blood gas parameters were comparable between the groups.

Conclusion: HFNO use for preoxygenation before and during induction in parturients undergoing cesarean section improved neonatal Apgar scores compared to conventional face mask oxygenation. These findings support HFNO as a safe and effective preoxygenation method in obstetric anesthesia.

INTRODUCTION

Pregnancy is characterized by respiratory and cardiovascular system changes. Functional residual capacity is decreased, and minute ventilation is increased in pregnant women. On the other hand, oxygen consumption is increased.[1] Therefore, airway management can become complicated.[2] The incidence of hypoxemia occurring during general anesthesia in pregnant women is common and can lead to serious fatal outcomes in both maternal and fetal terms. In a prospective multicenter study, preoxygenation was performed by giving oxygen with a flow of at least 12 L/min, and although induction was started after at least 90% FeO2 was reached, hypoxia during tracheal intubation was reported in 19% of the patients.[3] Besides, severe hypoxia was reported in 9.4% of the patients. In another study on parturients, it was reported that the incidence of severe hypoxia resulting in SpO_2 below 85% in induction was 2%.[4] Re-oxygenation after hypoxia brings the risk of aspiration pneumonia. The failure rate of preoxygenation with conventional methods has been reported as 30% in the non-pregnant population, and similarly 29% in the pregnant population.[5,6] The technique of applying preoxygenation with conventional methods in pregnant women is also controversial. It has been argued that four vital capacity breaths are effective.[7] On the other hand, it has been re-

ported that this is ineffective and requires eight vital capacity breaths.[8] The effectiveness of High-Flow Nasal Oxygenation (HFNO) for pre-oxygenation has been proven in non-parturient patients.[9] Its use is recommended during preoxygenation in the DAS difficult airway management guideline.[10] However, HFNO outcome in pregnant women are also controversial. In a study conducted in term parturients, a worse outcome was reported.[11] In another study, it was concluded that preoxygenation with HFNO is inadequate in term pregnant women and further studies are needed.[12] Au et al.[6] reported that the time period required for effective preoxygenation in parturients could not be determined. Our primary outcome measurement was the 1st and 5th min. Apgar scores in the newborn. Secondary outcome measurement was the intergroup comparison of cord blood gas analysis.

MATERIALS AND METHODS

This study protocol was reviewed and approved by Kocaeli University Clinical Research Ethics Committee (No: 2018/506, Date: 27/11/2018) Written informed consent was obtained from all participants prior to study enrollment. The study was conducted in accordance with the Declaration of Helsinki. This clinical trial was registered before patient enrollment.

This research is a prospective randomized study. Following the University Ethics Committee approval, the study was registered at clinical trials.gov (NCT03903003). The study was carried out on 106 term parturients undergoing elective caesarean section between January 1, 2019 and December 31, 2019. All patients provided written informed consent prior to enrollment, and the study was conducted in accordance with the principles of the Declaration of Helsinki. Inclusion criteria were the age between 18 and 40 years old, no known respiratory disorder, patients who refuse neuraxial block and are scheduled for elective surgery, American Society of Anesthesiologists risk score 2 and a gestational age between 37 and 41 weeks. Patients were randomized into two groups: Group 1 (HFNO, n=50) and group 2 (conventional, n= 52). Randomization was performed using Random Integer Generator software (https: www.random.org). While patients and anesthesiologists administering anesthesia were not blinded due to the nature of the intervention, the anesthesiologist responsible for evaluating the 1- and 5-minute Apgar scores and performing umbilical cord venous blood gas analysis remained blinded to group allocation to minimize assessment bias. Premedication was not administered. Patients' heads were elevated by 25° in the supine position. Preoxygenation was performed until the end-tidal oxygen (etO_2) level reached 90% in both groups. In Group 1 (HFNO), preoxygenation was initiated with the patients' mouths closed, using a fraction of inspired oxygen (FiO_2) of 1.0, a humidifier temperature of 37°C, and a flow rate of 20 L/min. The flow rate was gradually increased up to 60 L/min based on patient tolerance.

In Group 2 (conventional face mask), preoxygenation was performed with a tight-fitting oxygen face mask delivering 100% FiO_2 at a flow rate of 10 L/min, allowing spontaneous tidal volume breathing. Oxygenation continued until etO_2 reached 90% in both groups.

General anesthesia induction was performed with iv propofol 2.5 mg/kg, 1 mcg/kg fentanyl, 1,2 mg/kg rocuronium. Modified rapid sequence induction was performed.[13] Train of Four (TOF Watch) monitoring was performed at 1 Hz intervals, followed by tracheal intubation. Tracheal tube no. 6.5 or 7 mm were used by direct laryngoscopy. The time elapsed from the start of holding the laryngoscope until the end-tidal CO2 trace observation was recorded as the tracheal intubation duration. The patients were ventilated with a tidal volume of 6-8 mL/kg, a respiratory rate of 12/min, 6 cmH_2O PEEP and inspiration: Expiration ratio of 2. Maintenance was performed with sevoflurane 2% in a 50% mixture of oxygen and air. The demographic data and hemodynamic parameters were measured. Systolic blood pressure, diastolic blood pressure, heart rate, peripheral oxygen saturation values were recorded in preoxygenation phase, in preoperative period before induction and during the intraoperative period. Desaturation was defined as <95% according to the World Health Organization definition.[14] The 1- and 5-minute Apgar scores of the newborn were recorded. Umbilical cord venous blood gas analysis was recorded as pH, $PaCO_2$, PaO_2, HCO_3, lactate, base deficit and anion gap values.

Statistical Analysis

Mean, standard deviation, median, minimum, maximum, frequency and percentage values were used in the descriptive statistics of the data. The normality assumption of the continuous numerical variables was checked separately in the groups through Kolmogorov–Smirnov test. Independent sample t-test was used for the variables that were normally distributed while Mann-Whitney-U test was used for those that were not. Statistical analyses were performed using IBM SPSS Statistics 25.0 (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) package program. The significance level was determined as <0.05 for all analyses.

Sample size calculation

Power analysis of the study was performed through G Power 3.1.9.2 package program. In a confidence interval of 95%, the standard effect size of the study, which was conducted with 102 patients, was found to be 0.50 (effect size, medium level), the degree of freedom to be 1, and the power of the study to be 0.80.

RESULTS

A total of 5 patients were excluded from the study. One patient had a BMI>35, two patients had history of diabetes mellitus type 2 and two patients refused to participate. In total, data from 102 patients were analyzed.

The demographic data of groups were similar (p>0.05). The gestational age values of the groups were not found similar (p=0.001, Table 1). The tracheal intubation duration and newborn weights of the groups were found to be statistically similar (p=0.575 and p=0.397, respectively). Both 1st and 5th min Apgar scores were found significantly higher in HFNO group (p<0.001; p=0.001, respectively, Table 2). In cord venous blood gas analysis comparison, pH, PaO_2, $PaCO_2$, lactate and base deficit values were found statistically similar (Table 3).

Desaturation was not observed in any patients during laryngoscopy. The basal SPO_2 values and the SPO_2 values at the end of preoxygenation period were similar in both groups. The basal heart rates of parturients were statistically similar. The heart rates and maternal systolic blood pressure values of groups were similar before and after preoxygenation period. Before and after preoxygenation maternal diastolic blood pressure was found significantly higher in the HFNO group (Table 4).

DISCUSSION

In this prospective randomized study, we compared the effectiveness of preoxygenation through HFNO with conventional oxygen face mask in patients undergoing elective caesarean section. Maternal hemodynamic variables and cord blood venous gas analysis did not change, however both 1st and 5th min Apgar scores were found to be significantly higher in high-flow oxygenation group.

Extending the apneic period with high-flow oxygenation is successfully applied in pregnant women.[15] To the best of our knowledge, this study is the first to investigate the effects of high-flow oxygenation on fetus. Both high-flow oxygenation prevented the development of maternal desaturation, and provided better outcome in newborns. Siriussawakul et al.[16] administered oxygen to parturients using a nasal cannula with 3 L/min flow, and umbilical cord venous blood gases and Apgar scores in newborns did not show a significant difference when compared to pregnant women breathing room air. However, this study was performed in

Table 1. Demographic data of groups

	HFNO Group (n:50)	Conventional Group (n:52)	p*-value
Age (year)	29.50 (18-40)	30 (20-43)	0.976[m]
BMI (kg/m^2)	30 (25-33)	31 (26-38)	0.146[m]
Gestational age (week)	39 (28-40)	38 (38-40)	**0.001**[m*]

BMI: Body Mass Index. Data are presented as median (minimum–maximum). [m]: Mann-Whitney U test *p<0.05 was considered statistically significant.

Table 2. Comparison of newborn related data between groups

	HFNO Group (n:50)	Conventional Group (n:52)	p*-value
Tracheal Intubation duration (min)	1 (1-1.5)	1 (1-2)	0.575[m]
1-minute Apgar score	9 (3-10)	8 (3-10)	<0.001[m*]
5-minute Apgar score	10 (7-10)	10 (4-10)	0.001[m*]
Weight (kg)	3 (2.7-3.5)	3 (2.8-3.5)	0.397[m]

Data are presented as median (minimum–maximum). m: Mann-Whitney U test. *p<0.05 was considered statistically significant.

Table 3. The comparison of umbilical cord venous blood gas analysis

	HFNO Group (n:50)	Conventional Group (n:52)	p-value
pH	7.32 (7.27-7.37)	7.33 (7.27-7.37)	0.661[m]
PO_2 (mmHg)	34 (16-67)	29 (16-49)	0.078[m]
PCO_2 (mmHg)	46.22±5.30	47.25±4.79	0.308[t]
Lactate	1.49 (0.80-2.90)	1.50 (1.10-2.32)	0.114[m]
BE	-1 (-8-2)	-1 (-4-2)	0.642[m]

Data are presented as mean±standard deviation and median (minimum–maximum). m Mann-Whitney U test, tStudent's t-test.

Table 4. Comparison of maternal vital signs between groups

	HFNO Group (n:50)	Conventional Group (n:52)	p*-value
SpO_2 (%)			
Before Preoxygenation	99 (97-100)	99 (97-100)	0.751[m]
After Preoxygenation	100 (100-100)	100 (100-100)	1.000[m]
Heart rate (beat/min)			
Before Preoxygenation	85 (75-95)	84.50 (70-95)	0.345[m]
After Preoxygenation	98 (67-109)	97 (84-106)	0.051[m]
Systolic blood pressure (mmHg)			
Before Preoxygenation	124 (110-132)	120 (106-134)	0.345[m]
After Preoxygenation	126 (118-131)	124 (115-131)	0.134[m]
Diastolic blood pressure (mmHg)			
Before Preoxygenation	76.50 (70-85)	72.50 (70-85)	<0.001[m*]
After Preoxygenation	80 (75-85)	78 (75-83)	0.045[m*]

Data are presented as median (minimum–maximum). m Mann-Whitney U test. *p<0.05 was considered statistically significant.

spontaneously ventilating patients under spinal anesthesia. Therefore, the respiratory pattern of all patients could not be standardized. In our study, high-flow oxygen was given to patients undergoing general anesthesia and the mechanical ventilator parameters were standardized. As a result, blood gas parameters did not change, but Apgar scores improved. Although its results have been controversial in recent years, the effects of high-flow oxygenation in pregnant women have begun to be investigated frequently. In a study comparing the efficacy of preoxygenation methods performed with HFNO and conventional face masks on obstetric patients, the authors concluded that preoxygenation with HFNO delivered worse performance than that with face masks in maintaining etO_2 concentration above 90%.[17] The researchers declared that this could be because of the problem experienced by the patients in the HFNO group in keeping their mouths closed and the dilutional effect of the air intake. Opening the mouth while applying high-flow oxygenation reduces the effectiveness of the method as the amount of leakage increases. Pillai et al.[17] compared the effectivity of high-flow in patients with open and closed mouths. The authors stated that high-flow oxygenation was worse with open mouths than closed ones during the first 3 min of preoxygenation. The effectivity of closed-mouth high-flow oxygenation was found equivalent to conventional technique. In our study, reaching the end tidal oxygen concentration to 90% was our main goal during preoxygenation. However, a period exceeding 3 min was not observed in any of the patients. In order to ensure this, all patients were informed before obtaining their written consent preoperatively. A dedicated researcher was assigned to observe and keep their mouths closed during preoxygenation.

Conducted on healthy volunteers, a study compared preoxygenation applications with HFNO and conventional oxygen face masks. It was stated that the end-tidal O_2 concentration in the HFNO group was lower than that in the face mask group. They concluded that preoxygenation with HFNO was not a reliable method. However, in this study, it is noteworthy that the etO_2 value in the HFNO group showed a great deal of individual variation when compared to the face mask group.[18] Patient results may vary depending on body mass index, age, gender or diseases such as preeclampsia or eclampsia.

The Apgar score is a scoring method used worldwide to assess the condition of the newborn and their response to resuscitative interventions. Several factors may affect the Apgar score, including gestational age, maternal diabetes, BMI, smoking, medications, trauma, infection, hypovolemia, hypoxemia and low birth weight. In our study these parameters were found to be statistically similar. The lower limit value for a low Apgar score was determined as '<7'.[19,20] Umbilical cord blood gas analysis is an objective method that shows the oxygenation and metabolic status of the newborn at birth.[21,22] In our study, a similarity was observed between groups in terms of pH, pCO_2 and base deficit values. In addition, although there was no statistically significant difference, the pO_2 value was higher, lactate level was lower in the HFNO group. We are in the opinion that these better results might have been the reason for higher Apgar scores in this study. Obviously further studies with larger number of patients are needed on this subject.

As the hemodynamic variables were comparable, we concluded that preoxygenation with HFNO is a method that can easily be tolerated by patients.

Limitations

The major limitation of our study is that the amount of reactive oxygen species in umbilical cord or maternal blood samples has not been compared. Supplemental oxygen supplementation is known to increase these species. Therefore, there is a need for future research on this subject. The other limitation is the single-centered nature of our study. Prospective multicenter studies with more patients are needed.

Conclusion

In conclusion, preoxygenation with HFNO before general anesthesia induction in obstetric patients has positive effects on the newborn's 1st and 5th min Apgar scores. Although further studies are needed, we are in the opinion that the HFNO preoxygenation method should be more preferable compared to the preoxygenation method with conventional oxygen face mask technique in term parturients.

Ethics Committee Approval

The study was approved by the Kocaeli University Clinical Research Hospital Ethics Committee (Date: 27.11.2018, Decision No: 2018/506).

Informed Consent

Written informed consent was obtained from all participants. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Peer-review

Externally peer-reviewed.

Authorship Contributions

Concept: H.D. M.Y., E.O.Y.; Design: H.D. M.Y., E.O.Y., A.Z.T.C.; Supervision: K.T.S.; Data collection &/or processing: H.D., A.Z.T.C.; Analysis and/or interpretation: B.G., H.D., M.Y.; Literature search: B.G., H.D., K.T.S., A.S.; Writing: H.D. M.Y., E.O.Y., A.Z.T.C., K.T.S.; Critical review: M.Y., K.T.S., A.S.

Conflict of Interest

None declared.

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Sezaryenle Doğum Yapan Term Gebelerde Yüksek Akım Nazal Kanül Oksijen Uygulamasının Yenidoğan Sonuçlarına Etkisi: Prospektif Randomize Bir Çalışma

Amaç: Yüksek akım nazal oksijenasyon (YANO), gebe olmayan hastalarda iyi bilinen bir preoksijenasyon tekniğidir. Ancak, term gebelerdeki etkinliği belirsizliğini korumakta olup bazı çalışmalar yetersiz sonuçlar bildirmiştir. Ayrıca, bu hasta grubunda yenidoğan sonuçlarına ilişkin veriler sınırlıdır. Bu çalışma, genel anestezi altında sezaryen uygulanacak gebelerde YANO'nun yenidoğan sonuçlarına etkisini değerlendirmeyi amaçlamaktadır. Birincil sonuç olarak Apgar skorları, ikincil sonuç olarak ise umbilikal venöz kan gazı parametreleri incelenmiştir.

Gereç ve Yöntem: Etik Kurul onayı ve klinik çalışma kaydı (NCT03903003) sonrasında 102 term gebe rastgele iki gruba ayrıldı: YANO grubu (n=50) ve konvansiyonel yüz maskesi ile preoksijenasyon grubu (n=52). YANO grubuna 60 L/dk hızında oksijen, konvansiyonel gruba ise %100 oksijen 10 L/dk hızında uygulandı. End-tidal oksijen (etO_2) düzeyi %90'a ulaştığında indüksiyon başlatıldı ve entübasyon sırasında oksijenasyon sürdürüldü. Yenidoğanların 1. ve 5. dakikadaki Apgar skorları, umbilikal venöz kan gazı değerleri ve maternal hemodinamik parametreler kaydedildi.

Bulgular: YANO grubunda Apgar skorları hem 1. dakikada (9 (3-10) vs. 8 (3-10); $p<0.001$) hem de 5. dakikada (10 (7-10) vs. 10 (4-10); $p<0.001$) anlamlı olarak daha yüksekti. Kordon venöz kan gazı parametreleri gruplar arasında benzerdi.

Sonuç: Sezaryen uygulanacak gebelerde preoksijenasyon amacıyla YANO'nun indüksiyon öncesi ve sırasında kullanımı, konvansiyonel yüz maskesi oksijenasyonuna kıyasla yenidoğan Apgar skorlarını iyileştirmiştir. Bu bulgular, obstetrik anestezide YANO'nun güvenli ve etkili bir preoksijenasyon yöntemi olduğunu desteklemektedir.

Anahtar Sözcükler: Apgar skoru; sezaryen; preoksijenasyon; yüksek akım nazal oksijenasyon.