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CASE SERIES

Diagnosis of respiratory sleep disorders in newborns with suspected apneas: comparison between nocturnal saturometry and polygraphy

Diagnóstico de los trastornos respiratorios del sueño en recién nacidos con sospecha de apneas: comparación entre la saturometría nocturna y la poligrafía

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Abstract

Introduction: Night Continuous Saturometry (CSO_2) is used in Neonatal Units to detect events of hypoxemia in Newborns (NB) with apnea episodes. Polygraphy (PG) has a larger number of measuring channels. Our goal was to evaluate the diagnostic performance of CSO_2 compared to Polygraphy in NB with suspected sleep apneas. **Patients and Method:** Results of CSO_2 and PG performed simultaneously in RN with suspected apneas were retrospectively analyzed over a three-year period. A 2-channel Masimo Radical-7® pulse oximeter and an Apnea Link Plus® polygraph with 5 simultaneous recording channels were used. Altered PG was defined as: desaturation index under 80% per hour ≥ 1 and/or number of desaturations under 80% ≥ 20 seconds greater than one in the whole validated registry and/or hypoapnea apnea index ≥ 1 event per hour. In parallel, altered SpO_2C was defined when one or both of the 80% saturation criteria were altered. Sensitivity, specificity, predictive values and Likelihood Ratio (LLR) for CSO_2 were calculated. Results were expressed in absolute value, with 95% confidence interval. **Results**: Simultaneous 40 CSO_2 and PG were performed; 80% (32/40) of them were preterm infants, 60% (24/40) males. 38% (15/40) of the CSO_2 and 15% (6/40) of the PGs were altered ($p < 0.05$). CSO_2 has a 100% Sensitivity, 74% Specificity, 40% VPP, 100% VPN, LLR + 3.78 and LLR-0. **Conclusion**: In the studied NB, CSO_2 has a high diagnostic value, however, it may present false positives; It is suggested to use as a screening method and to perform diagnostic confirmation with another sleep test, such as PG.

Keywords:
Continuous nocturnal saturometry,
polygraphy,
newborns,
apneas

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Introduction

Sleep medicine has significantly advanced over recent decades, including, more recently, pediatric patients whom sleep studies allow the determination of relevant therapeutic behaviors[1-3].

Polysomnography (PSG) is the gold standard for studying sleep, however, it requires to be performed in a sleep laboratory and it is less accessible in our environment. There are simplified alternatives such as Polygraphy (PG) that allows assessing cardiorespiratory parameters: oxygenation, heart rate and presence of obstructive sleep apnea or central sleep apnea[4-6].

Recent studies suggest that the evaluation of children under 3 months of age using PG would provide useful clinical information. Brockmann et al. proposed baseline values for apneas, desaturation index under 80% and periodic breathing; suggesting to consider this test for the evaluation of these patients[1,7].

Continuous Overnight Pulse Oximetry (SpO_2) has been widely used in neonatal units. It has 2 recording channels, one for oxygen saturation and another one for heart rate; nevertheless, polygraphy has 3 additional sensors, such as nasal flow (nasal pressure transducer), microphone and thoracic movement sensor (chest strap). Having a flow sensor allows to define the presence of apneas, and chest straps allow to classify them as obstructive or central, thus facilitating a more accurate diagnosis of sleep disordered breathing (SDB) in this age group, with less possibility of error[8-11].

The diagnostic performance of overnight SpO_2, considering PG as a reference standard, has not been studied in neonatal patients. For this reason, the aim of this study was to evaluate the diagnostic performance of SpO_2 in newborns (NB) with suspected apneas.

Patients and Method

Design

This study corresponds to a diagnostic test study, where PG was considered as reference standard and SpO_2 as a test to be validated.

Sample

Preterm and term NB patients were considered (up to 3 weeks of corrected age) with suspected apnea, hospitalized in the Neonatology Service of Dr. Guillermo Grant Benavente Hospital of Concepción between June 2013 and June 2016. Patients had to have records of PG and SpO_2 made simultaneously. Exams whose validated record was less than 4 hours, NB with major malformations, neuromuscular diseases and/or heart disease were all excluded.

Variables

Demographic data, morbid and clinical background were registered as well as PG and SpO_2 results. To evaluate the SpO_2, a Masimo Radical-7® pulse oximeter was used, with 2 recording channels: oxygen saturation and heart rate. For its part, to perform the PG it was used a polygraph ApneaLink™ Plus (Resmed) with 5 simultaneous recording channels: nasal flow (nasal pressure transducer), oxygen saturation, heart rate, microphone and chest strap. Trained technicians accompanied the NB during the examination and recorded the following variables on an event recording sheet: beginning and end of sleep, awakening, feeding, controls, vomiting, cough, crying, and sensors loss (Appendix 1). Both tests were analyzed by a trained physician, following the recommendations of the American Academy of Sleep Medicine (AASM) and adaptations suggested by Brockmann et al.[4,7,14,15].

The polygraphic parameters that were recorded were: apnea/hypopnea index (AHI), central apneas index (CAI), obstructive apneas index (OAI), average and minimum saturation; besides the desaturations index ≤ 80% per hour. It was considered altered PG those that had a desaturations index (DI) under 80% per hour higher than or equal to 1 and/or number of desaturations under 80% higher than or equal to 20 seconds, higher than 1 and/or AHI higher than 1 event per hour.

On the other hand, in SpO_2 were recorded the average and minimum saturation, and desaturations index ≤ 80% per hour. SpO_2 was considered altered when it presented suggestive data of intermittent hypoxemia; desaturations index (DI) under 80% per hour higher than or equal to 1 and/or number of desaturations under 80% higher than or equal to 20 seconds, higher than 1.

The criteria of acceptability for PG and SpO_2 were considered at least 4 hours of recording, and less than 20% of the recording time occupied by disconnections and/or artifacts.

Ethical considerations

Each parent signed an informed consent for the test. The study was approved by the institutional Ethics Scientific Committee. **Statistical analysis.** It was used SPSS 20 ® software. Descriptive statistics were performed with average calculation and standard deviation for quantitative variables and percentages for qualitative variables. The correlation between the pulse oximetry results of both tests was calculated by calculating the Pearson correlation index (r). Once the correlation between these variables was determined, for paired samples it was used T-Student test to compare the parametric variables and for non-parametric variables, it was used McNemar test; both to verify the existence of significant differences between the SpO_2 and PG variables.

Moreover, diagnostic performance was also determined by calculating the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the diagnostic test. Finally, it was calculated the positive likelihood ratio (LR+). For all analyses, a $p \leq 0.05$ value was considered.

Results

Forty NB were included in the study, with an average corrected gestational age of 38±5 weeks at the time of examination; 64% of them were male (n = 24). Table 1 shows the biodemographic characteristics of the sample. Of the total number of tests performed, 38% (n = 15) of SpO_2 were altered in contrast to 15% (n = 6) of the PG ($p < 0.05$). Patients with polygraphy alterations presented concomitantly SpO_2 alterations. In addition, a positive correlation was observed between the saturation parameters measured through PG and SpO_2 (Table 2).

Within the group of subjects with altered tests, it was observed that of the preterm NB (80%, n = 32) a 35% of the total NB (n = 14) were found to have altered SpO_2 and 15% (n = 6) had altered PG.

Additionally, when comparing the suggestive criteria of intermittent hypoxemia between both tests, it was observed that in SpO_2, 27.5% (n = 11) had a desaturation index lower than 80% higher than 1 and 32.5% (n = 13) had at least a desaturation index lower than 80% for more than 20 seconds. Regarding to PG, only 7.5% (n = 3) had a desaturation index lower than 80% higher than 1 and only 5% (n = 2) had at least a desaturation lower than 80% for more than 20 seconds (Table 3).

In relation to the evaluation of the diagnostic performance of SpO_2, the results revealed a sensitivity and specificity of 100% and 74% respectively. For its part, the positive predictive value was 40% and the negative predictive value was 100%. Additionally, a positive likelihood ratio of 3.78 was obtained.

Discussion

This study was developed in order to evaluate the diagnostic performance of overnight pulse oximetry considering PG as reference standard. The main fin-

Table 1. General characteristics of NB considered in study

Variables	Total Sample (n = 40)
Male gender (%)	60 (n = 24)
Corrected Gestational Age (weeks) X±SD	38.4 ± 3.2
Premature (%)	80 (n = 32)
Birth Weight (g) X±SD	2157 ± 938
Birth Weight < 1500 gr (%)	37.5 (n = 15)

Table 2. Correlation between PG y SpO_2

Variables	Pearson Correlation Coefficient
Average saturation (%)	0.516**
Minimal saturation (%)	0.742**
DI less than 80%	0.649**
DI less than 80% and by more than 20 seconds	0.732**

Valor p: < 0,01 (**) DI: Desaturation index (event/hour)

Table 3. Comparison of polygraph and SpO_2 results

Variables	Polygraphs	SpO_2C	p value
Total validated exams	40	40	-
Total validated time (hrs)	7,7 ± 1,6	7,1 ± 2,2	0,14
Altered	6	15	0,007 *
Average saturation (%)	96,5 ± 2,0	96,8 ± 1,5	0,277
Minimal saturation (%)	78,9 ± 11,7	73,5 ± 14,3	0,066
ID less than 80%	0,35 ± 1,0	1,37 ± 2,8	0,031 *
ID less than 80% and by more than 20 seconds	0,05 ± 0,23	1,2 ± 2,7	0,008 *
AHI	0,96 ± 2,0	-	-

Valor p <0,05 (*). ID: Índice de Desaturación (evento/hora). AHI: Apnea Hypopnea Index (event/hour). Results are expressed as mean ± standard desviation.

dings revealed that SpO_2 has a sensitivity and specificity of 100% and 74% respectively; 100% PPV and 40% NPV.

The study sample was made of hospitalized and monitored patients in the Neonatology Service of our hospital with suspected apnea, for this reason, PG was considered the reference standard. In this regard, PG has shown a high sensitivity and specificity for the diagnosis of SDB compared to PSG in pediatric patients[9]. In this context, cut-off points were established according to recently published references[4,7,8]; establishing similar alteration criteria for both SpO_2 and PG, in which, additionally, the apnea/hypopnea index is considered a variable of interest[1,3].

For the performance of the SpO_2, we use digital signal extraction technology, of average reading every 2 seconds, because it allows improving the precision of results, it has a smaller alteration in situations of bad perfusion, noise, and movement. It has also shown to decrease the percentage of false alarms, unperceived phenomena, and artifacts[12-18].

The correlation analysis indicated that the saturation parameters show moderate to strong association between SpO_2 and PG. These results suggest the existence of an adequate validity of concurrent criteria between both measurements. However, the studied sample showed a higher proportion of altered SpO_2 compared to PG. The pulse oximetry parameter that showed the highest difference was desaturation of more than 80% for more than 20 seconds; probably due to the fact that PG presents a higher precision since it has more evaluation channels that allow us to discriminate against the presence of artifacts or events that could potentially alter the test.

SpO_2 detects all NB with altered PG (true positive), but also detects others that do not actually have the polygraphy alteration condition (false positives); significantly altering the magnitude of the positive predictive value. This result presents relevant clinical implications since according to our data, the probability that a patient actually presents an SDB when presenting an altered SpO_2 oscillates around 40%.

Finally, it is possible to conclude that in NB with suspected apneas considered in our study, SpO_2 showed a high sensitivity and specificity, despite a low positive predictive value. Accordingly, it is suggested to use it as a screening method. An altered SpO_2 must be complemented with a PG to confirm the diagnosis.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local

Rights to privacy and informed consent: The authors state that the information has been obtained anonymously from previous data, therefore, Research Ethics Committee, in its discretion, has exempted from obtaining an informed consent, which is recorded in the respective form

Financial Disclosure

Authors state that no economic support has been associated with the present study.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

Annexed 1. Ad hoc document for registration of events by parents or technicians

OVERNIGHT PULSE OXIMETRY/ POLYGRAPHY

I.- DATOS PERSONALES

Last Name		Mother's last name				Name	
Birth date		Age		Date		RUT	
Tutor						File	

II.- DIAGNOSES

1	
2	
3	

III.- OXYGEN THERAPY

Equipment		Start date				Hours use	
Indicated flow		Maneged flow					

IV.- OVERNIGHT PULSE OXIMETRY

Initial sat		Starting time	
Initial RR		Sleep time	
Initial HR		Wake up time	

EVENTS

SLEEP	
Start	Finish

FEEDING	
Start	Finish

DIAPER AND/OR/O SIGNOS VITALES CONTROL	
Start	Finish

MEDICINES	
Start	Finish

SENSOR OUTPUT	
Start	Finish

OTHER EVENTS		
Vomiting, cough, crying, etc	Start	Finish

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