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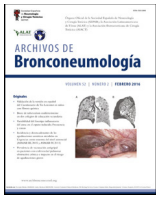

Original article

Non-anesthesiologist-administered Propofol is not Related to an Increase in Transcutaneous CO_2 Pressure During Flexible Bronchoscopy Compared to Guideline-based Sedation: A Randomized Controlled Trial

Roberto Mercado-Longoría, Carolina Armeaga-Azoños, Jasel Tapia-Orozco, Julio E. González-Aguirre*

Pulmonary and Critical Care Medicine Department, "Dr. José E. González" University Hospital, Nuevo León Autonomous University, Monterrey, N.L., Mexico

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ABSTRACT

Introduction: Evidence for the use of non-anesthesiologist-administered propofol for sedation during flexible bronchoscopy is scarce. The main objective of this study was to determine whether non-anesthesiologist-administered propofol balanced sedation was related to higher transcutaneous CO_2 pressure compared with current guideline-based sedation (combination midazolam and opioid). Secondary outcomes were post-procedural recuperation time, patient satisfaction and frequency of adverse events.
Methods: In this randomized controlled trial we included data from outpatients aged 18 years or older with an indication for flexible bronchoscopy in a university hospital in northern Mexico.
Results: Ninety-one patients were included: 42 in the midazolam group and 49 in the propofol group. During 60 min of transcutaneous capnometry monitoring, mean transcutaneous CO_2 pressure values did not differ significantly between groups (43.6 [7.5] vs. 45.6 [9.6] mmHg, $P = .281$). Propofol was related with a high Aldrete score at 5, 10, and 15 min after flexible bronchoscopy (9 [IQR 6-10] vs. 10 [9,10], $P = .006$; 9 [8–10] vs. 10 [IQR 10–10], $P < .001$ and 10 [IQR 9–10] vs. 10 [10], respectively) and with high patient satisfaction on a visual analogue scale of 1 (not satisfied) to 10 (very satisfied) (8.41 [1.25] vs. 8.97 [0.98], $P = .03$). Frequency of adverse events was similar among groups (30.9% vs. 22.4%, $P = .47$).
Conclusion: Compared with guideline-recommended sedation, non-anesthesiologist-administered propofol balanced sedation is not associated with higher transcutaneous CO_2 pressure or with more frequent adverse effects. Propofol use is associated with faster sedation recovery and with high patient satisfaction.
Clinical trial Registration: NCT02820051.

La administración de propofol por parte de no anestesiólogos durante la broncoscopia flexible no se relaciona con aumentos de la presión transcutánea de CO_2, en comparación con la sedación según las pautas: ensayo controlado aleatorizado

Palabras clave:
Broncoscopia
Sedación consciente
Hipoventilación
Midazolam
Bienestar del paciente
Propofol

RESUMEN

Introducción: Las pruebas disponibles del uso de propofol administrado por no anestesiólogos para la sedación durante la broncoscopia flexible son escasas. El objetivo principal del estudio fue determinar si la sedación equilibrada con propofol administrado por no anestesiólogos estaba relacionada con valores más altos de presión de CO_2 transcutánea, en comparación con la sedación según las pautas (una combinación de midazolam y un opiáceo). Las variables secundarias fueron el tiempo de recuperación después del procedimiento, el grado de satisfacción del paciente y la frecuencia de observación de efectos adversos.

* Corresponding author.
E-mail address: jeglza111@gmail.com (J.E. González-Aguirre).

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Métodos: En este ensayo controlado y aleatorizado se incluyeron datos de pacientes ambulatorios mayores de 18 años con indicación de broncoscopia flexible en un hospital universitario del norte de México.
Resultados: Se incluyeron 91 pacientes: 42 en el grupo de midazolam y 49 en el grupo de propofol. Durante los 60 min de monitorización de la capnometría transcutánea, no hubo diferencias estadísticamente significativas entre grupos en los valores medios de presión de CO_2 transcutánea (43,6 [5,7] vs. 45,6 [6,9] mm Hg, p = 0,281). El propofol se asoció con puntuaciones de Aldrete altas a los 5, 10 y 15 min después de la broncoscopia flexible (9 [IQR: 6-10] vs. 10 [9,10], p = 0,006; 9 [8-10] vs. 10 [IQR 10-10], p < 0,001 y 10 [IQR 9-10] vs. 10 [10] puntos, respectivamente) y con un alto grado de satisfacción de los pacientes en una escala visual de 1 (poco satisfecho) a 10 (muy satisfecho) (8,41 [1,25] vs. 8,97 [0,98], p = 0,03). No hubo diferencias en la frecuencia de efectos adversos (30,9 vs. 22,4%, p = 0,47).
Conclusión: En comparación con la pauta de sedación recomendada, la sedación equilibrada con propofol administrado por no anestesiólogos no se asocia con valores más altos de presión de CO_2 transcutánea ni con mayor frecuencia de efectos adversos. El uso del propofol se asocia con una recuperación de la sedación más rápida y con un mayor grado de satisfacción del paciente.
Número de registro del ensayo clínico: NCT02820051.

Introduction

Flexible bronchoscopy (FB) is a fundamental procedure in respiratory medicine. Although FB can be performed safely without sedation, 80% of patients prefer sedation during the procedure.[1] Currently, sedation and analgesia are considered the standard of care in patients without contraindication for its administration.[2] Although midazolam is recommended for sedation in most guidelines,[2–5] propofol has gained popularity, mainly due to its short recovery time. However, evidence for propofol use during FB is scarce, especially when it is not administered by ananesthesiologist.

Respiratory depression is a major concern during respiratory endoscopy. While SO_2 monitoring is performed in all patients undergoing FB, CO_2 monitoring is less common. For many years, CO_2 measurement required an arterial blood sample; however, it can now be monitored with transcutaneous capnometry. The transcutaneous pressure of CO_2($TcPCO_2$) is well correlated with $PaCO_2$,[6] and several authors have used transcutaneous capnometry in patients undergoing different sedation protocols for endoscopic procedures[7–9]; however, there is little evidence on $TcPCO_2$ changes in patients sedated with midazolam or propofol who have received concomitant intravenous opioids (e.g., balanced sedation).

In this randomized controlled trial, we evaluated ventilation response measured by transcutaneous capnometry in adult patients undergoing ambulatory FB who received non-anesthesiologist-administered propofol (NAAP) balanced sedation, and compared it with guideline-recommended sedation consisting of combination midazolam and opioid. Our primary outcome was to assess difference between groups in $TcPCO_2$ values during and after FB. We hypothesized that $TcPCO_2$ values would not be higher in patients who received NAAP balanced sedation. Secondary outcomes were procedural recovery time measured using the Aldrete scale, patient satisfaction, and frequency of adverse events.

Materials and Methods

Patients and Procedures

Between February and July 2014, we prospectively included ambulatory patients >18 years of age with an indication for FB. Bronchoscopy procedures were performed by respiratory and critical care medicine residents under the supervision of an associate professor in a tertiary-referral university hospital in northern Mexico. Patients with tracheostomy, known allergy to study drugs, psychiatric illness, pregnancy, American Society of Anesthesiologist physical status class IV or V, or capnometry sensor dysfunction were excluded.

Patients were assigned by block randomization to receive midazolam or propofol. In the midazolam group the initial dose was 0.05 mg/kg, and in the propofol group the starting dose was 0.1 mg/kg. Additional doses of the corresponding drug (2 mg of midazolam or 10 mg of propofol) were permitted to obtain a score of 3 to 4 on the observer's assessment of alertness/sedation scale. All patients received nalbuphine at a starting dose of 2 mg with additional doses of 1 mg if necessary. Lidocaine spray was applied to the pharynx and also to the nasal mucosa when bronchoscope was inserted through a nostril. Endobronchial topical lidocaine was applied using the spray-as-you-go technique, at a maximum dose of 7 mg/kg. Sedation and analgesia were prescribed by the resident responsible for conducting FB and administered by an auxiliary nurse without the support of an anesthesiology specialist.

$TcPCO_2$ measurement was carried out with the SenTec digital monitoring system (Artemis Medical, Kent, London) by applying a Stow–Severinghaus (V-Sign sensor) type sensor in the ear lobe. We monitored $TcPCO_2$ for 1 h from the start of FB, and recorded $TcPCO_2$ values every 5 min for the first 20 min and every 10 min up to 60 min. All patients received supplementary oxygen and were monitored with periodic non-invasive blood pressure measurements, continuous electrocardiogram, and SO_2 surveillance.

Residual sedation was measured on the Aldrete scale at 5, 10, and 15 min after FB. At the time of discharge from the bronchoscopy suite, satisfaction was assessed using a visual analog scale of 1 (not satisfied) to 10 (very satisfied). One investigator, blinded to the patient's study group, recorded all procedural data. The bronchoscopist was blinded to $TcPCO_2$ values.

Sample Size and Statistical Analysis

The sample was calculated for alpha 0.05, beta 0.20, standard deviation of 7.3,[8] minimum $TcPCO_2$ difference to detect of 5 mmHg, estimated loss to follow-up of 0.20, and two-tailed analysis. According to the above, the sample size was 42 patients per group.

We tested normal distribution with the Kolmogorov–Smirnov test. Data are shown as means and standard deviation for variables with normal distribution, and as median and interquartile range for non-normal variables. We used the *t*-test, the Mann–Whitney *U*-test, ANOVA, or chi-square as indicated. We defined a statistically significant difference as a *P* value <.05. The analysis was performed using SPSS version 18.0 for Windows (SPSS Inc., Chicago, IL).

Ethical Considerations

All participating physicians received formal training in procedural sedation with propofol from professors of the UANL