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Effects of propofol and dexmedetomidine in sleep videoendoscopy: a comparative study in Ukraine

Efekty stosowania propofolu i deksmetomidyny w trakcie wideoendoskopii snu: porównawcze badanie z Ukrainy

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ABSTRACT:

Introduction: Snoring and obstructive sleep apnea (OSA) are associate with a high socio-economic burden. According to statistics snoring is found in 44% of men and 28% of women aged 30 to 60 years. Treatment involves several main approaches including uvulopalatopharyngoplasty with or without tonsillectomy. Preparation for this procedure includes sleep videoendoscopy. Currently, we mainly use two effective agents, propofol and dexmedetomidine. That said, there is still no consensus on which one is safer and better.

Material and methods: The study involved 50 people aged 18 to 62 with a history of snoring and OSA, previously ineligible or insensitive to CPAP therapy, thus preparing for surgical treatment of these disorders. All patients were randomized to two study groups: group 1 with propofol as a sedative and group 2 with dexmedetomidine. Each treatment was divided into three periods: (1) initial testing before the use of intravenous hypnotic agents, (2) sedation, and (3) regaining consciousness. In each period, we measured the following parameters: minute ventilation, respiratory rate, oxygen saturation, blood concentration of hypnotic agent, BIS index. Statistical analysis was performed on IBM SPSS Statistics v. 22.

Results: The OAA/S scale showed that the recovery time after sedation was longer for dexmedetomidine than for propofol: 38 ± 10 min and 27 ± 3 min, respectively (p value = 0.305, which means no statistically significant difference between the groups). Based on monitoring of circulation and respiratory rate, heart rate tended to decrease with dexmedetomidine sedation and increase with propofol infusion. Blood pressure tended to drop in both groups, more so with dexmedetomidine. In the post-sedation period, blood pressure stabilized faster in the propofol group than in the dexmedetomidine group, but it was not statistically significant.

Conclusion: According to the study results, there was no statistically significant difference between the propofol or dexmedetomidine groups. However, the paper presents a small series of cases, therefore extensive clinical research is needed to clarify the problem further.

KEYWORDS: dexmedetomidine, obstructive sleep apnea syndrome, propofol, sleep videoendoscopy

STRESZCZENIE:

Wstęp: Chrapanie i zespół obturacyjnego bezdechu sennego (OBS) to problemy, które powodują duże obciążenie społeczno-ekonomiczne. Według statystyk, w ogólnej populacji świata chrapanie stwierdza się u 44% mężczyzn i 28% kobiet w wieku od 30 do 60 lat. Leczenie tego schorzenia obejmuje kilka głównych metod, w tym uwulopalatofaryngoplastykę z wycięciem migdałków lub bez. Przygotowanie do tej procedury obejmuje wideoendoskopię podczas snu. Obecnie podczas tego badania używa się głównie dwóch środków – propofolu i deksmedetomidyny, które wykazują swoją skuteczność. Niemniej jednak nadal nie ma zgody, który z nich jest bezpieczniejszy i lepszy.

Materiał i metody: W badaniu wzięło udział 50 osób w wieku od 18 do 62 lat z historią chrapania i OBS, wcześniej niekwalifikujących się lub niewrażliwych na terapię CPAP, przygotowujących się tym samym do leczenia operacyjnego wspomnianych zaburzeń. Wszyscy pacjenci zostali losowo przydzieleni do dwóch grup badanych: grupy 1. z propofolem jako środkiem uspokajającym i grupy 2. z zastosowaniem deksmedetomidyny. Każdy zabieg został podzielony na trzy okresy: (1) wstępne testy wykonywane przed wstrzyknięciem środków nasennych, (2) sedacje i (3) odzyskanie przytomności. W każdym okresie zmierzono parametry, takie jak: wentylacja minutowa, częstość oddechów, wysycenie tlenem, stężenie we krwi środka nasennego, wskaźnik BIS. Analiza statystyczna została przeprowadzona na IBM SPSS Statistics v. 22.

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Wyniki: Skala OAA/S wykazała, że czas powrotu świadomości po sedacji był dłuższy dla deksmedetomidyny niż dla propofolu: odpowiednio 38 ± 10 min i 27 ± 3 min (wartość p = 0,305, co oznacza brak statystycznie istotnej różnicy między grupami). Na podstawie monitorowania krążenia i częstości oddechu, akcja serca miała tendencję do zmniejszania się podczas sedacji deksmedetomidyną i zwiększania podczas infuzji propofolu. Ciśnienie krwi miało tendencję do spadku w obu grupach, bardziej w przypadku deksmedetomidyny. W okresie po sedacji w grupie propofolu ciśnienie tętnicze stabilizowało się szybciej niż w grupie deksmedetomidyny, ale nie stwierdzono istotności statystycznej.

Wnioski: Zgodnie z wynikami badań, nie stwierdzono istotnej statystycznie różnicy między grupami stosującymi propofol lub deksmedetomidynę. Jednak w tym artykule opisano małą serię przypadków, dlatego do wyjaśnienia tego problemu potrzebne są obszerne badania kliniczne.

SŁOWA KLUCZOWE: deksmetomidyn, propofol, wideoendoskopia snu, zespół obturacyjnego bezdechu sennego

ABBREVIATIONS

BIS – Bispectral index
CODP – Chronic obstructive pulmonary disease
CPAP – Continuous positive airway pressure
DISE – Drug-Induced Sleep Endoscopy
ECG – Electrocardiography
EEG – Electroencephalography
ESG – Electrosonography
OAA/S – Observer's Assessment of Alertness/Sedation Scale
OSA – Obstructive sleep apnea
RTG – Radiography

INTRODUCTION

Snoring and obstructive sleep apnea (OSA) are problems that place a high socio-economic burden. According to statistics, in the general population of the world, snoring is found in 44% of men and 28% of women aged 30 to 60 years [1]. OBS is probably the most widespread respiratory disorder; recent studies from the USA and Europe indicate that from 14% to 49% of middle-aged men have clinically significant sleep apnea [2]. The mechanism of this disease consists of relaxing of the pharyngeal muscles and soft palate, which causes tightening of the tongue tissues and obstruction of the upper respiratory tract. There is also contraction of the diaphragm, which creates negative pressure in the airways. OBS leads to: imbalance in the oxygen and carbon dioxide levels in the blood, hypoxia, mainly in the brain, which activates awakening [3].

Frequent awakenings during a night's sleep lead to: daytime sleepiness, decreased attention and efficiency, exacerbation of chronic diseases such as diabetes, hypertension, ischemic heart disease. So far, the "golden standard" of OSA treatment has been the use of continuous positive airway pressure therapy (CPAP).

That said, this method is associated with patient discomfort and reduced quality of life, and thus low compliance, especially in younger patients with mild and moderate OSA [4]. An alternative method of treatment involves surgical intervention – uvulopalatopharyngoplasty with or without tonsillectomy. An integral part of the operating procedure is drug-induced sleep endoscopy (DISE), which is a potential tool for assessing the degree of dynamic obstruction of the upper respiratory tract [5]. However, there is a shortage of literature that could allow to assess the effects of various anesthetic techniques, as they are particularly relevant to OSA patients [6]. At present, two main agents are used – propofol [7] and dexmedetomidine [8], which have proven to be effective. Nevertheless, there is still no consensus on which is safer and better.

In this connection, the aim of our study was to determine which hypnotic drug provides better results for DISE and poses lower risk to patients.

MATERIAL AND METHODS

This prospective randomized trial was conducted at the Otorhinolaryngology Department of Bogomolets National Medical University at the Kiev Clinical Hospital No. 2 of the Ukrainian railway JCS "Ukrzaliznytsia" between October 2019 and January 2020. The bioethical expertise and consent were made by the Commission on Issues of Bioethical Examination of the Bogomolets National Medical University (Protocol No.126 of October 14, 2019). All patients gave informed consent to participate in research.

The study involved 50 people aged 18 to 62 with a history of snoring and OSA, previously ineligible or insensitive to CPAP therapy, thus preparing for surgical treatment of these disorders. The exclusion criteria were: age below 18 and over 75, pregnancy, severe OSA, respiratory diseases such as: COPD, tuberculosis, bronchial asthma, cancer of any part of the respiratory system, severe stages of concomitant pathology (risk of ASA III and higher [9]), allergy to propofol and dexmedetomidine, gross deformities of the viscerocranium.

Before the procedure, all patients underwent ENT examination, basic examinations, including: blood count, blood biochemistry, ECG, and chest X-ray.

RANDOMIZATION AND BLINDING

All patients were randomized into two study groups: group 1 with propofol as a sedative and group 2 with dexmedetomidine. Tab. I. presents the patient characteristics in each group. There were no statistically significant differences.

Hypnotics were administered by anesthetists not involved in the study protocol. Parameter records were made by a blind assistant, who was not involved in drug selection and delivery.

Tab. I. Patient characteristics.

PARAMETERS	GROUP 1, PROPOFOL	GROUP 2, DEXMEDETOMIDINE	P- SIGNIFICANCE
Age, year	47 (+/- 9.2)	48 (+/- 10.7)	>0.05
Sex			>0.05
male	18	16	>0.05
female	5	7	>0.05
Weight, kg	89.35 (+/-10.32)	92.1 (+/- 9.56)	>0.05
Height, cm	171.75 (+/- 7.9)	174.25 (+/- 8.25)	>0.05
Body mass index	30.15 (+/- 2.85)	30.35 (+/- 2.25)	>0.05
Classification of the American Association of Anesthesiologists			>0.05
I	9	7	>0.05
II	14	16	>0.05

Tab. II. The only standards for the graphical representation of research results.

Acceptance	Assessed according to the suitability of requirements (no. 50)	Do not meet acceptance criteria (no. 3) Consent has been rejected (no. 1)
Randomization	Considered appropriate and randomized (no. 46)	
Definition	Group 1, propofol (no. 23)	Group 2, dexmedetomidine (no. 23)
Analysis	Analyzed (no. 23)	Analyzed (no. 23)

STUDY PROTOCOL

All patients refrained from eating any food for at least 8 hours prior to the surgery. In the operating room, the patients underwent: continuous ESG, pulse oximetry, non-invasive blood pressure measurement and Bispectral Index monitoring, where 100 represents the awake state and 0 represents the absence of EEG activity. A deliberate indicator was the BIS index in the range 70–90, which indicates deep sleep. Subjective measurement of the depth of sedation was performed by using the Alertness/Sedation Scale (OAA/S) [10] with targets of 2–4, where a score of 2 represents a mild level of sedation and 4 represents a moderate level of sedation. Group 1 received propofol at an initial dose of 2 μg/kg and group 2 received dexmedetomidine at an initial dose of 1.1 μ/kg, followed by an increase to the necessary level of sedation under control of the BIS index.

Each treatment was divided into three periods: (1) initial testing before injecting the hypnotics, (2) sedation, and (3) regaining consciousness. Parameters such as: minute ventilation, respiratory rate, oxygen saturation, blood concentrations of hypnotic agents, BIS index were measured in each period. At the same time, cardiopulmonary monitoring was performed to control the patient's condition (recording of heart rate, blood pressure) in accordance with the recommendations of the American Sleep Association [11].

A heart rate of fewer than 50 bpm persisting for 15 seconds during surgery was treated intravenously with atropine 0.5 mg. Mean arterial pressure <30% of the baseline value was controlled by intravenous infusion of crystalloids [12].

STATISTICAL ANALYSIS

The statistical analysis was performed with IBM SPSS Version 22 software package (sub-license agreement no. 138 of April 8, 2016 between LLC "Prognostychni rishenia" and the Bogomolets National Medical University). Variables in both groups were compared using an independent continuous t-test (or the Mann–Whitney U test, if applicable). A chi-squared test was used for categorical variables (Fisher's exact test). A p-value ≤ 05 was considered significant with the 95% confidence interval.

RESULTS

A total of 50 patients were studied. Four people were excluded because they did not meet the inclusion criteria and one refused consent. In total, 46 patients were enrolled in this study. Following written informed consent, all were randomly assigned to two groups: 1. – propofol, n = 23 and 2. – dexmedetomidine, n = 23, machine-generated, randomly using sealed envelopes. There were no voluntary opt-outs in the present study. None of the patients had intraoperative or postoperative complications. Fig. 1. shows a flow chart of trial reporting. Tab. I. presents the epidemiological characteristics of each group.

The OAA/S scale showed that the recovery time after sedation was longer for dexmedetomidine than for propofol: 38 ± 10 min and 27 ± 3 min, respectively (p value = 0.305, which means no statistically significant difference between the groups).

Tab. III. The effect of propofol and dexmedetomidine on basic sedation index.

PARAMETERS	GROUP 1, PROPOFOL			GROUP 2, DEXMEDETOMIDINE					
	Primary analysis	Sedation	Restoration of consciousness	Primary analysis	P – significance	Sedation	P – significance	Restoration of consciousness	P – significance
minute ventilation of the lungs, l/min	8.1 ± 0.9	7.9 ± 1.2	8.6 ± 0.8	8.2 ± 1.3	0.53	7.4 ± 1.1	0.76	7.8 ± 1.2	0.58
respiratory rate, min.	15.66 ± 3.4	17.26 ± 3.7	16.44 ± 3.53	14.0 ± 3.14	0.72	14.66 ± 2.0	0.54	14.7 ± 2.8	0.7
peripheral oxygen saturation, %	96.8 ± 1.3	95.6 ± 1.1	97.8 ± 1.2	96.6 ± 1.4	0.9	95.4 ± 1.0	0.9	96.6 ± 1.5	0.57

Tab. IV. Sedation with propofol and dexmedetomidine during hypoxic ventilation.

PARAMETERS	GROUP 1, PROPOFOL			GROUP 2, DEXMEDETOMIDINE					
	Primary analysis	Sedation	Restoration of consciousness	Primary analysis	P – significance	Sedation	P – significance	Restoration of consciousness	P – significance
Bispectral index	95 ± 2	76 ± 5	93 ± 4	96 ± 2	0.72	82 ± 7	0.49	92 ± 3	0.84
Blood concentrations of hypnotic agents, ng/ml	no	1.26 ± 0.37	0.44 ± 0.13	no	-	0.66 ± 0.14	0.14	0.32 ± 0.07	0.43

Based on the monitoring of circulation and respiratory rate, heart rate tended to decrease with dexmedetomidine sedation and increase with propofol infusion.

Blood pressure tended to drop in both groups, more so with dexmedetomidine. In the post-sedation period, blood pressure stabilized faster in group 1 than in group 2, but no statistical significance was found. Detailed results for both groups with the calculated p value are presented in Tabs. II, III.

CONCLUSIONS

This study revealed that there was no statistically significant difference between groups using propofol or dexmedetomidine during OSA surgery This implies that dexmedetomidine is not a more favorable option than propofol and the latter may be a better choice given its lower price. That said, there are merely a few studies of similar situations described in the article and broad-based clinical trials are needed to clarify this issue.

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