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Sedation with propofol in digestive endoscopy administered by gastroenterologists. Experience in a Venezuelan hospital

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ABSTRACT

Objectives: propofol is a rapid acting hypnotic that is becoming the drug of choice for sedation in digestive endoscopy worldwide. There is some controversy with regard to the use of propofol by physicians who are not anesthesiologists. We present our experience of the administration of propofol by endoscopist and nursing personnel.

Methods: this was a retrospective study of sedation in endoscopy. Propofol was exclusively used and administered by the endoscopist who performed the procedure and the nursing staff. All patients included were of a low and moderate surgical risk (ASA I, II and III). No complementary medication was used such as benzodiazepines or opiates.

Results: a total of 70,696 digestive endoscopy procedures performed between 2002 and 2017 were included in the study. Propofol was administered in an induction bolus of 10 to 50 mg, continuing with intermittent boluses of 10 to 20 mg, according to the patients' response. The incidence of complications was very low, assisted ventilation with a mask was required on 78 (0.11%) occasions. Only one case required endotracheal intubation and two patients had significant hypotension that required the administration of ephedrine. The average recovery time of all neuropsychomotor functions after the procedure was 15 minutes; 98% of patients reported a good or excellent level of

tolerance and clearly remembered the details of the interview one hour after the procedure.

Conclusions: the use of propofol as a sedative in digestive endoscopy is a safe and effective technique, provided that it is administered and controlled by the endoscopist and nursing staff in properly selected patients. This allows gastroenterologists to achieve adequate sedation.

Key words: Sedation with propofol by non-anesthesiologists. Sedation in digestive endoscopy. Complications of sedation.

INTRODUCTION

Adequate sedation is necessary for the comfort and peace of mind of physicians and patients during endoscopic procedures. Nowadays, it is unacceptable to perform this type of procedure without adequate sedation (1,2). Benzodiazepines and opioids have been used for many years in digestive endoscopy. Propofol is a rapid acting hypnotic with a short duration; this was initially used by anesthesiologists but has recently become more popular in endoscopy. Propofol allows a greater satisfaction of the patient and shorter recovery times without a significant increase in side effects in relation to the traditionally used benzodiazepines and opioids (3).

Sedation leads to an increase in cost and risk. Better equipped endoscopy rooms and the assistance of anesthesiologists during the procedures is necessary in some cases. This situation has led to a search for ways that allow gastroenterologists to achieve adequate sedation without the need of an anesthesiologist during the procedure. In the United States, the term endoscopy directed propofol sedation (sedation with propofol directed by the endoscopist) has been introduced. A set of requirements are established that guarantee safety and cover the aspects of legal protection in this type of sedation (4-7).

We present our experience using sedation with propofol administered by the endoscopist and the nursing staff that are appropriately trained in the digestive exploration unit of the Hospital de Clínicas Caracas (Venezuela), between 2002 and 2017.

MATERIAL AND METHODS

This was a retrospective study. Propofol administered by trained nurses has been used under the indication and control of the endoscopist in the digestive explorations unit of the Hospital de Clínicas Caracas since 2002. The examinations were conducted in a room equipped with cardiopulmonary resuscitation (CPR) equipment and all personnel involved had updated training in CPR. Patients were selected according to the criteria accepted by the American Association of Anesthesiology (ASA) as ASA I, II or III. ASA IV and V patients, cases older than 70 years, a history of previous anesthesia related problems, allergy to eggs, soy or sulfas, or long and complex procedures, difficult airways, morbid obesity and sleep apnea were excluded from the study.

All patients were monitored by pulse oximetry, heart rate and blood pressure measurements. Three continuous liters of oxygen per nasal cannula were supplied in all cases. A peripheral vein was catheterized in one of the upper limbs using a catheter from 22 to 24 G for the administration of propofol. Sedation was initiated with a bolus of propofol of 10 to 50 mg and continued with intermittent boluses of 10 to 20 mg, according to patient response. No complementary medications such as benzodiazepines or opiates were used. Once the procedure was completed, the patient was transferred to the recovery room located in the same area of the digestive exploration unit where they remained under permanent observation and continuous monitoring until the baseline condition was restored. An accompanying person with the patient was required in order to perform the procedure.

RESULTS

During the study period, the number of endoscopic procedures performed in the digestive exploration unit and sedation by gastroenterologists with propofol was of 70,696 (Table 1); 38,317 (54.2%) were female and 32,379 (45.8%) were male. The mean dose of propofol was 160 mg (range 60-450).

With regard to the first 4,200 procedures, the rate of ventilatory complications was 0.15%; five patients required manual ventilation with a mask and there was one case of endotracheal intubation. During the first 7,000 procedures, the rate of ventilatory complications was 0.12%, eight cases required assisted ventilation with a mask and one case required endotracheal intubation. Upon completion of the study (70,696 patients), 78 (0.11%) patients required assisted ventilation with a mask and there was only one case

of endotracheal intubation. Two patients had significant hypotension that required the use of ephedrine. The mild and moderate oxygen desaturations recorded by pulse oximetry were easily controlled using maneuvers that released the airflow in the oropharyngeal area such as hyperextension of the neck, projection of the jaw, aspiration of accumulated secretions, use of the Mayo cannula and increased oxygen flow supplied by a nasal cannula. There were no cases of rhabdomyolysis. The average recovery time of all neuropsychomotor functions after the procedure was 15 minutes; 98% of the patients reported a good or excellent level of tolerance and clearly remembered the details of the interview one hour after the endoscopy.

DISCUSSION

The results of propofol sedation in 70,696 patients are presented in this article and we have previously reported preliminary data (8,9). There were no serious complications such as rhabdomyolysis (10). The level of sedation can be superficial (anxiolysis), moderate or deep and general anesthesia can be achieved with agents such as propofol (11). The goal for gastroenterologists is to reach an adequate level of sedation under which procedures can be performed and the cardiopulmonary function remains normal.

Propofol is a hypnotic with a sedative, antiemetic and amnesic effect, with no analgesic effect. It is thought that it acts on the cerebral gabaminergic system, although its exact mechanism of action is unknown. When administered intravenously, its maximum effect is reached within two minutes and due to the rapid metabolism of the drug, the effect lasts from four to eight minutes. The effect of the initial dose is difficult to predict as it is influenced by age, sex, body weight and comorbidities. As with other drugs, adjustment of the dosage is one of the fundamental aspects for an effective and safe sedation. In this study, an induction bolus of 10 to 50 mg was slowly administered and then continued with intermittent boluses of 10 to 20 mg. The drug is liposoluble and is metabolized by the liver with renal elimination. It should not be administered to people that are allergic to eggs, soy or sulfas. Pain in the injection site can occur in one third of cases. The level of sedation with propofol is close to the level of anesthesia, so it must be administered carefully. Adverse effects are rapidly reverted by discontinuation of the drug due to its rapid metabolism. There is currently

no antagonist medication. The drug was approved for use in 1977 as an agent to induce and maintain anesthesia in adults and children over three years of age. The drug label includes a note that literally says "it must be used by people trained in the administration of general anesthesia" (12). However, this drug has become increasingly used worldwide by non-anesthesiologist medical doctors.

Nowadays, due to cost limitations and the availability of anesthesiologists, the use of propofol by non-anesthetists has become widespread in various types of procedures such as digestive endoscopy. In 2007, Külling et al. (13) published a prospective study that included 27,061 procedures (gastroscopies and colonoscopies) where propofol was administered by an endoscopy nurse supervised by the gastroenterologist. Only pulse oximetry and clinical evaluation were used to monitor patients. Only six patients required mask ventilation, and endotracheal intubation was not required in any of the cases.

The review by Deenadayalu (14) evaluated 456,918 patients who were sedated only with propofol under a gastroenterologist directed procedure. Assisted ventilation with a mask was required in 322 cases, intubation was required in four cases and there were three deaths. These fatal cases were evaluated retrospectively and these patients did not fulfill the necessary requirements for sedation without an anesthesiologist. In 2009, Rex et al. (15) published a review of 646,080 patients from 28 centers, in which endoscopic procedures were performed with propofol administered by the endoscopy team without the assistance of an anesthesiologist. Only eleven cases required endotracheal intubation and none had permanent neurological sequelae. There were four deaths of severely ill patients with ASA III or higher. A total of 489 patients required assisted mask ventilation, most of them during upper digestive tract procedures. This was possibly due to the fact that these patients required a higher than average level of sedation, coughing and accumulation of secretions in the pharynx and a possible laryngospasm. The overall mortality in this review was 1 per 161,515 cases, a favorable result when compared with the complications observed with benzodiazepines and opiates, which is in the order of 11 per 100,000 procedures (16).

The endoscopist and the auxiliary personnel must be trained in the management of propofol from a theoretical and practical point of view and must also be able to handle the support techniques that allow the maintenance of the airway and the wellbeing of the patient in a critical situation (17). According to our experience, we do not recommend

combining propofol with other drugs, since there is no reduction in the incidence of adverse effects and it increases the recovery time of the patient (18). We also think that the use of pharyngeal anesthesia in gastroscopy has no value in terms of patient comfort or reducing the amount of propofol required. We did not observe differences in the dose of propofol required or recovery times with the use of CO_2 instead of air in colonoscopy or prolonged procedures.

It is essential in all cases to have a prior evaluation, control and surveillance scheme (19,20) that allows the minimization of complications. In our experience, an adequate medical history should be obtained before endoscopy (21), with an emphasis on comorbidity factors that may affect sedation, such as allergies, medication, previous sedation, alcoholism and ASA classification (22). The American Society of Anesthesiology allows the administration of propofol by non-anesthesiologists (23) up to ASA III. After the procedure and before discharging the patient, an adequate monitoring of oxygen levels, hemodynamic parameters, level of consciousness and degree of mobility should be maintained. Complications related to sedation represent more than a third of complications attributed to some endoscopic procedure. The type of procedure and sedation should be clearly explained to the patient and a signed consent obtained that clarifies who is responsible for the sedation.

Nowadays, numerous clinical studies and many professional societies in Europe and the United States authorize the use of propofol by physicians who are not anesthesiologists, with clear pre-established conditions. Therefore, this type of sedation can be performed with adequate legal medical coverage (24).

In summary, our experience of 70,696 sedations with propofol performed by gastroenterologists during digestive endoscopy was satisfactory. The results of this study are in accordance with the general evidence with regard to the safety of propofol use by non-anesthesiologist physicians, provided that the adequate requirements for the administration of the drug are met.

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Table 1.

Procedures	*Number of cases*
Gastroscopies	22,623
Colonoscopies	8,484
Gastro + colonoscopy	29,278
ERCP	3,835
Endoscopic ultrasound	2,728
Others (enteral prosthesis, placement and removal of intragastric balloon, dilations)	3,748

ERCP: endoscopic retrograde cholangiopancreatography. Propofol: average dose used, 160 mg; maximum dose, 450 mg; minimum dose, 60 mg.