

ORIGINAL PAPERS

Safety of continuous propofol sedation for endoscopic procedures in elderly patients

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ABSTRACT

Objective: to evaluate safety of continuous propofol sedation in elderly patients who undergo endoscopic procedures and investigate risk factors to develop complications in the geriatric population.

Material and methods: patients who received endoscopist-directed propofol sedation were classified into two groups according to age. Group I: > 80 years; Group II: < 80 years. Propofol was administered by continuous intravenous infusion to achieve deep sedation. Arterial oxygen saturation, heart rate, blood pressure, and electrocardiographic records were monitored during the procedure. Therapy and complications secondary to sedation were recorded.

Results: one thousand two-hundred and ninety-five endoscopic procedures (gastrosopies, colonoscopies and endoscopic ultrasonographies) were included. The dose of propofol was lower and therapy was more frequently performed in Group I. There were no differences between sedation-related complications in both groups (Group I: 15.4%; Group II: 14%; *p*, NS). Patients in Group I showed greater tendency to develop severe oxygen desaturation in the colonoscopy and endoscopic ultrasonography procedures. In the univariate analysis, a higher dose of propofol was associated with the appearance of complications (157.4 ± 84.4 vs. 121.3 ± 89.6 mg) in elderly patients but it was not associated with severe oxygen desaturation.

Conclusions: continuous propofol sedation during endoscopic procedures in elderly patients > 80 years is as safe as in younger patients.

Key words: Sedation. Endoscopy. Elderly.

Martínez JF, Aparicio JR, Compañy L, Ruiz F, Gómez-Escolar L, Mozas I, Casellas JA. Safety of continuous propofol sedation for endoscopic procedures in elderly patients. *Rev Esp Enferm Dig* 2011; 103: 76-82.

Received: 07-07-10.

Accepted: 14-10-10.

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INTRODUCTION

Sedation administration in the Endoscopy Units is still a controversial practice. Detractors of this procedure argue that it carries added risks for the patient and diminishes the endoscopists ability. In theory, deciding which patients need sedation is not easy since a reliable methodology to predict tolerance to endoscopic procedures is not available (1). However, sedation in digestive endoscopy is a widespread practice. In a Survey conducted in hospitals in Andalucia, half of the Endoscopy Units suggested that sedation must be administered in two thirds of the colonoscopy procedures and concluded that anesthesiology resources must be improved (2).

Propofol is a short-acting, intravenously administered hypnotic agent that is more and more used in endoscopic sedation (3). As it has a relative narrow therapeutic range, it might cause the patients to enter states of deep sedation or general anesthesia requiring mechanical ventilation. There is no specific antidote for propofol (4). Despite this fact, safety of propofol sedation in endoscopic procedures, even without anesthesiologist assistance, has been shown in numerous studies (5-17).

Elderly patients usually show higher cardiovascular and pulmonary basal dysfunction. These patients are highly susceptible to hypoventilation and apnea due to changes in the pharmacokinetic and the pharmacodynamic profile. Thus, it has been proved that patients > 90 years present similar plasma propofol levels to younger controls although dose in older patients was 40% lower (18,20). Though this group of patients shows better tolerance to endoscopic procedures without sedation (18,21), several studies suggest that conscious and deep sedation are safe (5,18,22-26). Moreover, some authors have suggested that the use of propofol by the endoscopy unit personnel may be efficient and safe even in elderly patients (5,26-30), but the use of continuous propofol infusion in these group of patients is not reported.

The aim of this study is to evaluate the safe use of continuous propofol sedation in elderly patients who undergo

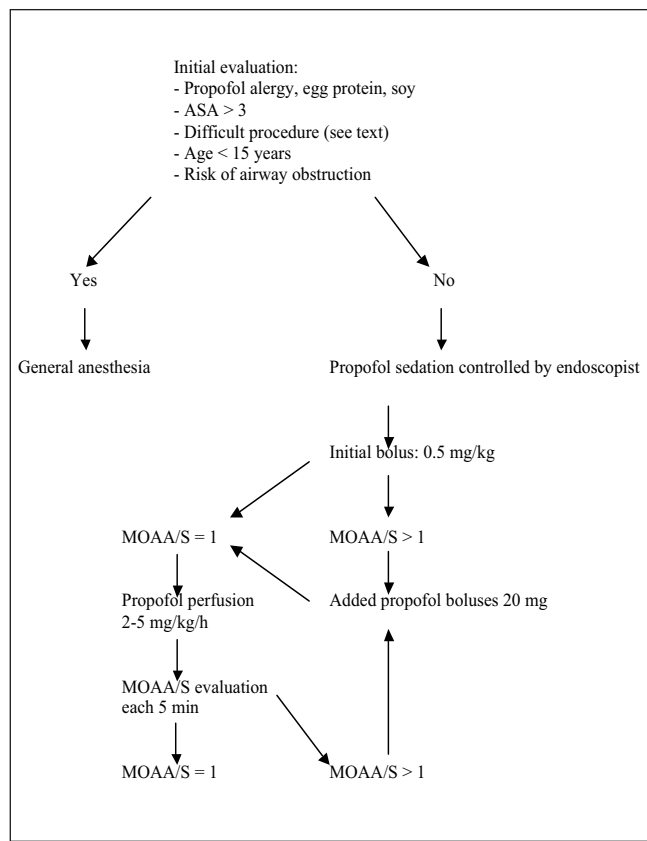


Fig. 1. Approach to sedation management.

endoscopic procedures. We also aim to investigate risk factors to develop complications in the geriatric population.

METHODS

A prospective observational cohort study was performed between April and November 2009. All the patients in our Unit who underwent gastroscopy, colonoscopy or endoscopic ultrasonography (EUS) under deep endoscopist-directed propofol sedation were prospectively included. Patients who did not receive propofol sedation (because of patient's refusal or contraindication) and those whose examination was supervised by an anesthesiologist were excluded. Administration of propofol was contraindicated in those patients who were allergic to propofol, egg proteins, or soy. As recommended (4), the procedures were performed under anesthesiologist supervision in case of patients classified as ASA score > III, complex procedures (i.e. endoscopic retrograde cholangiopancreatography, percutaneous endoscopic gastrostomy, esophageal stents, achalasia), patients < 15 years, and presence of pathological anatomical features associated with a higher risk of airway obstruction during the procedure. The study was approved by the ethics committee of Hospital General Universitario de Alicante. All

patients signed specific informed consent for endoscopic procedure and sedation.

Patients were classified in two groups according to age: Group I: patients ≥ 80 years; Group II: patients < 80 years. One endoscopist, a nurse and a practical nurse were present in each room. One nurse was in charge of patient monitoring and administration of propofol under endoscopist supervision. All the endoscopies were performed by five experienced endoscopists with more than 1000 procedures per year. The endoscopists and the nurses were trained in propofol sedation in our Unit after some years of experience in the management of this drug under anesthesiologist supervision and all of them were advanced cardiac life support-certified. Propofol was administered according to the standard protocol in our Unit (Fig. 1): Induction dose by 0.5 mg/kg intravenous bolus followed by a continuous intravenous perfusion using a perfusion pump (Perfusor fm B/Braun) at 2-5 mg./kg/h (at the discretion of the endoscopist, an initial perfusion at 4mg/kg/h that was modified in order to keep deep sedation level, that is MOAA/S score of 1) (31). Sedation level was controlled by the nurse. Perfusion was modified during procedure and/or 20 mg boluses were added on demand to keep deep sedation level. Initial propofol bolus and added propofol boluses were administered by the nurse according to the endoscopist's orders. All patients were treated by oxygen therapy with nasal cannula at a flow of 2 L/min. Arterial oxygen saturation, heart rate and electrocardiographic records were carefully monitored. Blood pressure was monitored every five minutes. A special form was purposely designed to record demographic data (age, sex), past medical history (ASA classification of anesthetic risk)(32), endoscopic procedures (gastroscopy, colonoscopy, EUS and EUS-guided fine-needle aspiration), type of endoscopic therapy if performed, total dose of propofol, previous use of sedative drugs and presence of sedation-related complications (desaturation, bradycardia and hypotension) or procedure-related complications (bleeding, perforation).

Definitions

- Oxygen desaturation: Mild oxygen desaturation was defined as oxygen arterial saturation < 90% and severe oxygen desaturation as < 85% for at least 10 seconds. Oxygen desaturation was managed according to our protocol: increase of the nasal oxygen flow to 6 L/min and assisted mask ventilation if previous measure is not effective.
- Bradycardia: We considered that the patient had bradycardia when heart rate was 45 beats per minute for at least 10 seconds. Bradycardia was treated with 1mg atropine intravenously.
- Hypotension was defined as systolic arterial pressure < 90 mm Hg. It was managed by the administration of intravenous saline infusion.

Table I. Characteristics of patients and endoscopic procedures in each group

	Group I n = 149	Group II n = 1146	p
Sex [n,(%)]			< 0.001
Male	59 (40%)	638 (56%)	
Female	90 (60%)	508 (44%)	
Age [mean (range)]	83.5 (80-96) yr	57.5 (15-79) yr	n. a.
Dose of propofol [mean + sd]	126.8 ± 70.6 mg	190.9 ± 103.2 mg	< 0.001
ASA 3 [n,(%)]	35 (23.5%)	136 (11.9%)	< 0.001
Endoscopic therapy [n,(%)]	41 (27.5%)	204 (17.8%)	0.04
Use of sedative drugs [n,(%)]	15 (10.1%)	104 (9.1%)	0.39
Previous co-morbidity [n,(%)]	84 (56.4%)	364 (31.8%)	< 0.001

sd: standard deviation; n.a.: not appropriate.

- Endoscopic therapy was: endoscopic polypectomy, balloon or Savary-Gilliard dilatation, variceal band ligation, vascular lesions, hemostatic techniques, foreign body removal, prosthesis placement and endoscopic mucosectomy. Fine-needle aspiration during EUS was also considered as endoscopic therapy for comparison purposes.

Statistical analysis

Statistical analysis was performed with SPSS 11.0 software. Categorical variables were compared by the (2) test. Kolmogorov-Smirnov test was used to determine parametric distribution of continuous variables. Parametric variables were compared by the Student t test and non-parametric variables were compared by the Mann-Whitney U test. $P < 0.05$ indicated significant differences between variables.

RESULTS

A total of 1650 procedures were included. Among them, 355 (8.2% ≥ 80 years; 91.8% < 80 years) were performed under anesthesiologist supervision and 1,295 procedures in 1,076 patients received endoscopist-directed propofol sedation. There were no differences in the necessity of anesthesiologist supervision between patients > 80 year old and patients under this age ($p = 0.7$). Type of endoscopic procedures was: 464 (35.8%) gastroscopies, 523 (40.4%) colonoscopies, 126 (14.1%) combined, and 182 (9.7%) EUS. One hundred and forty-nine procedures (11.5%) belong to Group I and 1,146 (88.5%) to Group II. Mean age (standard deviation) in Group I was 83.5 (3.4) years and in Group II was 57.5 (14.9) years. Data from both groups are shown in table I. In Group I there were more women, they showed higher ASA score and had more commonly previous co-morbidity. Distribution of the ASA classification in each group was as follows: Group I: ASA 1: 6 (4%), ASA 2: 108 (72.5%), ASA 3: 35 (23.5%); Group II: ASA 1: 356 (31.1%), ASA 2: 654 (57.1%) ASA 3: 136 (11.9%). In Group I patients received a lower dose of propofol and fre-

quency of endoscopic therapy was higher. Complications appeared in 184 (14.2%) procedures [mild oxygen desaturation 111 (8.6%); severe oxygen desaturation 43 (8.6%); bradycardia 25 (1.9%); hypotension 13 (1%)]. Only 17 patients required bag-mask ventilation and FiO_2 100% (5 in Group I and 12 in Group II). The procedure could not be completed in only two patients (both in Group II). Endotracheal intubation was not necessary. None of the patients had to be attended as a consequence of sedation-related complications. Only one perforation was reported. No case of procedure-related significant bleeding was reported. None of the patients died.

There were not differences concerning complications between both groups: 23 complications (15.4%) in Group I and 161 (14.0%) in Group II; p : NS. There were not significant differences concerning severe oxygen desaturation between both groups [Group I: 8 (5.4%); Group II: 35 (3.1%); p : NS.]. Although differences were not significant (table II), patients in Group I showed greater tendency to develop severe oxygen desaturation in the colonoscopy and EUS procedures. A univariate analysis was carried out in Group I to determine risk factors to develop sedation-related complications during endoscopic procedures. A higher dose of propofol was significantly associated with appearance of complications such as: mild desaturation, bradycardia and hypotension (157.4 ± 84.4 mg in those patients who developed any complication versus 121.3 ± 66.7 mg in those patients who did not develop complications, $p = 0.02$), but it was not particularly associated with severe oxygen desaturation (150.7 ± 89.0 mg vs. 125.5 ± 69.6 respectively, p : NS). Patient history and endoscopic therapy did not influence appearance of complications (table III). The same univariate analysis was performed in Group II in order to compare these data with the data from patients < 80 years. No risk factors for the development of complications were reported (data not shown).

DISCUSSION

Necessity and safety of sedation in elderly patients have become controversial because of the increased de-

Table II. Development of complications in each group according to type of endoscopic procedure

<i>Endoscopic procedure</i>	<i>Group I</i>	<i>Group II</i>	<i>p</i>
Gastroscopy			
Dose of propofol	89.68 ± 46.45	140.87 ± 72.06	<0.001
Total complications	3 ± 53	34 ± 8,4	n.s.
Severe desaturation	0	10 ± 2.5	n.s.
Colonoscopy			
Dose of propofol	134.62 ± 60.42	205.75 ± 84.47	<0.001
Total complications	15 ± 28.3	98 ± 20.9	n.s.
Severe desaturation	5 ± 9.4	19 ± 4	0.08
Gastro + colonoscopy			
Dose of propofol	158.43 ± 96.47	251.80 ± 160.62	<0.01
Total complications	15 ± 4.8	14 ± 8,7	n.s.
Severe desaturation	0	2 ± 1.2	n.s.
Endoscopic ultrasonography			
Dose of propofol	184.72 ± 67.78	224,50 ± 85.47	0.06
Total complications	4 ± 22.2	15 ± 13.9	n.s.
Severe desaturation	3 ± 6.7	4 ± 3.7	0.06

Dose of propofol is expressed by: mean ± standard deviation.

mand for endoscopic procedures in the geriatric population. While some experts are against sedation due to its potential adverse events and to the acceptable tolerance to endoscopic procedures by elderly patients(12,21), several studies support safety of sedation in the geriatric population(5,18,22-26). Further, it has been recently published that detection rate of neoplastic lesions (its prevalence increases as we get older) is partially depended on the use of sedation(33) so necessity for sedation in endoscopic procedures is strengthened, specially in the geriatric population.

There are several methods for propofol administration, but the use of an infusion pump without anesthesiologist supervision is not widespread(4). In fact, our study is the

first one that evaluates propofol infusion in elderly patients. Furthermore, the presence of an anesthetist to administer deep sedation with propofol in the Digestive Endoscopy Unit is controversial(34). Several national and international guidelines(4,31) recommend the presence of a cardio-respiratory reanimation trained nurse to monitor vital signs and to administer propofol. Due to human resources problems, we rarely have at our disposal a second nurse exclusively in charge of sedation. Given our good results, we suggest the possibility of having a member of the nursing staff in charge of patient monitoring and propofol administration following the instructions of the endoscopist.

We have not found differences concerning sedation-related complications in patients ≥ 80 years in a detailed series of endoscopic procedures under deep sedation with propofol. Complications occurred in 15.4% of elderly patients versus 14% of younger patients. We would like to highlight that severe complications occurred in 5% of the cases, none of the patients had sequel and none of the patients died. A recent descriptive study on octogenarians reported similar results. In the mentioned study, patients underwent a percutaneous endoscopic gastrostomy procedure with endoscopist-administered propofol. Sedation-related complications occurred in 17% of patients but they were corrected immediately without sequel (26). In our study, stratification according to endoscopic procedure revealed tendency to higher incidence of severe oxygen desaturation in elderly patients who underwent colonoscopy and EUS. This finding may be explained by the higher dose of propofol. Age and severe complications were not related when the patient underwent gastroscopy + colonoscopy despite the doses of propofol

Table III. Risk factors for the appearance of complications in Group I

	<i>Complicaciones totales OR (IC 95%)</i>	<i>p</i>	<i>Desaturación grave OR (IC 95%)</i>	<i>p</i>
Sex				
Men	1.5 (0.6-3.6)	n.s.	0.9 (0.2-4.0)	n.s.
Women	1		1	
Classification ASA				
ASA ≥ 3	1.2 (0.4-3.3)	n.s.	2.0 (0.5-9.0)	n.s.
ASA < 3	1		1	
Endoscopic therapy				
Yes	1.9 (0.7-4.8)	n.s.	0.9 (0.2-4.5)	n.s.
No	1		1	

were higher than the doses for the colonoscopy. The poor number of patients included in this category may explain this controversy. Two randomized, controlled studies have been performed so far(29,30) to compare sedation with propofol versus sedation with combined midazolam and meperidine in patients > 80 years who underwent ERCP, double balloon enteroscopy or EUS. Though average doses of propofol in both studies (322 and 376 mg respectively) are higher than our dose (224 mg during EUS), complication rate is similarly poor and without severe consequences for the patient. Safe use of propofol is supported by these data. On the other hand, 2 other studies reported that complication rate in elderly patients was even lower(20,28). Thus, Heuss et al(28) reported 4.7% oxygen desaturation in patients > 85 years whereas Hourichi et al(20) reported 1.7% complication rate in patients > 90 years who underwent several endoscopic procedures. Both studies achieved moderate sedation so we can conclude that their doses were appreciably lower than our doses.

It could be argued that complication rate in patients $\geq$ 80 years is not higher than in younger patients because the dose of propofol was significantly lower in those patients. This fact is shared by several studies comparing elderly and young people(7,20,27,28,35,36). This hypothesis is supported by the fact that, as we have observed, dose increase is the only risk factor to develop complications in patients $\geq$ 80 years. Several studies confirm this hypothesis(6,7,37). However, we do not aim to show that elderly patients develop more complications than younger patients under the same dose of propofol. We used the required dose to achieve deep sedation (MOAA/S score of 1) and elderly patients achieved deep sedation with a lower dose. In fact, it has been proved that elderly patients require a lower dose of propofol to reach similar plasmatic levels to younger people(20,36). The absence of differences regarding the development of sedation-related complications might be explained by the fact that we selected a healthy subgroup of octogenarians. However, these patients showed even higher co-morbidity than younger ones, what is also reflected in the increase of the ASA classification of anesthetic risk according to other studies(27-29,38). Moreover, in our study, among the 355 patients who needed anesthesiologist supervision only 8.2% were $\geq$ 80 year old and the differences between these patients and those who were not octogenarians were not significant. On the other hand, the use of sedative drugs in elderly patients might be another hypothetical factor but we have not found differences between our groups of patients.

Elderly people underwent more endoscopic procedures not only because of the pathology detected but also because of the performance of palliative procedures. Nevertheless, we have not observed that ASA score and endoscopic therapy are associated with a higher incidence of sedation-related complications in elderly patients. Greater number of women in our study may reflect a higher prevalence of female in this age group in our en-

vironment. We have not observed that appearance of complications during continuous propofol sedation is influenced by sex.

In conclusion, continuous propofol infusion at a necessary dose to achieve deep sedation during endoscopic procedures in elderly patients $\geq$ 80 years is as safe as in younger patients.

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