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Original Article

A single dose of propofol can produce excellent sedation and comparable amnesia with midazolam in cystoscopic examination

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Abstract

BACKGROUND: In this study we compared the sedative and amnesic effects of propofol with midazolam in cystoscopy examination.

METHODS: This prospective clinical trial was done on 44 adults, with American Society of Anesthesiology physical status I, II, III, who were candidate for cystoscopic examination. Patients were recruited according to convenience sampling method and randomized into two equal groups. In study group, propofol plus fentanyl and in control group midazolam plus fentanyl were given intravenously. Vital signs and SaO_2, the number of patients movements, presence of eyelid movements and verbal contact all at the first and 10^{th} minutes after beginning the procedure were recorded. Also, frequency distributions of patients recalls, VAS (visual analog scale) for pain and VAS for satisfaction scores were evaluated in recovery room.

RESULTS: Frequency distribution of patients movements, frequency distribution of verbal contact and eyelid movements at the first and 10th minutes were higher in midazolam group ($P<0.05$). There were a lower VAS pain score and higher VAS satisfaction score in propofol group ($P = 0.009$ and $P = 0.041$ respectively).

CONCLUSIONS: Propofol was more effective than midazolam in inducing deep sedation and immobility in patients undergoing cystoscopy examination, without interfacing patients with additional danger.

KEYWORDS: Propofol, midazolam, cystoscopy.

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Adequate patient sedation is mandatory for most interventional endoscopic procedures [1]. Cystoscopy is one of the common and invasive diagnostic procedures of genitourinary tract diseases [2]. Local, regional, general anesthesia and various methods of intravenous sedation may be used to control pain and discomfort during these procedures [2]. Intravenous sedation with benzodiazepines is standard practice in the performance of interventional endoscopic procedures [1]. Midazolam is chosen frequently because it has potent amnesic properties, some anxiolytic effects and a short elimination half-life. However, the sedative and amnesic effects of benzodiazepines sometimes do not provide adequate patient comfort during endoscopic procedures [1,3-5]. Propofol also was applied to produce sedation in a few clinical situations [1,6,7]. It is a sedative-hypnotic agent, with a short duration of action and a more rapid recovery time (10-20 min) compared with the available benzodiazepines [1,8-10]. On the other hand, propofol is relatively expensive and may lead to cardiorespiratory depression when used in higher doses [11,12]. In this study, we compared desirable and undesirable effects of midazolam and propofol in cystoscopy examination.

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Methods

In a prospective clinical trial study, following approval of the scientific research committee in Isfahan University of Medical Sciences and getting informed consent, 44 adult (40-65 years) patients with American Society of Anesthesiology (ASA) physical status I, II and III, who were candidates of diagnostic cystoscopy procedure were selected according to convenience sampling method and randomized into two groups. Patients were excluded from the study if they had psychological problems, drugs or alcohol abuse, drugs allergies or pregnancy. Before beginning the procedure, we described visual analog scale (VAS) for pain score and VAS for satisfaction score for all patients. After connecting to standard monitor, baseline vital signs and arterial saturation of oxygen ($SąO_2$) were recorded and then sedation was induced with propofol, 0.75 mg/kg, plus fentanyl, 50 µg, in study group and midazolam, 3 mg, plus fentanyl, 50 µg, in control group intravenously. Doses of medications were selected according to sedative doses used in previous studies (2-4 mg for midazolam and 0.5-1.5 mg/kg for propofol) and also routine method of analgesia with midazolam in our center and a pilot study with 0.5 mg/kg, 0.75 mg/kg and 1 mg/kg dosages of propofol. When verbal contact and eyelid reflex were abolished, the surgeon was let to enter the cystoscope. Then, vital signs and SaO_2 at the first and 10^{th} minutes after beginning the examination were registered because: 1- entering the instrument is the most painful time and 1 minute after that was the best time to evaluate changes in vital signs and SaO_2;. 2- it was a short procedure, and since a single dose of both drugs were used then, the durations of actions of both were important in our study. Patients movements were recorded with two grades: without movement and with movement. Frequencies of eyelid movements and presence or absence of verbal contact at the first and 10^{th} minutes after beginning the procedure were recorded too. Any interventional airway maneuvers were recorded according to: use of face mask, insertion of airway and elevation of mandible**.** These measurements were designed according to second and third levels of standards and intents of sedation and analgesia (The Joint Commission on Accreditation of Health Care Organization. Standards and intents of sedation and analgesia). Patients recalls were measured with two grades: no recall and recall, in the recovery room. VAS for pain score and VAS for satisfaction score were evaluated in recovery room, when the patients were full awake and were able to respond to questioner. Data were analyzed using t-test and Chi-square test, where they were appropriate.

Results

In this research, 44 adult patients were studied. There were no statistical differences in age, weight, sex, ASA physical status and duration of examination between two groups (table 1). Baseline heart rate (HR), blood pressure (BP), respiratory rate (RR) and SaO_2 were comparable in the propofol and midazolam groups (table 1), but a statistically significant difference in 10^{th} minute mean arterial pressure was noted which was lower in propofol group (table 2). There were no statistical differences between two groups for overall interventional airway management. Frequency distribution of patients movements was higher in midazolam group (table 3). Eyelid movements and verbal contact were higher in midazolam group in the first and10th minutes after beginning the procedures (table 3). Numerical patients recalls were not significant between two groups (table 3). There were a lower VAS for pain score in propofol group (0.54 ± 0.80) versus that in midazolam group (2.04 ± 2.35) and higher VAS for patient's satisfaction score in propofol group (9.4 ± 0.79) comparing with midazolam group (8.2 ± 3.55) (P = 0.009 and P = 0.041, respectively).

Discussion

Propofol and midazolam are used extensively for both general anesthesia and sedation. Intravenous sedation with benzodiazepines is the standard practice in the performance of endoscopic procedures. Previous studies showed

Table 1. Patient characteristics and duration of examination.

	Propofol group	Midazolam group	P value
Age (year)	52.5 ± 8.98	52.0 ± 8.20	0.874
Weight (kg)	63.4 ± 15.38	62.6 ± 9.18	0.832
Sex (M/F)	12/10	12/10	1
Duration of examination (min)	16.8 ± 3.94	16.1 ± 2.14	0.481
SBP (mmHg)	135 ± 22.62	133.2 ± 21.90	0.788
DBP (mmHg)	84.1 ± 10.19	83.6 ± 11.35	0.890
MBP (mmHg)	101 ± 13.44	101 ± 14.56	0.998
Respiratory rate (per minute)	12.9 ± 1.35	13.4 ± 1.29	0.18
Hart rate (per minute)	79.95 ± 10.78	84.8 ± 8.65	0.11
SaO_2 (%)	96.5 ± 12.01	96.5 ± 1.87	0.878
ASA I/II/III (n)	13/7/2	16/4/2	0.569

The differences between both groups were not statistically significant.
SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, MBP: Mean Blood Pressure.

Table 2. Mean changes of vital sign 1 and 10 minute after beginning of cystoscopy.

Vital sign	Time	Midazolam	Propofol
Systolic blood pressure (mmHg)	1 minute	-4.5 ± 11.0	-11.9 ± 18.2
	10 minutes	-3.6 ± 11.7	-23.6 ± 7.3
Diastolic blood pressure (mmHg)	1 minute	-3.6 ± 9.1	-1.6 ± 5.2
	10 minutes	-5.2 ± 15.1	-6.6 ± 8.6
Mean blood pressure*	1 minute	-1.2 ± 8.6	-6.3 ± 11.0
	10 minutes	-2.1 ± 7.1	-13 ± 9.1
Respiratory rate (n)	1 minute	-2.1 ± 1.0	0.5 ± 1.2
	10 minutes	0.2 ± 1.1	0.4 ± 2.0
Heart rate (n)	1 minute	0.7 ± 6.4	0.1 ± 9.0
	10 minutes	0.8 ± 5.9	1.6 ± 9.3

*P ≤ 0.001

Table 3. Frequency distribution of airway intervention, patients movement, verbal contact, eyelid movement and patients recalls.

	Propofol group	Midazolam group	P value
Airway intervention			
Face mask	15	17	0.356
Insertion of airway	4	1	
Jaw thrust maneuver	3	4	
Patients movements	6 (27.3%)	12 (54.6%)	0.044
Verbal contact			
1 minute	6 (72.7%)	16 (72.7%)	0.003
10 minutes	11 (50%)	21 (95.5%)	0.001
Eyelid movements			
1 minute	6 (27.3%)	15 (68.2%)	0.007
10 minutes	9 (40.9%)	20 (90.9%)	0.001
Patients recalls	7 (31.8%)	10 (45.4%)	0.059

that sometimes benzodiazepine could not provide adequate amnesia and sedation during invasive intervention [1,3-5]. This study showed that propofol could produce better examination condition for cystoscopy corresponding to midazolam because of fewer patients movements during the procedure. Other studies also showed similar or better condition with propofol than midazolam [1,6]. This study also revealed that patient's pain score was lower and

patient's satisfaction score was higher in propofol group. Although propofol is a potent hypnotic agent with rapid onset and offset of sedation, it has more cardio-respiratory depressive effects than midazolam [11,12]. However, stability of vital signs and SaO_2 were comparable between two groups and the frequency of interventional airway managements such as insertion of airway and chin lift maneuver was not significantly higher in propofol group. Our findings were also consistent with Andrew et al study on children undergoing propofol sedation for MRI [13]. This study also demonstrated a reduction in BP and stability of HR in both groups. The reduction in BP in our study was in the same direction of Win et al study, but the finding about HR is different than that in latter study which could be due to patient's position and higher doses of drugs used in Win study [7]. According to latter study, propofol induces predominance of parasympathetic activity and midazolam induces predominance of sympathetic activity during conscious sedation [7]. We concluded that single dose of propofol can produce good sedation and examination condition and also comparable amnesia with midazolam in patients undergoing cystoscopy examination without interfacing patients with additional danger.

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