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Randomized Clinical Trial

Safety of applying midazolam-ketamine-propofol sedation combination under the supervision of endoscopy nurse with patient-controlled analgesia pump in colonoscopy

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Abstract**AIM**

To compare the results of midazolam-ketamine-propofol sedation performed by an endoscopy nurse and anaesthetist during colonoscopy in terms of patient satisfaction and safety.

METHODS

American Statistical Association (ASA) I - II 60 patients who underwent colonoscopy under sedation were randomly divided into two groups: sedation under the supervision of an anaesthetist (SSA) and sedation under the supervision of an endoscopy nurse (SSEN). Both groups were initially administered 1 mg midazolam, 50 mg ketamine and 30-50 mg propofol. Continuation of sedation was performed by the anaesthetist in the SSA

group and the nurse with a patient-controlled analgesia (PCA) pump in the SSEN group. The total propofol consumption, procedure duration, recovery times, pain using the visual analogue scale (VAS) and satisfaction score of the patients, and side effects were recorded. In addition, the patients were asked whether they remembered the procedure and whether they would prefer the same method in the case of re-endoscopy.

RESULTS

Total propofol consumption in the SSEN group was significantly higher ($P < 0.05$) than that in the SSA group. When the groups were compared in terms of VAS score, recovery time, patient satisfaction, recall of the procedure, re-preference for the same method in case of re-endoscopy, and side effects, there were no significant differences ($P > 0.05$) between the two groups. No long-term required intervention side effects were observed in either group.

CONCLUSION

Colonoscopy sedation in ASA I - II patients can be safely performed by an endoscopy nurse using PCA pump with the incidence of side effects and patient satisfaction levels similar to sedation under anaesthetist supervision.

Key words: Midazolam-ketamine-propofol combination; Patient-controlled analgesia pump; Nurse-administered sedation; Colonoscopy

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Core tip: Sedation is frequently performed during interventional procedures such as colonoscopy. In cases where there are not enough anaesthetists, there are a variety of sedation protocols that can be applied by educated non-anaesthesia personnel. In our study, we showed that midazolam-ketamine-propofol combination can be applied under the supervision of an endoscopy nurse.

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INTRODUCTION

Gastrointestinal endoscopy practices have been increasing worldwide. During colonoscopy, patients do not want to be awake because of severe abdominal pain, cramps and bloating, as well as embarrassment^[1]. The demand for sedation in colonoscopies is increasing because of the influence of image quality in colorectal

cancers and the increase in expectation of painless treatment of patients^[2].

A variety of sedation techniques are used during colonoscopy. Sedoanalgesia, deep sedation under the supervision of anaesthetist (SSA), sedation under the supervision of nurse, and computer-assisted sedation with target-controlled devices are among these techniques^[3]. Medications and applied techniques vary between clinics. The most commonly used agent is midazolam, either alone or in combination with an opioid (meperidine, fentanyl or alfentanil). The second most frequently used agent is propofol, which may be used alone or in combination with an opioid analgesic agent or midazolam^[2]. Propofol is a short-acting sedative agent without analgesic properties^[4]. Therefore, when propofol is used alone, high doses are required to tolerate some invasive procedures. This can lead to life-threatening conditions such as hypotension and respiratory depression^[5]. Adding opioids to propofol reduces the incidence of side effects and allows patients to feel less pain during the procedure. It also reduces propofol injection pain^[6]. Better results are obtained when propofol combined with ketamine, which provide dissociative anaesthesia^[7]. Both fentanyl and ketamine provide anaesthesia, analgesia, and anxiolysis. The delayed peak levels and prolonged duration of action of fentanyl are significant disadvantages. After intravenous administration, it reaches its peak level in 4-6 min, and its duration of action ends in 20-40 min. Ketamine also has a good safety profile with the advantage of preserving spontaneous breathing and protective airway reflexes^[8,9]. In our study, these features are important for sedation safety, since sedation is performed by non-anaesthesia personnel.

It is claimed that the application of propofol without an anaesthetist is dangerous. Even in the United States, the Food and Drug Administration recommends that the propofol should only be administered by trained anaesthesia personnel^[10,11]. However, a worldwide study has shown that no major complications occur in patients (less than 1% of 142863 patients)^[12]. The patient-controlled analgesia (PCA) pump was developed for postoperative pain control. In this regard, the patient applies his own pain medication according to his need. The PCA pump has been used with the same logic to provide sedation rather than analgesia in several studies. There are also studies where sedation applications have been performed under the supervision of a nurse or endoscopist using these pre-programmed devices^[13]. In this study, we aim to compare the application of midazolam-ketamine-propofol combination by endoscopy nurse with PCA pump and anaesthetist in terms of patient satisfaction, side effects and safety.

MATERIALS AND METHODS

After receiving the approval of the ethical committee

of the Medical School of Erciyes University and the informed consent of the patients, the study included the American Statistical Association (ASA) I - II 60 patients who underwent elective colonoscopy between 18 and 75 years of age. The study protocol was registered at ClinicalTrials.gov (NCT03607110, <https://clinicaltrials.gov/ct2/show/NCT03607110>). ASA III-IV-V patients who had uncontrolled chronic disease (uncontrolled diabetes mellitus and hypertension), severe respiratory and cardiopulmonary insufficiency or liver and kidney failure who did not accept the method were not included in the study. Patients with a history of long-term analgesic, opioid, and sedative use, with hypersensitivity to soybean oil or eggs, and drugs used in our study, with pregnancy or suspected pregnancy or lactating, and with the use of antipsychotic or antidepressant drugs were also excluded in the study.

Before the procedure, the group in which the patients were included was randomly determined by the endoscopy nurse. The patients were given a proper diet before the procedure, and intestinal cleansing was implemented. After 8 h of fasting, the peripheral vascular route was opened with a 20 G cannula, and 8 mL/kg/h crystalloid solution was administered. Prior to sedation, all patients were monitored for heart rate, mean arterial pressure, and peripheral oxygen saturation (SpO₂) measurements. All patients were given 5 L/min oxygen via nasal cannula. Colonoscopy was performed by two experienced endoscopists who were trained in the same centre on the same dates.

During the procedure, the monitored data and the cardiopulmonary side effects were recorded once a minute for the first 5-min period and once every 5 min in the next period. In the SSA group, the anaesthetist was at the patient's bedside. A total of two nurses, one trained for sedation and the other who assisted the endoscopist during the colonoscopy, were present in the supervision of endoscopy nurse (SSEN) group. The sedation-trained nurse was informed about possible side effects during the procedure such as desaturation (< 90%), hypotension (systolic < 90 mmHg), and bradycardia (< 50) and was also trained to perform the necessary interventions (such as jaw-thrust and head tilt chin lift manoeuvres or using oropharyngeal airway in case of desaturation or atropine administration in case of bradycardia or 250 cc of fluid loading in case of hypotension). If hypotension continued, 5-10 mg intravenous ephedrine was administered. In cases where peripheral oxygen saturation did not increase or continued to decline (below 85), the anaesthetist would intervene. In the case of long-term desaturation, the materials required for emergency airway management (bag mask ventilation, intubation, etc.) were available in the endoscopy room to provide respiratory support. The anaesthetist was not at the patient's bedside in the SSA group. However, the anaesthetist was ready in the endoscopy unit for intervention in emergency situations such as intubation and cardiopulmonary resuscitation.

Sedation protocol: Both groups were initially administered 1 mg midazolam, 50 mg ketamine, and 30-50 mg propofol (30 mg in patients over 65 years old and 50 mg in patients under 65 years old). Afterwards, the propofol required for the SSA group was determined and administered by the anaesthetist to provide adequate sedation and patient comfort. For the SSEN group, sedation was continued by the endoscopy nurse using a PCA pump (Accumate 1100; Woo Young Medical, Seoul, Korea). Each time the endoscopy nurse pressed the PCA pump according to the patient's clinical response or tolerance, the patient was administered 10-20 mg propofol (10 mg in patients over 65 years old, 20 mg in patients under 65 years) with a delay of about 10-20 s. At the end of the procedure, the total drug consumption, procedure duration, and patient eye opening/recovery times were recorded.

Patient Satisfaction: Patients were monitored until the Aldrete Recovery Score (ARS) was ≥ 9 . Patients with ARS ≥ 9 were transferred to another eligible unit. To evaluate patient satisfaction, the patients were asked questions about the procedure. A visual analogue scale (VAS) was used to evaluate the pain after the procedure. Patients were asked to rate their pain on a scale of 0-10, where 0 meant "no pain" and 10 meant "worst imaginable pain".

Patients were also questioned about whether they remembered the operation and side effects. Side effects such as hypotension, bradycardia and desaturation, which require serious and rapid intervention, and frequently encountered side effects such as nausea, vomiting, and headache, which may adversely affect patient satisfaction, were included in the patient follow-up form. In addition to these side effects, the endoscopy nurse was informed about complications related to ketamine, such as emergence reactions, hypertension, tachycardia, visual hallucinations, vivid dreams, tonic-clonic movements, diplopia, and nystagmus. However, these side effects were not separately listed on the patient follow-up form, but were instead included under the title of other side effects. In addition, patient satisfaction was determined by a four-point satisfaction score (1 very good, 2 good, 3 not bad, 4 bad). Two days after the procedure, the patients were asked whether they would prefer the same method again in the case of a repeat endoscopy, and their answers were recorded. Patients were questioned for possible delayed side effects when they were contacted 2 d after the colonoscopy to determine method preference.

Statistical methods

Mean, standard deviation (SD), median, minimum, maximum, frequency, and ratio values were used in the descriptive statistics of the data. The distribution of the variables was measured by the Kolmogorov-Smirnov test. A Mann-Whitney *U* test was utilized in the analysis of quantitative independent data. A chi-square test was employed to analyse qualitative independent data, and

Table 1 Patient demographic data, *n* (%)

		Endoscopy Nurse		Anaesthetist		<i>P</i>
		mean ± SD	Median	mean ± SD	Median	
Age		53.6 ± 15.5	57.5	59.9 ± 11.8	62.0	0.113 ¹
Sex	Female	18 (60.0)		17 (56.7)		0.793 ²
	Male	12 (40.0)		13 (43.3)		
ASA	I	18 (60.0)		11 (36.7)		0.071 ²
	II	12 (40.0)		19 (63.3)		

¹Mann-Whitney *U* test; ²Chi-square test. ASA: American statistical association.

Table 2 Propofol consumption, durations (reaching the cecum, operation, and recovery), patient satisfaction, operation re-preference, and recall of the procedure, *n* (%)

		Endoscopy Nurse		Anaesthetist		<i>P</i>
		mean ± SD	Median	mean ± SD	Median	
Propofol consumption dose		83.0 ± 57.1	70.0	59.7 ± 17.5	50.0	0.014 ¹
Reaching the cecum (min)		5.8 ± 4.9	5.5	4.9 ± 2.2	4.0	0.004 ¹
Total operation (min)		13.7 ± 7.2	13.0	9.5 ± 3.6	8.5	0.022 ¹
Eye opening/Recovery (min)		1.6 ± 1.2	1.0	2.0 ± 0.8	2.0	1.000 ¹
VAS		0.5 ± 0.8	0.0	0.5 ± 0.9	0.0	0.803 ¹
Patient Satisfaction	Very good	19 (63.3)		12 (40.0)		0.098 ²
	Good	10 (33.3)		13 (43.3)		
	Not bad	1 (3.3)		5 (16.7)		
	Bad	0 (0)		0 (0)		
Operation re-preference		30 (100.0)		28 (93.3)		0.492 ²
Recall of the procedure	(-)	27 (90.0)		27 (90.0)		1.000 ²
	(+)	3 (10.0)		3 (10.0)		

¹Mann-Whitney *U* test; ²Chi-square test. VAS: Visual analogue scale.

a Fischer test was used when chi-square test conditions were not met. In all analyses, $P < 0.05$ was considered statistically significant. SPSS 22.0 software was used for the analyses.

RESULTS

There was no significant difference ($P > 0.05$) between the SSA and SSEN groups in terms of demographic data such as age, gender distribution, and ASA distribution. Patient demographic data is given in Table 1.

The total propofol used in the SSEN group was significantly higher ($P < 0.05$) than in the SSA group. Reaching the cecum and total procedure time in the SSEN group was significantly higher ($P < 0.05$) than in the SSA group (Table 2).

When patients were asked about their satisfaction, one patient in the SSEN group and five patients in the SSA group expressed their satisfaction as "not bad", while the rest of the patients expressed their satisfaction as "good" or "very good". In each groups, three patients said that they remembered the procedure. All patients in both groups, except for two patients in the SSA group, stated that they would prefer the same method for the second time. However, when the groups were compared in terms of patient satisfaction, recall of the procedure, and preferring the same method in the case of repeat endoscopy, there was no significant difference ($P > 0.05$) between the two groups (Table 2).

Patient pain was evaluated by VAS score after the

procedure. The highest recorded VAS value was 4, and only one patient in each group had a VAS score of 4. The mean VAS score in each group was 1. Recovery times were also similar between the two groups. There was no statistically significant difference ($P > 0.05$) between the two groups in terms of VAS score or recovery time.

The two groups were also compared in terms of hemodynamic parameters recorded during the procedure. Pulse values taken at the baseline, first minute, second minute, third minute, fourth minute, fifth minute, eighth minute, and afterwards did not significantly differ between the two groups ($P > 0.05$). While the systolic and diastolic pressure values of the SSA and SSEN groups did not significantly differ ($P > 0.05$) at baseline or the first, second, third, or fourth minute, the systolic and diastolic pressure values were significantly lower ($P < 0.05$) in the SSEN group compared to the SSA group in the fifth and eighth minutes, and afterwards. SpO₂ values for the baseline and first minute were significantly higher in the SSEN group compared to the SSA group ($P < 0.05$). There was no significant ($P > 0.05$) difference in SpO₂ values for the second, third, fourth, or eighth minute or afterwards between the two groups (Table 3).

The groups were also compared in terms of side effects that might occur during the procedure. In each groups, hypotension and headache occurred in two patients. Bradycardia was observed in only one patient in the SSEN group. When the groups were compared in

Table 3 Hemodynamic changes during the procedure

		Endoscopy Nurse		Anaesthetist		P ¹
		mean ± SD	Median	mean ± SD	Median	
Pulse (beats per minute)	Baseline	82.8 ± 13.3	82.5	84.2 ± 11.7	85.5	0.673
	1 st min	81.4 ± 13.3	79.0	85.7 ± 14.6	84.0	0.251
	2 nd min	80.9 ± 13.8	79.0	83.5 ± 17.9	81.0	0.716
	3 rd min	80.8 ± 13.5	79.0	80.7 ± 19.2	79.5	0.704
	4 th min	81.0 ± 15.3	80.0	80.1 ± 18.5	77.5	0.665
	5 th min	81.9 ± 14.6	81.0	80.5 ± 18.8	78.0	0.414
Systolic blood pressure (mmHg)	≥ 8 th min	81.1 ± 14.7	78.5	77.5 ± 14.4	75.0	0.336
	Baseline	131.0 ± 20.5	131.5	136.1 ± 22.3	135.0	0.412
	1 st min	126.2 ± 17.6	121.0	129.9 ± 19.4	132.5	0.579
	2 nd min	124.2 ± 13.6	125.0	125.7 ± 29.5	121.5	0.519
	3 rd min	123.4 ± 13.9	122.0	126.5 ± 27.9	123.0	0.952
	4 th min	126.5 ± 15.9	125.0	131.8 ± 30.3	129.5	0.448
Diastolic blood pressure (mmHg)	5 th min	123.8 ± 13.4	122.0	139.3 ± 28.7	141.0	0.014
	≥ 8 th min	124.1 ± 17.2	120.5	142.3 ± 26.7	141.0	0.003
	Baseline	73.2 ± 12.3	70.5	73.4 ± 13.4	74.0	0.871
	1 st min	70.6 ± 10.2	69.5	74.7 ± 14.0	74.0	0.183
	2 nd min	71.1 ± 11.1	71.0	72.9 ± 18.3	69.0	0.988
	3 rd min	71.2 ± 11.1	70.0	76.3 ± 18.2	75.5	0.359
SpO ₂	4 th min	72.8 ± 11.1	72.0	78.7 ± 17.9	80.5	0.175
	5 th min	69.2 ± 11.5	69.5	81.9 ± 17.2	82.0	0.002
	≥ 8 th min	73.2 ± 11.8	70.5	83.4 ± 16.8	82.0	0.005
	Baseline	96.7 ± 1.9	97.0	94.4 ± 2.7	94.0	0.000
	1 st min	96.0 ± 2.8	97.0	94.7 ± 2.4	95.0	0.014
	2 nd min	96.5 ± 3.5	97.0	95.3 ± 2.2	95.5	0.071
	3 rd min	96.2 ± 2.8	97.0	95.9 ± 2.0	95.5	0.307
	4 th min	96.4 ± 2.3	97.0	96.3 ± 1.9	96.0	0.502
	5 th min	95.1 ± 5.3	97.0	96.1 ± 1.7	96.0	0.685
	≥ 8 th min	96.1 ± 2.3	97.0	96.0 ± 1.4	96.0	0.422

¹Mann-Whitney *U* test.

terms of desaturation, four patients in the SSEN group and one patient in the SSA group had desaturation. Nausea and vomiting were not seen in either group. However, there was no statistically significant difference ($P > 0.05$) between the two groups (Table 4).

DISCUSSION

In the majority of developed countries, various sedation applications are used for endoscopic procedures in low-risk patients. When we examined the agents used for analgesia and sedation in endoscopic procedures over time, meperidine was first used as an analgesic, followed by extensive use of a meperidine-diazepam combination. This often preferred combination is accepted as a traditional sedation method. Later, midazolam was preferred in endoscopy sedation because of its shorter duration of action and higher efficacy than diazepam. A few years after midazolam, the ultra-short acting hypnotic agent propofol started to be used^[2].

Propofol sedation is becoming more popular due to its features, such as pain relief during endoscopy and the ability to have a quick recovery time^[3]. However, it is controversial whether propofol should be applied by anaesthesia personnel or educated non-anaesthesia personnel. In European and American guidelines, it is stated that sedation applied by non-anaesthesia personnel should be applied only in low-risk patients

and that sedation personnel should be qualified to rescue patients from any level of sedation, including general anaesthesia^[14]. However, it has been shown in various studies that sedation performed by non-anaesthesia personnel can be safely performed as long as it is performed by educated personnel^[15-18]. Walker *et al*^[19] showed that sedation performed by non-anaesthesia personnel during colonoscopy can be applied more easily and with lower risk than esophago-gastroduodenoscopy. In a study/review by Rex *et al*^[16], records of sedation applications performed by non-anaesthesia personnel from various centres around the world have been reviewed and evaluated. In this review/study involving 646080 patients, only 11 cases of emergency endotracheal intubation and four deaths were reported.

In guidelines for propofol administration of non-anaesthesia personnel, it has been stated that ASA III or higher patient procedures, long complex procedures, and difficult airway conditions require an anaesthetic personnel^[14,20]. In our study, only ASA I - II patients were included in the study. There are a variety of studies on sedation applications without anaesthesia personnel in colonoscopy patients. Patient-controlled sedation (PCS) studies were conducted in which the patient determined his/her own sedation level with PCA pump^[13,21]. In this method, the patients press the button when they feel uncomfortable. A certain

Table 4 Side effects experienced by patients during the procedure, *n* (%)

		Endoscopy Nurse	Anaesthetist	<i>P</i> ¹
Cardio pulmonary	Hypotension	2 (6.7)	2 (6.7)	1.000
	Bradycardia	1 (3.3)	0 (0.0)	1.000
	Desaturation	4 (13.3)	1 (3.3)	0.161
Other side effects	Nausea and Vomiting	0 (0.0)	0 (0.0)	1.000
	Headache	2 (6.7)	2 (6.7)	1.000

¹Chi-square test.

period of time passes until they are sedated. In these studies, it is mentioned that patients suffer from pain, although not severe. Feeling pain and time to become sedated may cause patients to opt out of the method. For this reason, SSEN sedation practices have rapidly increased in recent years. Several studies have shown that SSEN sedation and colonoscopy practices are safe and effective^[19,22,23]. A study comparing PCS with SSEN showed that many patients prefer SSEN instead of PCS because of the anxiety they feel^[24]. After this study, we also recommend SSEN instead of PCS. We applied propofol with the PCA pump to reduce human-caused mistakes. The PCA pump allows us to easily and repeatedly dispense the right dose of medicine without requiring our attention.

In the study by Poon *et al.*^[25], it was found that SSEN with PCA pump was effective and safe in healthy individuals undergoing colonoscopy. In another study by Liu *et al.*^[26], while a group was administered propofol-alfentanil via SSEN with PCA pump, opioid-benzodiazepine was administered to the other group by an anaesthetist. As a result of the study, there was no significant difference between groups in terms of side effects, pain scores, and the willingness to repeat the colonoscopy with the same sedation method. In the SSEN group, it was stated that only deeper sedation was obtained. Since two sets of sedation protocols were applied, it was thought that this situation was caused by the difference in drug combinations used rather than the SSEN method.

In a sedation protocol, the total amount of drug used is reduced due to the synergistic effect of drugs on each other formed by adding adjuvant drugs in addition to propofol^[6]. Total doses of propofol used in previous studies ranged from 124 to 188 mg^[19,25-28]. Lower levels of propofol were used in studies where propofol was used in combination with other medicines^[25,26] when compared studies where propofol alone used^[19,27,28]. In our study, propofol consumption decreased, as expected, when used in combination with ketamine, which provides analgesia and dissociative anaesthesia, and midazolam, which has amnesic and sedative properties. The total amount of propofol used in both groups was significantly lower than previous studies in which the SSEN method was applied. Propofol consumption in the SSEN group and SSA group was 83.0 ± 57.1 , 59.7 ± 17.5 respectively. In our study,

propofol consumption was significantly higher in the SSEN group. The reason for this significant difference in propofol consumption was thought to be the longer duration of the procedure in the SSEN group. The duration of the procedure was significantly higher in the SSEN group than in the SSA group. The endoscopist stated that the two sedation methods did not affect the difficulty of operation. Therefore, this difference may be due to the small number of patients or the fact that the procedure was performed by two different endoscopists.

Cardiovascular and respiratory depression can be observed during sedation. Our most important goal during colonoscopy sedation is to ensure patient safety and comfort. For this reason, we aimed to have less cardiovascular and respiratory side effects by using lower doses of propofol with a combined sedation protocol. Propofol does not have any analgesic activity. However, it has a synergistic effect when used with analgesic agents^[29]. In a study by Hsu *et al.*^[30], one patient group underwent gastrointestinal endoscopy with propofol alone and the other group with propofol-midazolam-fentanyl combination. As a result, the propofol alone group had higher total propofol consumption and incidence of hypotension; the recovery time of this group was also longer. Some clinicians avoid propofol administration without an anaesthetist because of the absence of a propofol antidote in a possible cardiopulmonary complication. However, the short duration of the propofol balances this negative feature. In our study, we did not observe serious long-term side effects in any of the patients. All of the cardiopulmonary side effects that occurred ended quickly (less than 30 s) without the need for intervention. Of course, a much safer SSEN application can be achieved when the patient is closely followed up and the sedation practitioner is trained in cardiopulmonary resuscitation. Only low-risk patients with ASA I - II were included in our study, but Heuss *et al.*^[31] showed that propofol can be safely applied in gastrointestinal endoscopy even in high-risk patients. They stated that these patients should be more closely monitored in terms of desaturation and that propofol use in these patients would be appropriate at doses of 10%-20% lower than in ASA I - II patients.

Complications such as emergence reactions, hypertension, tachycardia, visual hallucinations, vivid dreams, tonic-clonic movements, diplopia, nystagmus,

increased intracranial pressure, and increased intra-ocular pressure are among the complications associated with ketamine^[32]. Even 24 h after application, side effects such as severe confusion, hallucinations, unusual thoughts, or extreme fear can be seen^[33]. In our study, nausea, vomiting, and agitation were possible side effects due to ketamine in the sedation protocol, but we did not observe these in any of the patients in either group^[34]. The use of ketamine in combination with low doses of propofol and midazolam may have reduced the incidence of side effects. Guit *et al*^[35] showed that ketamine-related side effects are reduced when ketamine is combined with propofol.

In our study, several questions were asked to patients to determine patient satisfaction, which is one of our primary goals. There was no significant difference between the groups in terms of patient satisfaction score and re-preference for the same sedation method in case of repeated endoscopy. All of the patients in the SSEN group and 93.3% of the patients in the SSA group stated that they would prefer the same sedation method in the case of repeat endoscopy. Similarly, Poon *et al* reported that 92% of patients would prefer the same sedation method in a new endoscopy procedure^[25]. One of the questions asked to evaluate patient satisfaction is whether the patient remembered the operation. There was no significant difference between the groups in terms of recall of the procedure. Adequate sedation and pain control provide a comfortable and successful colonoscopy. When the pain status of the patients was questioned, 96.6% of the patients in the SSEN group and 86.6% of the patients in the SSA group were found to have a VAS below 1. Liu *et al*^[26] also compared the two sedation methods under the supervision of an anaesthetist/nurse using PCA pump. In their study, there was no significant difference between the groups in terms of patient satisfaction and VAS values.

In conclusion, our study demonstrated that the combination of midazolam-ketamine-propofol could be administered under the supervision of an anaesthetist or an endoscopy nurse with a PCA device in colonoscopy sedation of low-risk (ASA I - II) patients with similar side effects. There is a need for further studies with ASA III -IV patients and also with more patients.

A small sample size of ASA I - II patients with low cardiovascular risk was included in the study. The expected incidence of adverse events is less than 0.01%, and studies with a small sample size may reduce this rate.

ARTICLE HIGHLIGHTS

Research background

Sedation is performed in many centres during the colonoscopy procedure. However, since there are a limited number of anaesthesiologists, there are centres where colonoscopy is performed without sedation. In the literature, there are several studies in which colonoscopy sedation is performed without anaesthesia personnel. In this study, we aim to evaluate the patient satisfaction and the side effects of colonoscopy sedation performed by endoscopy nurse

with patient-controlled analgesia (PCA) pump.

Research motivation

In studies where colonoscopy sedation is performed under the supervision of a nurse, propofol is often used alone or in combination with agents such as fentanyl, meperidine or midazolam. Ketamine, which protects spontaneous breathing and protective airway reflexes by providing dissociative anaesthesia, is not used in adult colonoscopy patients. In our study, we wanted to determine the advantages and disadvantages of ketamine in combination with propofol and midazolam without anaesthesia personnel during colonoscopy.

Research objectives

It is aimed to perform ketamine-midazolam-propofol sedation with minimum side effects and to obtain the best patient satisfaction under the supervision of a nurse in low-risk colonoscopy patients. Individual dose errors were minimized by using a PCA pump.

Research methods

Sixty American Statistical Association (ASA) I - II patients who underwent colonoscopy were included in the study. Patients were randomly divided into two groups [sedation under the supervision of anaesthetist (SSA) and sedation under the supervision of endoscopy nurse (SSEN)]. Both groups were initially administered 1 mg midazolam, 50 mg ketamine, and 30-50 mg propofol. The required dose of propofol in the SSA group was then determined and administered by the anaesthesiologist. In the SSEN group, the continuation of sedation was carried out by the nurse with PCA pump. Data such as patient satisfaction, incidence of side effects, total drug consumption, and procedure duration were recorded, and differences among the groups were evaluated.

Research results

There were no statistically significant differences ($P > 0.05$) between the two groups in terms of patient satisfaction, the rate of re-preference for the same method in case of repeat endoscopy, and the side effects. Total propofol consumption in the SSEN group was significantly higher ($P < 0.05$), whereas the systolic and diastolic pressure values were significantly lower ($P < 0.05$) at 5 min and after 8 min. Reaching the cecum and total procedure time were significantly longer ($P < 0.05$) in the SSEN group. There were no significant prolonged side effects in either group.

Research conclusions

In ASA I-II patients, sedation under the supervision of nurses with PCA pump in colonoscopy has similar side effects and patient satisfaction levels as sedation under SSA.

Research perspectives

There is a need for further studies with ASA III-IV patients and also with more patients.

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