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- Falta el anexo 1 que menciona el texto y que sí aportan en la versión en español.

OR 5713 inglés

Effectiveness and safety of gastrointestinal endoscopy during a specific sedation training program for non-anesthesiologists

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ABSTRACT

Introduction: sedation is a key component for the improvement of sedation quality. A correct administration requires appropriate training. We performed a study to compare sedation effectiveness, safety and patient satisfaction when administered by gastroenterologists, with and without specific training.

Methods: a training program enrolled a group of gastroenterologists (trained group, n = 4) and their results were compared to those from a non-trained group (n = 3). ASA 1-3 patients who had undergone sedation by a gastroenterologist using midazolam and fentanyl were included over a period of 30 months. Safety was assessed in terms of

the complication rate, effectiveness was assessed via the rate of completed endoscopic procedures and patient satisfaction was evaluated via a phone interview the day after the procedure.

Results: a total of 3,475 patients were sedated by gastroenterologists during the study period. Significant differences were found that favored the trained group for completed procedures (5.6% *vs* 8.9%). A lower rate of excessive sedation (1.3% *vs* 8.61%), hypoxemia (0.72% *vs* 2.49%) and post-procedural pain (1.8% *vs* 4.3%) were also achieved. Patient satisfaction surpassed 99.5% and there were no significant differences between groups.

Conclusions: our sedation training program improved the effectiveness and safety outcomes when compared to sedation administered by gastroenterologists without this specific training.

Key words: Endoscopy. Gastroenterology. Sedation. Training.

INTRODUCTION

The number and complexity of endoscopic procedures, as well as concern with regard to quality and safety have steadily increased over the past few years (1-4). Sedation is a key component for maximum quality (4-11), particularly given the number of patients with no underlying conditions who undergo gastrointestinal endoscopy, which has a considerable reported risk of sedation-related adverse events (12,13). Recommendations have been issued with regard to the necessary training that doctors and nurses should receive in order to provide sedation during gastrointestinal endoscopy safety, with an improved patient satisfaction (6,14-16). In Spain, sedation training is provided for non-anesthesiologists during their internship under the supervision of an endoscopy specialist, with no anesthesiologist present.

While sedation with propofol has become widespread (17), a combination of benzodiazepine and opioid remains the regimen of choice amongst non-anesthesiologists (7). Many studies have assessed sedation with benzodiazepines and opiates, either alone or in combination. However, there are few studies that deal with specific sedation training for nurses or gastroenterologists (18,19). This is also the case

for the comparison of sedation with propofol by anesthesiologists and non-anesthesiologists (20,21). As with many authors and professional associations (6,10,22,23), we think that appropriate training reduces sedation-related adverse events and improves patient satisfaction. Our hypothesis is that adequate training will improve clinical outcome. The goal of this study was to compare the effectiveness and safety of sedation, as well as patient satisfaction when administered by gastroenterologists, with and without specific training.

METHODS

This retrospective observational study was performed in compliance with the Declaration of Helsinki. All participants provided their informed consent in writing. The study was carried out at the Hospital Povisa, in Vigo (Galicia, Spain), which has 450 beds, 12 operating suites and three endoscopy rooms with seven gastroenterologists and 30 anesthesiologists.

Patients

The study enrolled all patients sedated for elective or emergency gastroscopy and/or colonoscopy over a 30 month period, starting in February 2010. Patients were enrolled by their reference endoscopist. High-risk subjects were assigned to anesthesiologist-administered sedation and low-risk subjects were assigned to gastroenterologist-directed sedation with midazolam and/or fentanyl (Fig. 1). The following patients are managed by anesthesiologists according to our protocol: ASA 4 cases, prior intolerance of an endoscopic procedure with moderate sedation, a history of adverse reactions to anesthesia or allergies to benzodiazepines or opioids, unfavorable anatomy (Mallampati class IV, significantly limited neck mobility or oral aperture < 3 cm) and the inability to understand the endoscopy procedure or a scheduled complex/therapeutic endoscopic procedure (bands, polypectomy, etc.). Endoscopy-related sedation was administered by a gastroenterologist with the help of a nurse who was exclusively responsible for patient monitoring and drug administration as instructed. All patients received supplementary oxygen.

Training course

A course on sedation for patients undergoing digestive endoscopy using midazolam and fentanyl as sedatives was given before study onset. All seven gastroenterologists were split up into two groups according to whether they had completed the course or not, that is, trained group (n = 4) and non-trained group (n = 3). The four trained endoscopists were the first to accept our invitation. None of the seven gastroenterologists had attended any specific courses on sedation that could have a potential impact on the results of the study. All participant physicians were instructed on the use of the study software, patient screening criteria and target sedation levels.

The sedation training course for gastroenterologists and patient-monitoring nurses included both theoretical and practical assignments (6). Theoretical training included the use and interpretation of a sedation scale. A description of sedatives (midazolam and fentanyl) and their antagonists (flumazenil and naloxone) was provided (emphasizing the repeated administration of low-dose anesthetics to reach appropriate sedation levels), including pharmacokinetic data and drug-drug interactions. Training in pre-sedation assessment was also included. Gastroenterologists were trained in airway assessment. Other aspects included monitoring criteria, hypoventilation clinical signs, electrocardiography and heart rate monitoring. Practical and theoretical assignments included instructions on airway opening and the use of supraglottic airway devices. Furthermore, a theoretical and practical module on cardiopulmonary resuscitation was also given, which included the use of a defibrillator. Practical cases were resolved using a patient simulator that mimicked real-life scenarios and provided expertise to respond to serious complications such as hypoxemia, hypotension and advanced airway management. Finally, practical cases also included actual sedated patients, under the supervision of anesthesiologists.

Sedation protocol

The sedative agents, midazolam and fentanyl, were selected due to their safety profile and antidote availability, even though in our study antidote use would entail an inappropriate sedation depth. Propofol was not accepted according to the prescription

specifications of the drug. The initial dose of midazolam was 2-2.5 mg, with an adjustment dose of 1 mg and a reduction of 50% in patients older than 60 years of age. Fentanyl was used for supplementary analgesia at a dose of 1-2 μg kg^{-1}. Naloxone was used as an opioid antagonist at 0.1-0.2 mg by an intravenous route. Flumazenil, a benzodiazepine antagonist, was administered at a dose of 0.2 mg/15 seconds, with additional 0.1-mg doses (maximum 1 mg). Common antagonist use was considered as off-protocol.

Sedation levels were defined by the European Society of Anesthesiology (10), previously used in similar studies (24) (level 1: fully awake; level 2: somnolence; level 3: apparently asleep but responding to verbal stimuli; level 4: apparently asleep but responding to strong physical stimuli; level 5: asleep, comatose, not responding to physical stimuli). Our sedation target was level 3.

Data collection

A software application was developed for pre-sedation assessment (including an electronic clinical decision aid) to ensure that all gastroenterologists followed one protocol for patient assignment. This software indicated whether sedation was administered by a gastroenterologist or must be performed by an anesthesiologist. However, the decision of the physician was final.

All data were recorded in a computer system that captured electronically monitored parameters (electrocardiogram, pulse oximetry, respiratory rate and blood pressure) and secured manual data entry using warnings for the required missing fields. A checklist (25), recordings of sedation level every five minutes and a control list for specific adverse events that was completed before discharge to the recovery room were also included. Pain was scored using the Keele's scale (0: none, 1: mild, 2: moderate, 3: severe; and 4: unbearable) (26) and recovery was assessed using a modified Aldrete's scoring system (Aldrete score ≥ 9 required for discharge).

Adverse events were identified based on automated data recordings by the monitors and incidents collected by adverse event checklists. Data with regard to patient comfort throughout the procedure, adverse events within 24 hours after discharge and overall patient satisfaction were collected via a telephone follow-up interview on the

day after discharge.

Outcome variables

The following variables were used:

Effectiveness: colonoscopy was considered as complete when cecal intubation or the foreseen target were reached. Gastroscopy was considered as complete when the second/third portion of the duodenum or the foreseen target were reached (27,28).

Safety: adverse events occurred during endoscopy or within 24 hours after the procedure were classified, as shown in annex 1.

Satisfaction: overall satisfaction was assessed on a modified five-point Likert scale (29), commonly used in the outpatient surgery suite of our hospital.

Statistical analysis

Quantitative variables are expressed as the median and interquartile range; variables did not meet the Shapiro-Wilk test of normality or Levene's test of homoscedasticity. Qualitative variables are expressed as a number and percentage. Continuous or discrete non-categorical variables were compared using the Wilcoxon's test and categorical variables were compared using the Chi-square or Fisher's exact tests.

A propensity score was estimated to coincide with several baseline characteristics (gastroscopy yield, smoker status, heart valve disease, age, sex and body mass index) in the patients assigned to the trained *versus* untrained gastroenterologist groups. Distributions for each group (31) are shown as violin plots (density) superimposed on boxplots.

After applying the Benjamini and Yekutieli penalization method for multiple testing (32,33), a p-value < 0.0031 was considered as statistically significant. All statistical analyses were performed using the SPSS for Windows version 20 (IBM Corp., Armonk, NY, USA) or R 3.0.1 (201, R Development Core Team, Vienna, Austria) package.

RESULTS

During the study period, 3,475 patients were sedated by gastroenterologists, 2,070 in the trained arm and 1,405 in the non-trained arm (Fig. 1). Both groups had similar

baseline characteristics (Table 1). Significant differences were found between the groups in terms of drug administration (number of doses and doses/boluses), as shown in figure 2. The trained group used significantly lower doses per bolus and a higher number of boluses. With regard to fentanyl, the differences in the total dosage between both groups of gastroenterologists were not statistically significant (Fig. 2). With regard to effectiveness, the trained group had a lower number of incomplete procedures, which was statistically significant (5.6% *vs* 8.9%, $p < 0.001$) (34). When procedure discontinuation causes were analyzed individually, significant differences that favored the trained group were only found for the "inadequate sedation" (item 2.3% *vs* 6.7%, $p < 0.001$) (Table 2).

Statistically significant differences were only found for three aspects related with complications. Firstly, the trained group had a lower excessive sedation rate (1.3% *vs* 8.61%, $p < 0.001$) (Table 2) and required flumazenil less frequently (0.4% *vs* 7.5%, $p < 0.001$). Secondly, significant differences that favored the trained group were found with regard to the incidence of hypoxemia (0.72% *vs* 2.49%, $p < 0.001$). Thirdly, the incidence of pain upon endoscopy completion was very low (2.8% during the stay in the recovery room) and pain rates were also lower in the trained-group, which was statistically significant (1.8% *vs* 4.3%, $p < 0.001$). There was also a significantly lower use of painkillers among patients sedated by the trained group (2.8% *vs* 5.3%, $p < 0.001$). However, no significant differences were found between the groups with regard to discomfort within 24 hours following endoscopy according to the follow-up phone call the day after the procedure (23.6% *vs* 25.2%). With regard to satisfaction, there were no significant differences in the proportion of patients who regarded themselves as "very satisfied" (84.6% *vs* 83.9%) or "satisfied" (15.1% *vs* 15.6%).

DISCUSSION

The effectiveness of a sedation training program for non-anesthesiologists which aimed to improve digestive endoscopy-related sedation outcomes was assessed. Our findings identified differences that favored the trained group, with positive effects both on effectiveness and safety.

In terms of effectiveness, the rate of completed procedures was satisfactory at 90.9%. The success rate was 93.1% when cases with poor bowel preparation (2) or colitis (27) were excluded. Furthermore, the success rate in the trained group was 94.4%, which was significantly higher than that in the non-trained arm. Overall, incomplete procedure rates in both groups closely approached acceptable figures (34), even when bearing in mind that colon cancer screening programs recommend a colonoscopy completion rate of 95% (2,27,28). In addition, there were no significant differences in endoscopy discontinuation causes, which indirectly points to a technical consistency between both groups and would prevent a bias in the study, with the exception of "inadequate sedation", which is the focus of the sedation program. Furthermore, there were differences that favored the trained group (2.3% *vs* 6.7%; $p < 0.001$).

With regard to the procedure safety analysis, we believe that the use of lower, more frequently repeated doses of sedatives led to a decrease in the number of excessive sedations, i.e., a sedation level > 3, which was 1.2% for the trained group *vs* 8.3% for the non-trained group ($p < 0.001$) (Table 2). However, most published studies define excessive sedation based on the development of adverse events. These results are better than those reported by the study of Patel et al. (35) which also used midazolam and opioids and the incidence of undesired deep sedations was 26% for upper endoscopies and 11% for colonoscopies.

The most common adverse events included tachycardia (11.68%), hypertension (11.45%), bradycardia (6.35%) and hypotension (5.23%, and there were no differences between groups. Our results are higher than those of the study by Agostoni et al. (8), who reported rates of 1.78% for hypotension, 1.16% for bradycardia and 0.39% for hypertension. This higher rate of tachycardia and hypertension is accounted for by a greater sympathetic nervous response when the sedation level is limited (mild-moderate sedation). Respiratory adverse events were rare in our study. The hypoxemia rate was low, which we associated with a restricted sedation level (level 3) that ensured spontaneous ventilation in low-risk patients, with consistent oxygen administration in all cases. However, some studies report a high rate of hypoxemia in patients sedated with midazolam. Kauling et al. (39) reported an incidence of 41.9% and Qadeer et al. (40), an incidence of 51%. However, other authors have reported

much lower values. Agostoni et al. (8) reported a rate of 1.24% and McQuaid et al. (41) reported a rate of 4.7%; a similar incidence of 4% was also reported with the use of midazolam for deeper sedation during thoracoscopy (42).

Respiratory complications represent a common indication for reverting sedation. The most important reason for using reversion agents was a fall in SaO_2 (64.4%) according to a report by Hung et al. (43). There were no deaths in our study. However, the sample size was too small to allow for significant conclusions of mortality. The wide variation in mortality rates associated with digestive endoscopy-related sedation (e.g., 1/3,182 [44], 1/5,631 [8], 1/161,520 [38]) no doubt reflects the wide proportion of high-risk and low-risk patients included in reported studies.

A lower incidence of post-sedation pain that favored the trained group (1.8% *vs* 4.3%; $p < 0.001$) was also found but the incidence in both groups was lower than that reported by Ghanouni et al. (36). Pain data for patients undergoing digestive endoscopy are scarce. A study in Norway of pain in colonoscopy patients found that 23.7% of subjects who received sedatives or painkillers reported moderate or severe pain (37). In a study by Ekkelenkamp et al. (4) that used midazolam and fentanyl, 7.7% of patients experienced discomfort during the procedure. Interestingly, this rate is much higher than the rate of 4.1% of an inadequate sedation found in our study, which we consider an intraoperative pain marker. However, a small study of patients that underwent interventional colonoscopy procedures by Kravochuck et al. (34) found a correlation between intraoperative pain and endoscopist technical expertise, but not sedation level score. The number of patients who required analgesia was not negligible (2.82%), but was lower than that reported by Ghanouni et al. (14%) (36) and for patients undergoing ambulatory surgery (9%) (38).

The most important aspect in our training program was the pharmacology and drug administration. Pain reduction is related to appropriate opiate dosage, excessive sedation is related to bolus administration and increased numbers of completed procedures may be related to repeat doses and the ability to maintain patients sedated when the endoscope reaches the hepatic flexure and ascending colon. In our study, specifically trained gastroenterologists used lower sedative doses and a higher number of boluses, which complied with the guidelines taught during the course (Fig.

2). They also wait longer in order to allow an adequate sedation to be achieved before starting the endoscopic procedure (Fig. 3), but there were no significant differences in total procedure length.

Our study has some potential limitations. First, it was a single-center study, which limited the number of professionals enrolled in the training program. Secondly, groups were not randomized. Therefore, gastroenterologists in the trained group might have had skills that differed from those of their colleagues in the non-trained group and we cannot guarantee that there was no cross-training between both groups. However, uncontrolled skills in the non-trained group would have been beneficial in terms of patient outcome. Thirdly, while participating gastroenterologists did not differ in terms of clinical experience in sedation, implementing a program for newly-certified gastroenterologists would have been useful to prevent a potential influence of clinical experience on the results. Furthermore, the training program was specifically designed for our hospital and may not be easily implemented in other centers. Finally, even though we included a high number of patients, the rate of adverse events was low, which reduces the odds of identifying risk factors associated with these events. In view of these limitations, we must interpret our results cautiously with regard to their implication for the development and generalization of training programs. However, we believe our study provides relevant information that could guide future studies.

To conclude, our sedation training model for gastroenterologists improves outcome in terms of effectiveness (higher number of completed procedures) and safety (reduced hypoxemia and pain rates).

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Table 1. Demography of patients included in the study

Subgroup	Trained	Non-trained		Total
No. of patients	2,070	1,405		3,475
Sex (M/F)	832/1,238	524/881	0.94	1,356/2,119
	Median IQR	Median IQR	p < 0.0032†	Median IQR
Age (years)	54.8 (43.0-65.5)	54.0 (42.3-66.1)	1	54.8 (42.7-65.7)
BMI (kg/m^2)	25.6 (23.0-28.7)	26.0 (23.3-29.1)	0.18	25.8 (23.1-28.9)
	n (%)	*n* (%)	p < 0.0032†	*n* (%)
Colonoscopies	1,679 (81.1)	1,106 (78.7)		2,785 (80.1)
Gastroscopies	273 (13.2)	254 (18.1)	0.03	527 (15.2)
Both	118 (5.7)	45 (3.2)	< 0.001*	163 (4.7)
Inpatients	188 (9.1)	111 (7.9)	0.22	299 (8.6)
Outpatients	1,882 (90.9)	1,294 (92.1)		3,176 (91.4)
Elective	2,029 (98.0)	1,391 (99.0)	0.022	3,420 (98.4)
Emergency	41 (2.0)	14 (1.0)		55 (1.6)
ASA 1	597 (28.8)	389 (27.6)		986 (28.4)
ASA 2	1,230 (59.4)	881 (62.7)	0.006	2,111 (60.7)
ASA 3	243 (11.7)	131 (9.3)		374 (10.8)
ASA 4	0	4 (0.1)		4 (0.1)
Concomitant conditions				
Atrial fibrillation	61 (3.0)	35 (2.5)	0.421	96 (2.8)
Ischemic cardiopathy	99 (4.78)	34 (2.41)	< 0.001*	133 (3.82)
Heart valve disease	0	11 (0.8)	< 0.001*	11 (0.3)
Dilated cardiomyopathy	0	3 (0.2)	0.035	3 (0.1)
Pacemaker	6 (0.3)	3 (0.2)	0.663	9 (0.2)
Dyslipidemia	415 (20.0)	288 (20.5)	0.745	703 (20.2)
Blood hypertension	404 (19.5)	267 (19.0)	0.7	672 (19.3)
Smoker	235 (11.3)	221 (15.7)	0.4	456 (13.1)
Diabetes	114 (5.5)	86 (6.1)	0.44	200 (5.8)

Obesity (BMI > 30 kg/m^2)	386 (18.6)	293 (20.8)	0.18	679 (19.5)
Psychiatric disorder	371 (17.92)	275 (19.57)	0.219	646 (18.58)
Alcoholism	37 (1.8)	35 (2.5)	0.153	72 (2.1)
Gastroesophageal reflux	102 (4.9)	54 (3.8)	0.129	156 (4.5)
Peptic ulcer	68 (3.3)	41 (2.9)	0.65	107 (3.1)
Hiatal hernia	61 (2.9)	43 (3.1)	0.84	104 (3.0)
Asthma	89 (4.3)	67 (4.8)	0.51	156 (4.5)
COPD	61 (2.8)	33 (2.4)	0.36	94 (2.7)
Sleep apnea	22 (1.1)	8 (0.6)	0.122	30 (0.9)

*Statistically significant difference. †Trained group *vs* non-trained group.

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Table 2. Effectiveness, safety and satisfaction degree results

Group	*Trained*	*Non-trained*		*Total*
No. of patients	2,070	1,405		3,475
	n (%)	*n* (%)	p < 0.0031	*n* (%)
Effectiveness				
Complete procedures	1,904 (92.0)	1,254 (89.3)		3,158 (90.9)
Incomplete procedures	166 (8.0)	151 (10.7)		317 (9.1)
Colonoscopies	149 (8.8)	134 (12.1)	0.006	283 (10.1)
Gastroscopies	10 (3.66)	12 (4.72)	< 0.001*	22 (4.17)
Both	7 (5.9)	5 (11.1)	< 0.001*	12 (7.36)
Inadequate sedation	48 (2.3)	94 (6.7)	<0.001*	142 (4.1)
Anatomic changes	50 (2.4)	37 (2.6)		87 (2.5)
Adhesions	29 (1.4)	6 (0.4)		35 (1.0)
Diverticulosis	21 (1.0)	10 (0.7)		31 (0.9)
Tumors	19 (0.9)	10 (0.7)		29 (0.8)
Inadequate preparation	45 (2.2)	25 (1.8)		70 (2.0)
Severe colitis	11 (0.5)	4 (0.3)		15 (0.4)
Adjusted analysis[†]				
No. of patients	2,016	1,377		3,393
Incomplete procedures	112 (5.6)	123 (8.9)	< 0.001*	235 (6.9)

*Statistically significant difference. [†]After excluding patients with poor preparation and with severe colitis (27).

Intra-procedural complications				
Hypertension	224 (10.82%)	174 (12.38%)		398 (11.45%)
Hypotension	99 (4.78%)	83 (5.9%)		182 (5.23%)
Bradycardia	128 (6.18%)	93 (6.61%)		221 (6.35%)
Tachycardia	218 (10.53%)	188 (13.38%)		406 (11.68%)
Hypoxemia	15 (0.72%)	35 (2.49%)	< 0.001*	50 (1.43%)
Excessive sedation	27 (1.3%)	121 (8.61%)	< 0.001*	148 (4.25%)

Bleeding	1 (0.04%)	0		1 (0.02%)
Post-procedural pain				
Mild	38 (1.8)	60 (4.3)	<0.001*	98 (2.8)
Moderate	3 (0.1)	2 (0.1)		5 (0.1)
1 analgesic	58 (2.8)	74 (5.3)	<0.001*	132 (3.8)
2 analgesics	6 (0.3)	9 (0.6)		15 (0.4)
Patient satisfaction degree				
No. of outpatients	1,882 (90.9)	1,294 (92.1)		3,176
Patients who answered the phone	972 (51.6)	678 (52.4)		1,650 (52.0)
Very satisfied	822 (84.6)	569 (83.9)		1,391 (84.3)
Satisfied	147 (15.1)	106 (15.6)		253 (15.3)
Moderately satisfied	2 (0.2)	3 (0.4)		5 (0.3)
Unsatisfied	0	0		0
Very unsatisfied	1 (0.1)	0		1 (0.1)

*Statistically significant difference.

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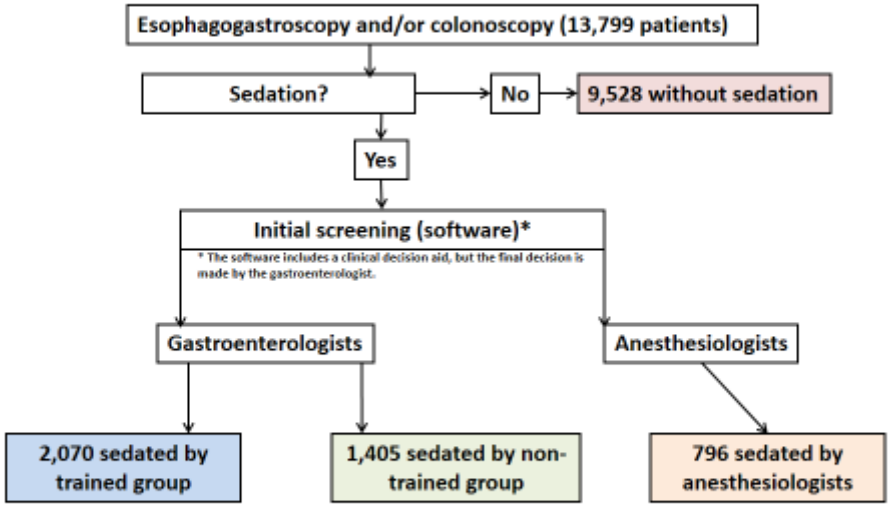

Fig. 1. Schematic diagram showing the distribution of patients scheduled for digestive endoscopy according to sedation status and sedation-administering staff.

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Fig. 2. Comparison of midazolam and fentanyl use between the trained group and the non-trained group.

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Fig. 3. Comparison of procedure length (min) between both groups.