Comparing the efficacy and safety of Dexmedetomidine/Ketamine with Propofol/Fentanyl for sedation in colonoscopy patients: A double-blinded randomized clinical trial

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Research article

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Abstract

Background

In this double-blinded randomized clinical trial, we aimed to compare safety and efficacy of combination of dexmedetomidine and ketamine (DK) with propofol and fentanyl (PF) for sedation in colonoscopy patients.

Methods

In this study, 64 patients undergoing colonoscopy were randomized in two groups, A, receiving PF, and B receiving DK for sedation. Among 64 patients, 31 patients included in PF and 33 patients included in DK group. Both groups were similar in terms of demographics. Patients' sedation score (based on Ramsy scale) and vital signs recorded at the times of 2, 5, 10 and 15 minutes. Complications including apnea, hypotension, hypoxia, nausea and vomiting along with gastroenterologist satisfaction and patients' pain score (based on Wong Baker faces pain assessment scale) recorded by a checklist. Data were analyzed by SPSS V.18, using chi-square, independent t-tests and repeated measure analysis with a p value < 0.05 significance level.

Results

The mean score of sedation was 4.82 ± 0.49 in DK group and 5.22 ± 0.45 in PF group (*p value = 0.001*). Serious complications, including hypotension (*p value = 0.005*) and apnea (*p value = 0.10*) were significantly higher in PF group. Satisfaction of gastroenterologist (*p value = 0.400*) and patients' pain score (*p value = 0.900*) were similar among groups.

Conclusion

Combination of DK provides sufficient sedation with less complications in compare with PF in colonoscopy patients.

Trial registration

The study protocol designed on the basis of Helsinki declaration for ethical consideration and was approved by the Ethics Committee of Qom University of Medical Sciences (ethics code: IR.MUQ.REC.1397.149); the study was also registered at the Iranian Center for Clinical Trials (No. IRCT20161205031252N11).

Key Massages

- DK regimen is less effective than PF in sedation score, but has less serious adverse effects too.
- DK is a more safe combination for sedation in ambulatory setting, with satisfactory sedative effects.

Background

Colonoscopy is an effective technique for the treatment of colon polyps and identification of non-malignant lower gastrointestinal diseases. Also, it is one of the most successful methods used to screen colorectal cancer, which effectively reduces mortality rate due to such cancers. Although colonoscopy is a time-effective, available technique performed as an outpatient, it usually causes significant pain and anxiety in patients. Intravenous sedation can effectively control the patient's pain and discomfort and let the physician more extensive employ this technique. For this purpose, different agents are used as single or in combination regimens (1, 2).

Propofol is a drug widely used for sedation during colonoscopy, but hypotension and, more importantly, respiratory depression are complications that limit its employment (3, 4). Dexmedetomidine, an alpha-2-adrenergic receptor agonist, is a drug used alone or in combination with other analgesic agents for sedation during colonoscopy. The long time to recovery and prolonged hospital stay are the main concerns about using this drug, which makes it less popular as a sole sedative agent in the outpatient setting. Using dexmedetomidine in combination with other medications can reduce the required dose as well as the side effects (5).

The current study aimed at comparing the efficacy and side effects of propofol and fentanyl, as agents commonly used in compare with dexmedetomidine and ketamine for sedation and analgesia in patients undergoing colonoscopy.

Methods

The present double-blinded, randomized, clinical trial aimed at comparing the sedative and side effects of a combination of dexmedetomidine and ketamine (DK) with propofol and fentanyl (PF) to induce analgesia in patients undergoing colonoscopy. The study population consisted of candidates for colonoscopy referring to Colonoscopy Unit in Shahid Beheshti Hospital in Qom, Iran. The sample size was determined maximum eight subjects in each group using two population means, according to the findings of the study by Goyal et al. (5), and considering different outcomes including hypotension, hypoxemia, and apnea; however, the sample size was increased to 32 subjects in each group in order to normalize distribution and better observe complications.

Inclusion criteria were: being eligible for colonoscopy, age above 18 years, the American Society of Anesthesiologists physical status (ASA-PS) class 1 and 2, and willingness to participate in the study. Exclusion criteria were: a history of allergy to the drug, drug addiction, and use of psychiatric drugs, ASA class ≥ 3, known psychological problems, emergency cases, and unwillingness to participate in the study.

Subjects were selected through consecutive sampling. The patients were divided into two groups of A and B using permuted block randomization. The size of blocks was 4 and were selected by casting dice. Allocation to the treatment groups A and B was performed by simple randomization (coin toss). The

study was a double-blinded trial and both the patient and physician assessing the outcomes were unaware of the treatment type.

After assigning patients to treatment groups and obtaining the written informed consent from them, the demographic information including gender, age, height, and weight as well as primary vital signs including systolic blood pressure, mean arterial pressure, blood oxygen saturation (SpO_2), and heart rate were recorded in the checklist of each patient.

Sedation was induced in group A (PF) using midazolam (0.02 mg/kg), fentanyl (1 μg/kg), and propofol (1 mg/kg) and in group B (DK) using midazolam (0.02 mg/kg), dexmedetomidine (0.3 μg/kg), and ketamine (0.25 mg/kg).

Sedation score was assessed using Ramsey sedation scale at 2, 5, 10 and 15 minutes. Sedation score and vital signs of each patient at predetermined time points, total dose administered, duration of colonoscopy, intraoperative complications including nausea, vomiting, bradycardia, hypotension, chills, delusions, hallucinations, apnea, and the degree of gastroenterologist satisfaction with the procedure as totally satisfactory (easy to perform), satisfactory (difficult to perform), and unsatisfactory (impractical) were recorded in the checklist of each patient. Besides, recovery assessments including time the patient entered to the recovery room, interval between colonoscopy completion and discharge, pain score at discharge using the Wong Baker faces pain assessment scale, patient satisfaction at discharge (i.e., totally satisfactory, satisfactory, and unsatisfactory), and recovery complications including nausea, vomiting, bradycardia, hypotension, shivering, delusions, hallucinations, and apnea were recorded in each patient's checklist.

Data were analyzed by SPSS version 18 software using descriptive statistics including mean and standard deviation and analytical statistics including chi-square and independent t-test, as well as repeated measure analysis. P-value < 0.05 was considered significant.

Ethical considerations: The study process and possible complications were explained to patients and they were asked to sign the informed consent forms in case of willingness to participate in the study. The study protocol designed on the basis of Helsinki declaration for ethical consideration and was approved by the Ethics Committee of Qom University of Medical Sciences (ethics code: IR.MUQ.REC.1397.149); the study was also registered at the Iranian Center for Clinical Trials (No. IRCT20161205031252N11).

Results

Of the 64 participants in the current clinical trial, 31 patients (11 male and 20 female) were in the Propofol&Fentanyl (PF) group and 33 patients (16 male and 17 female) in the Dexmedetomidine&Ketamine (DK) group. Patients were randomly divided into two treatment groups and the demographic variables including gender, age, weight as well as primary vital signs including SpO_2, heart rate, systolic blood pressure, and mean arterial pressure were compared between the groups and no

significant difference was observed. Table 1 shows the mean of the variables as well as the *p values* for the two groups.

Table 1
Patients demographics and baseline parameters in both groups.

		Propofol + Fentanyl	Dexmedetomidine + Ketamine	P-value
Sex	**Male**	11 (35.5 %)	16 (48.5%)	0.293*
	Female	20 (64.5 %)	17 (51.5 %)	
Age		47.74 ± 15.19	41.18 ± 14.13	0.078#
Weight		74.08 ± 14.31	76.51 ± 11.56	0.456#
Primary O2 Saturation		97.74 ± 2.08	98.00 ± 1.32	0.561#
Primary HR		83.32 ± 16.99	84.81 ± 15.59	0.718#
Primary MAP		88.87 ± 18.91	93.42 ± 20.04	0.354#
Primary SBP		125.23 ± 23.05	125.76 ± 19.32	0.920#

HR: Heart rate, MAP: Mean arterial pressure, SBP: Systolic blood pressure

* Chi−square test

Independent samples T−test

The mean sedation score was 5.22 ± 0 0.45 in patients receiving PF and 4.82 ± 0 0.49 in the ones who received DK, and the difference between the groups was statistically significant (*p value = 0.001*); in other words, patients receiving PF had a higher sedation score.

Assessment of vital signs during colonoscopy in two groups showed that SpO_2 (*p value = 0.000*), systolic blood pressure (*p value = 0.004*), and mean arterial pressure (*p value = 0.001*) in patients receiving DK was significantly higher than the ones who received the PF; in other words, patients in the DK group experienced lower levels of hypotension and desaturation. There was no significant difference in heart rate changes between the two groups.

In terms of patient's vital signs in recovery, there was no significant difference between the two groups in systolic blood pressure and heart rate, but SpO_2 (*p value = 0.030*) and mean arterial pressure (*p value = 0.037*) were higher in the DK group. Assessment of pain score in recovery using visual analogue scale showed no significant difference between the two groups. Table 2 shows the mean vital signs, sedation score, and pain score of the two groups during colonoscopy and in recovery.

Table 2
Sedation score, pain score and vital signs during colonoscopy and recovery in both groups.

	Colonoscopy		P-value*	Recovery		P-value*
	Propofol + Fentanyl	Dexmedetomidine + Ketamine		Propofol + Fentanyl	Dexmedetomidine + Ketamine	
Sedation score	5.22 ± 0.45	4.82 ± 0.49	0.001	-	-	-
Mean SBP	102.45 ± 16.61	113.81 ± 13.34	0.004	104.51 ± 12.60	109.77 ± 12.59	0.100
MAP	73.12 ± 13.22	83.96 ± 12.75	0.001	74.40 ± 9.60	79.48 ± 9.50	0.037
HR	75.77 ± 14.25	75.50 ± 14.37	0.938	76.20 ± 11.96	78.02 ± 12.43	0.555
O2 saturation	96.16 ± 2.55	98.33 ± 1.07	0.000	96.88 ± 1.48	97.58 ± 1.02	0.030
Mean pain score	-	-	-	1.17 ± 0.31	1.16 ± 0.34	0.900

HR: Heart rate, MAP: Mean arterial pressure, SBP: Systolic blood pressure

* Independent samples T−test

In terms of complications during colonoscopy, hypotension (*p value = 0.005*) and apnea (*p value = 0.010*) were significantly more common in the PF group. There was no significant difference between the two groups in terms of bradycardia and agitation. Assessment of recovery complications showed that patients in the DK group had higher rates of nausea (*p value = 0.000*) and dizziness (*p value = 0.003*). There were no significant differences between the two groups in other complications including bradycardia, hypotension, apnea, vomiting, and shivering. The details of complications observed during colonoscopy and recovery in the two groups are shown in Table 3.

Table 3
Complications during colonoscopy and recovery in both groups.

Colonoscopy			P-value*	Recovery			P-value*
Complication	P + F N (%)	D + K N (%)		Complication	P + F N (%)	D + K N (%)	
Bradycardia	2 (6.5)	5 (15.2)	0.240	Bradycardia	0 (0.0)	1 (3.0)	0.516
Hypotension	16 (51.6)	6 (18.2)	0.005	Hypotension	13 (41.9)	7 (21.2)	0.074
Apnea	6 (19.4)	0 (0.0)	0.010	Apnea	2 (6.5)	0 (0.0)	0.231
Agitation	0 (0.0)	1 (3.0)	0.516	Nausea	0 (0.0)	11 (11.3)	0.000
				Vomiting	0 (0.0)	1 (3.0)	0.516
				Shivering	2 (6.5)	0 (0.0)	0.138
				Dizziness	0 (0.0)	8 (24.2)	0.003

P: Propofol; F: Fentanyl; D: Dexmedetomidine; K: Ketamine

* Chi–square test

In terms of the degree of gastroenterologist satisfaction, 27 out of 31 subjects in the PF group had satisfactory outcome (93.1%), while it was 29 out of 33 (87.9%) in the DK group; the difference between the groups was statistically insignificant (*p value = 0.400*). In terms of assessments after recovery, 18 out of 31 patients (64.3%) in the PF group had complete satisfaction; it was 24 out of 33 (72.7%) in the DK group and no significant difference was observed between the groups (*p value = 0.478*).

The trend of changes in SpO_2 during colonoscopy (*p value = 0.000*) and recovery (*p value = 0.030*) was significantly different between the two groups (Fig. 1A). Heart rate variations were not different between the two groups either during colonoscopy (*p value = 0.911*) or recovery (*p value = 0.555*) (Fig. 1B). In the case of mean arterial pressure, changes during colonoscopy showed no significant difference between the two groups (*p value = 0.073*), but the changes were significant in recovery (*p value = 0.037*) (Fig. 1C). Results of repeated measure analysis of changes in vital signs including systolic blood pressure, mean arterial pressure, heart rate, and SpO_2 during colonoscopy and recovery showed significant differences in systolic blood pressure during colonoscopy between the two groups (*p value = 0.038*), but the difference was not significant in recovery (*p value = 0.100*) (Fig. 1D). Changes in sedation score were significantly different between the two groups (*p value = 0.003*) (Fig. 2), but there was no significant difference between the groups in terms of changes in pain score in recovery (*p value = 0.009*) (Fig. 3).

Discussion

Colonoscopy is the standard method for colorectal cancer screening as well as the diagnosis and sometimes treatment of colon lesions, which can be performed as outpatient under sedation. Since the patient does not need to be hospitalized for colonoscopy, the ideal sedation for this procedure, in addition to proper analgesia and sedation, should have a rapid onset of action and termination of effect with no cardiovascular outcomes leading to instability, and minimum side effects with a smooth and easy recovery in order to accelerate patient's readiness for discharge.

Today, colonoscopy in many protocols is performed using Propofol alone and fentanyl is not routinely administered. The measure is primarily taken in order to avoid exacerbation of respiratory depression caused by the main drug, Propofol, and also shortening the time to recovery, but such protocols cause a significant pain to the patient, which cannot be managed other than pain medication, and since neither Propofol nor midazolam have any analgesic effects, deleting fentanyl from the protocol is not ethical based on the patient's rights, although with the help of midazolam given as a premedication, the patient does not remember pain after the procedure. Given to this point, in the present study, Ketamine and Dexmedetomidine were utilized to induce analgesia in the intervention group, both of which have analgesic effects, especially the ketamine, which the analgesic effect of its sub-anesthetic doses is confirmed and during the procedure neither reduces patient's consciousness nor independently develops respiratory depression (6, 7).

The findings of the present study, comparing the results of the PF and DK groups, showed that patients who received PF had significantly higher sedation based on their Ramsey score. A study by Karanth et al., (8) comparing the efficacy and side effects of Dexmedetomidine and Propofol in sedation of patients undergoing colonoscopy shows that there was no significant difference in analgesic effects between the two agents. This finding was different from that of the current study, although in the present study, despite the higher sedation score in the PF group, there was no significant difference between the two groups in the satisfaction degree of the physician and patient with the procedure and pain reported by patients in recovery. This means that both drugs provided acceptable sedation and accordingly had not superior to each other in terms of sedation. In addition, a moderate sedation level for many outpatient procedures, including colonoscopy, will meet the goals, with less hemodynamic and respiratory complications.

One of the concerns regarding the use of Propofol for sedation is respiratory complications including hypoventilation and apnea and hypotension (9). The findings of the present study indicated that patients receiving PF had lower SpO_2 and blood pressure compared to the ones receiving DK and were more at risk of hypotension and apnea. Results of a large retrospective study on 996 patients receiving Propofol or Dexmedetomidine for sedation before MRI showed that patients receiving Propofol had more hemodynamic complications, including hypotension and bradycardia. Although both Propofol and Dexmedetomidine decrease blood pressure and heart rate due to their sympatholytic effect, these changes were significantly higher in patients receiving Propofol (10). This finding was also observed by other studies comparing Propofol and Dexmedetomidine effects; hence, Dexmedetomidine is a safer agent than Propofol in terms of hemodynamic stability (11, 12). Results of a clinical trial by Alizadehasl

et al., comparing the efficacy and side effects of Dexmedetomidine and Propofol for sedation before transesophageal echocardiogram (TEE) suggested that Dexmedetomidine, in addition to appropriate sedation, causes stable hemodynamic conditions in cardiac patients who were candidates for TEE and provides greater satisfaction in both the patient and physician (13). For colonoscopy, usually the initial dose of the drug provides appropriate sedation until the end of the procedure. In longer procedures, the results of researches indicate that lower bolus dosing and then continuous drug infusion during the procedure was associated with fewer side effects compared to higher doses (14, 15).

Dexmedetomidine is an alpha-2-adrenergic receptor agonist and specifically exerts its effect on the locus coeruleus. The specific chemical properties of this drug makes it less suppressive to the respiratory center compared to GABA agonists such as Propofol, and thus provides greater satisfaction with sedation in outpatient procedures. In addition, since Propofol has a narrow therapeutic range and may cause deep sedation with a slight change in serum levels of the drug, its application may lead to greater respiratory complications (16–18). In the present study, patients in the PF group experienced a higher rate of apnea, which was in line with the results of the studies by Wu (12) and Ahmed (10).

Ideal sedation during procedures, in spite of controlling the pain and anxiety in the patient, should allow the physician to perform the procedure easily and does not cause a severe loss of consciousness and complication in the patient. Achieving all of these goals requires a careful and appropriate choose of the drug and the dosage. Evidence suggests that the use of a combination of two or more drugs reduces the required dose and the side effects of each drug. A study by Yin et al., on elderly patients who were candidates for upper gastrointestinal endoscopy suggested that patients treated with Propofol plus Dexmedetomidine had lower complications and higher satisfaction with the procedure compared to the ones treated with Propofol alone or in combination with other drugs including Sufentanil and Ketamine (19). In the present study, patients in the DK group had higher stability and fewer complications compared to the ones in the PF group. Although in the present study, the incidence of complications such as nausea and dizziness in recovery was higher in the DK group, the overall patient satisfaction with sedation was not significantly different between the two groups. Satisfaction of the gastroenterologist with sedation in patients was similar in both groups. Results of other studies also indicate that, in spite of the mild side effects observed in recovery in patients receiving Dexmedetomidine, patients' satisfaction with sedation was desirable using this agent (20).

It is also important to note that not using Fentanyl in the DK group may represent a strategy for painful diagnostic and therapeutic measures in patients who are advised not to use opioids for any reason (21).

The strengths of this study include appropriate blindness and elimination of the impact of the anesthesiologist or gastroenterologist awareness on their clinical judgment. Frequent measurements of the parameters examined during sedation and recovery also enhance the validity of the results obtained. However, the small sample size can be considered as one of the limitations of the present study. Although the sample size was accurately calculated according to previous studies and even more patients were enrolled to increase the validity of the findings, more extensive studies are required to obtain more

conclusive results about the superiority of the introduced combination and its cost effectiveness. Also, racial differences in terms of the distribution and metabolism of drugs and also the efficacy of a combination in a certain race or its inefficiency in another race should not be overlooked.

Conclusions

Overall, the findings of the present study indicated that adding DK, in spite of its higher cost, to the administered regiment provides a safer sedation in patients undergoing colonoscopy due to its hemodynamic and respiratory stability. This is especially important during colonoscopy because patients are usually positioned sideways and sometimes semi prone, which makes access and maintenance of airways difficult. On the other hand, since colonoscopy is a technique used for colorectal cancer screening mainly performed on people over 50 with a risk of vascular disease, it is associated with greater risks of hemodynamic changes. Hence, the advantage of using DK for colonoscopy against its cost seems reasonable.

Abbreviations

DK
Dexmedetomidine/Ketamine
PF
Propofol/Fentanyl
TEE
Transesophageal Echocardiogram

Declarations

Ethics approval & consent to participate

The study process and possible complications were explained to patients and they were asked to sign the informed consent forms in case of willingness to participate in the study. The written informed consent obtained from study participants. The study protocol designed on the basis of Helsinki declaration for ethical consideration and was approved by the Ethics Committee of Qom University of Medical Sciences (ethics code: IR.MUQ.REC.1397.149); the study was also registered at the Iranian Center for Clinical Trials (No. IRCT20161205031252N11).

Consent for publication

Not applicable.

Availability of data and material

All data and materials are available from the corresponding author.

Competing interests

The authors declare that they have no competing interests.

Funding

Not applicable.

Authors Contribution

[R Aminnejad], [H Shafiee], [F Alemi], [A Hormati], [M Saeidi], [SM Sabouri] and [M Aghaali]: Designing the study, performing the procedures, preparing article draft and revising. [S Ahmadpour]: Revising the article. [M Hormati]: Performing, data collection, preparing article draft and revising the article.

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Figures

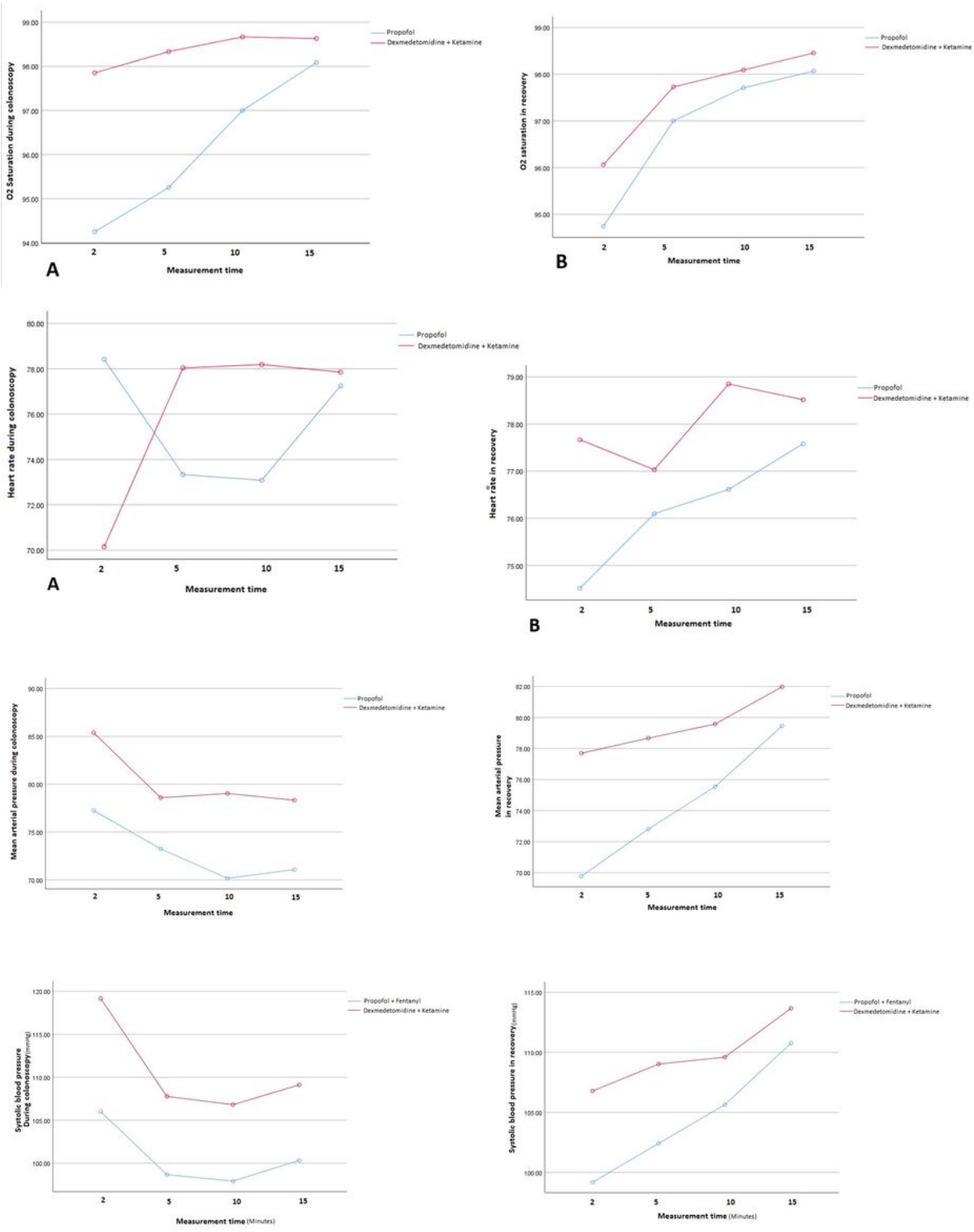

Figure 1

Results of repeated measure analysis of patients' vital signs during colonoscopy and recovery in both groups; A- O2 saturation, B- Heart rate, C- Mean arterial pressure, D- Systolic blood pressure.

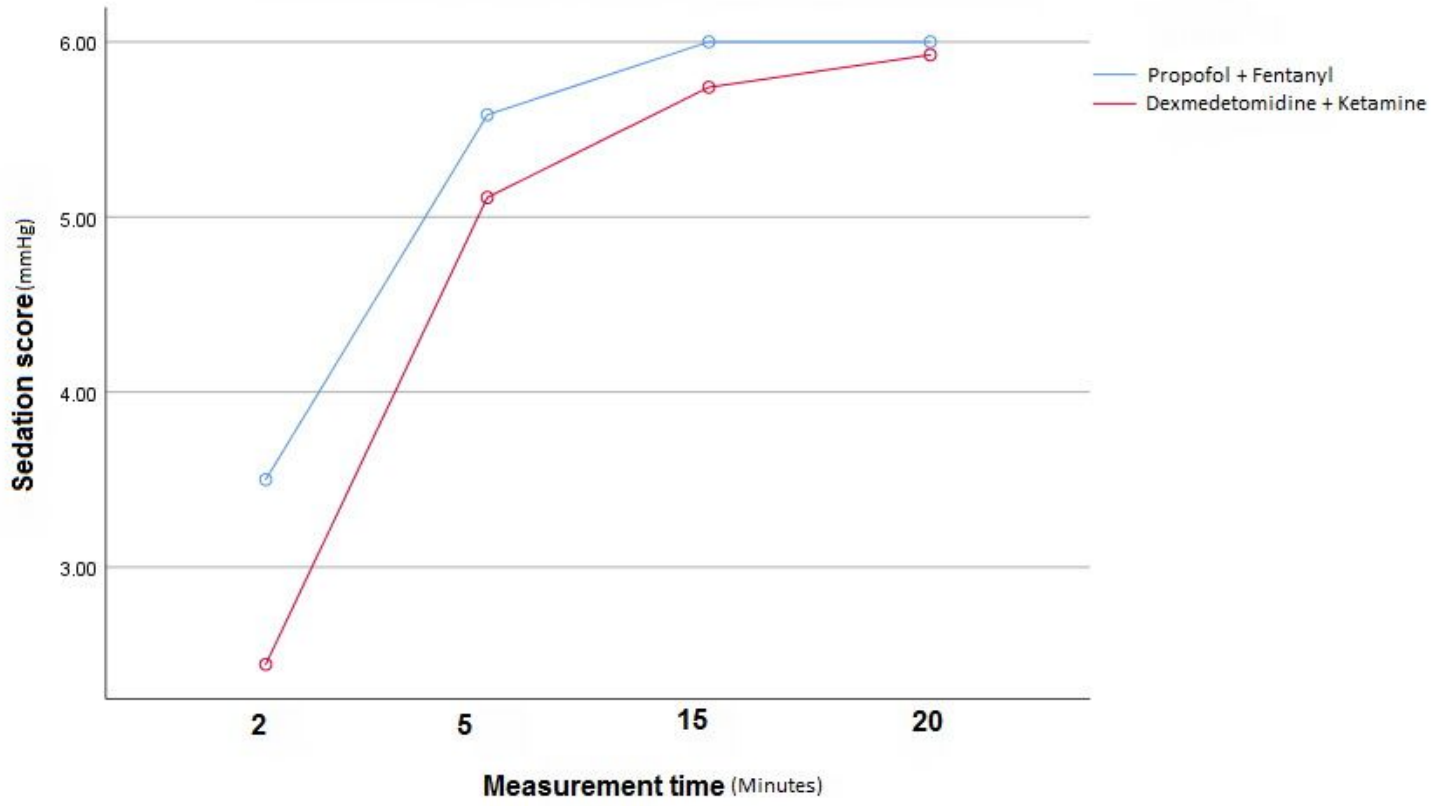

Figure 2

Results of repeated measure analysis of patients' sedation score during colonoscopy.

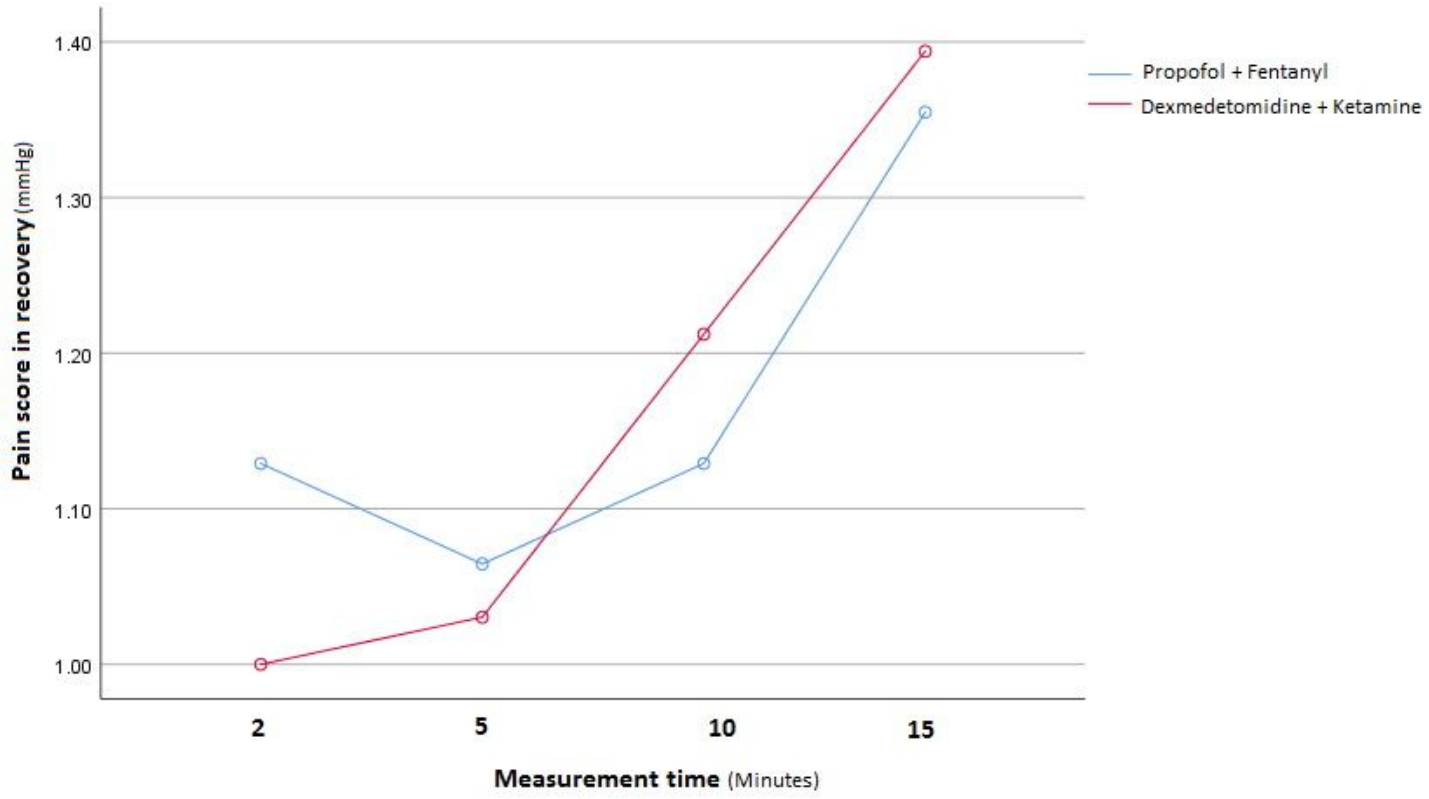

Figure 3

Results of repeated measure analysis of patients' pain score in recovery.