Al-Azhar International Medical Journal

Volume 5 | Issue 5 Article 57

5-31-2024
Section: Anesthesiology

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How to Cite This Article

Moawad, Ayman Ahmed; El-Garhy, Ahmed Mahmoud Mohamed Mohamed; and Shamloul, Mohamed Mohamed Salah Eldin (2024) "Comparative Study of Fentanyl, and Dexmetomidine as an Adjuvant to Propofol for Colonoscopy," *Al-Azhar International Medical Journal*: Vol. 5: Iss. 5, Article 57.
DOI: https://doi.org/10.58675/2682-339X.2459

ORIGINAL ARTICLE

Comparative Study of Fentanyl, and Dexmetomidine as an Adjuvant to Propofol for Colonoscopy

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Abstract

Background: ***Colonoscopy induces considerable discomfort and anxiety. Administration of a single anesthetic agent may result in insufficient sedation and pain relief, leading to excessive drug consumption and an escalation in unwanted side effects.***

Aim: ***The study's objective effectiveness of the propofol-fentanyl and propofol-dexmedetomidine combinations in patients having colonoscopy .***

Method: ***colonoscopy patients prospective, randomized, double-blinded, controlled trial conducted on 66 patients undergoing elective colonoscopy. Patients were assigned randomly into two equal groups. Group 1 received Fentanyl 1 µ/kg, combined with propofol 2 mg/kg bolus dose and 9 - 12 mg/kg/hr maintenance in the first 15 minutes, then propofol 6 - 9 mg/kg/hr for the remaining procedure. Group 2 received dexmedetomidine one µ/kg and propofol at the same regimen as group 1.***

Results: ***Dexmedetomidine had a more speedy recovery from anesthesia than fentanyl. After 5 minutes in the PACU, all individuals in the dexmedetomidine group exhibited a modified aldrete score (MAS) of 9, while the median MAS in the fentanyl group was 7 (P=0.001). Oxygen saturation was significantly higher in dexmedetomidine than in fentanyl (97.6% vs. 94.7%). Severe bradycardia and hypotension were not reported in the two groups. No difference was reported regarding the analgesic efficacy, complications, and satisfaction. Nausea was less frequent with dexmedetomidine.***

Conclusion: ***The combination of dexmedetomidine and propofol provided more appropriate analgesia and sedation results with a higher quality of recovery compared to fentanyl and propofol for colonoscopy.***

Keywords: Colonoscopy, Dexmedetomidine, Fentanyl, Propofol, Sedation

1. Introduction

Colonoscopy is a highly successful method for treating colon polyps and diagnosing nonmalignant lower gastrointestinal illnesses. Additionally, it is regarded as one of the most efficacious techniques employed for the detection of colorectal cancer, resulting in a significant decrease in mortality rates associated with such malignancies. Colonoscopy, while being a convenient and readily accessible outpatient procedure, typically induces considerable discomfort and anxiety. Intravenous sedation can efficiently manage the patient's pain and discomfort, enabling the physician to apply this treatment more extensively. Several medications are employed individually or in conjunction with regimens .[1]

Propofol is the predominant intravenous hypnotic medication, often delivered at an administered dose of 2.5 mg per kilogram of body weight. The onset and duration of its action are speedy. The primary cardiovascular hazard associated with propofol is hypotension.[2] Several substances can serve as adjuvants to propofol. The present pharmacological regimen comprises benzodiazepines, primarily diazepam, in conjunction with an opioid, typically fentanyl or remifentanil, as well as ketamine and dexmedetomidine. Administering a single medication may result in insufficient sedation and pain relief, leading to excessive drug consumption and an escalation in unwanted side effects. Therefore, it is preferable to utilize combination medications with distinct pharmacological effects .[3]

Accepted 21 May 2024.
Available online 31 May 2024

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https://doi.org/10.58675/2682-339X.2459

Dexmedetomidine, a well-known sedative, stimulates adrenergic alpha-two receptors in the central nervous system, leading to pain relief and decreased sympathetic activity.[4] It diminishes the sensation of pain. Dexmedetomidine, unlike other sedatives, facilitates rapid restoration of consciousness. Even when administered in large dosages, dexmedetomidine does not aggravate the respiratory system, and its severity is lower compared to other sedatives.[5,6] The research aims to appraise and compare the effectiveness of the propofol-fentanyl and propofol-dexmedetomidine combinations in patients having colonoscopy.

2. Patients and methods

This study is a clinical trial that follows CONSORT principles. It is a prospective, randomized, double-blinded, controlled study that was organized at the colonoscopy unit of Al-Azhar University Hospitals between January 2023 and October 2023.

The trial comprised patients between the ages of 21 and 60 who had an ASA categorization of I or II and were scheduled for elective colonoscopy. The procedure was planned to last between 15 and 40 minutes. The exclusion criteria encompassed pre-existing cardiovascular, hepatic, and renal conditions, patient non-compliance, psychological ailments, drug hypersensitivity, coagulation abnormalities, and patient unwillingness to take part.

The sample size analysis was accomplished by adopting the work conducted by Amri et al. [6]. Epi Info STATCALC is utilized for estimating the sample size, taking into account the following presumption: - A confidence level of 95% is used, with a power of 80% for both sides. An error of 5% was observed in the computed odds ratio, which amounted to 1.115. The ultimate maximum sample size extracted from the Epi-Info output was 60. If we assume a dropout rate of 10% over the follow-up period (f), the cumulative number of cases (N) would be 66.

The trial comprised 66 patients, who were randomly assigned into two equally sized groups using a computerized random generator. Group 1 consisted of 33 patients, administered fentanyl 1 µ/kg (fentanyl 50 mcg/ml, Hameln; Netherlands), combined with an initial dosage of propofol at 2 mg/kg (Propofol 1% 10 mg/ml, Homburg; Germany). Subsequently, they administered a continuing dose of propofol at 9 - 12 mg/kg/hr for the first 15 minutes. The administration of propofol infusion was preserved at 6-9 mg/kg/hr for the remainder of the procedure. Group 2 (consisting of 33 patients) administered Dexmedetomidine at a dosage of 1 µ/kg (Precedex 4 mcg/ml, Pfizer. Inc, New York, USA). This was followed by an initial injection of propofol at 2 mg/kg before the procedure. Subsequently, the patients were administered a continuing dosage of propofol at a rate of 9 - 12 mg/kg/hr for the first 15 minutes. The administration of propofol was preserved at a dosage of 6-9 mg/kg/hr for the duration of the surgery. The objective of medication infusion in both groups is to sustain a modified Ramsay Sedation Score of 3–4.

2.1.Procedure

Comprehensive evaluations of all patients were conducted the day before the surgical procedure. Patients were engaged to gather information about their drug usage and their previous encounters with anesthesia or corresponding issues. Routine tests such as chest X-ray and electrocardiogram (ECG) were conducted as necessary in each patient. Patients were directed to observe overnight fasting before surgery, per the protocol.

The patients were relocated to the preparation room 40 minutes before the initiation of anesthesia. They received a reminder regarding the protocol and instructions on utilizing the visual analog scale score (VAS). Upon approaching the room, the patient was positioned in the left position, and the knees flexed. The usual monitoring for the participant included using the Bene View T5 monitor manufactured by Mindray Biomedical Electronics Co. in Shenzhen, China. This monitor was used to measure non-invasive blood pressure, pulse oximetry, capnogram, and ECG leads were connected to the patient. A 20-gauge cannula was utilized to gain IV access. Preloading was achieved using a volume of 3 ml per kilogram of normal saline. The group assignment performed anesthesia induction. Patients were administered oxygen via a nasal cannula at a flow rate of 2-4 liters per minute. The study medications were administered using a 50-ml syringe and an electronic infusion pump manufactured by Mindray Biomedical Electronics Co., located in Shenzhen, China. Subsequently, the colonoscopy commenced after 2 minutes of anesthetic induction.

Hypotension is characterized by a systolic blood pressure measurement below 90 mmHg or a mean blood pressure below 60. It was managed by administering fluid shock and gradually increasing IV dosages of ephedrine to 6mg. The bradycardia condition, characterized by a heart rate of less than 50 beats per minute, was combated by administering an intravenous bolus injection of atropine at a dosage of 0.6 mg. The patient's apnea, bradypnea, or hypoxia was tackled by providing manual ventilation.

The primary outcome, MAS, was assessed at reaching PACU and again at 5, 10, 15, and 30 minutes. The secondary outcome measurements encompassed demographic information,

hemodynamic metrics, the Modified Ramsey Sedation Scale, the Visual Analog Scale, the use of intraoperative fentanyl supplemental analgesia, the occurrence of post-procedure problems, and satisfaction.

2.2.Statistical analysis

The documented results were processed using SPSS version 23.0, a statistical tool for social sciences developed by SPSS Inc. in Chicago, Illinois, USA. Quantitative data was reported using the mean standard deviation and ranges for variables that followed a parametric (normal) distribution. Reporting was accomplished for variables that did not follow a normal distribution, utilizing a median with an interquartile range (IQR). Additionally, qualitative characteristics are represented in the form of numerical values and percentages. The Independent-samples t-test compares two parametric means, while the Mann-Whitney U test is suitable for non-parametric presentation. The Chi-square test was utilized to compare groups with qualitative data. The confidence interval was established at 95% with a corresponding margin of error of 5%. The p-value was deemed significant, considering its value was less than 0.05. For statistical purposes, a p-value of 0.05 or higher was considered non-significant.

3. Results

Subjects gave written informed consent once the University's Ethics Committee approved the study. Incorporating human subjects in this study, the researchers followed all of the rules laid down in the Declaration of Helsinki, which is part of the World Medical Association's Code of Ethics.

Figure 1 represents the CONSORT flowchart illustrating the procedural steps of the investigation. Concerning demographic information, no significant distinctions were demonstrated among the study arms concerning age, gender, weight, BMI, and ASA physical status. Furthermore, this study demonstrated that participants in the DEX group had a more rapid recuperation from anesthesia in comparison to the fentanyl group. After 5 minutes in the PACU, all individuals in the DEX group exhibited a modified aldrete score (MAS) of 9, while the median MAS in the fentanyl group was 7 (P=0.001). The Fentanyl group achieved a 100% reporting of MAS=9 within 15 minutes. Following 30 minutes, all patients in both groups reported MAS of 10 and were subsequently discharged to the ward without any safety concerns (Table 1).

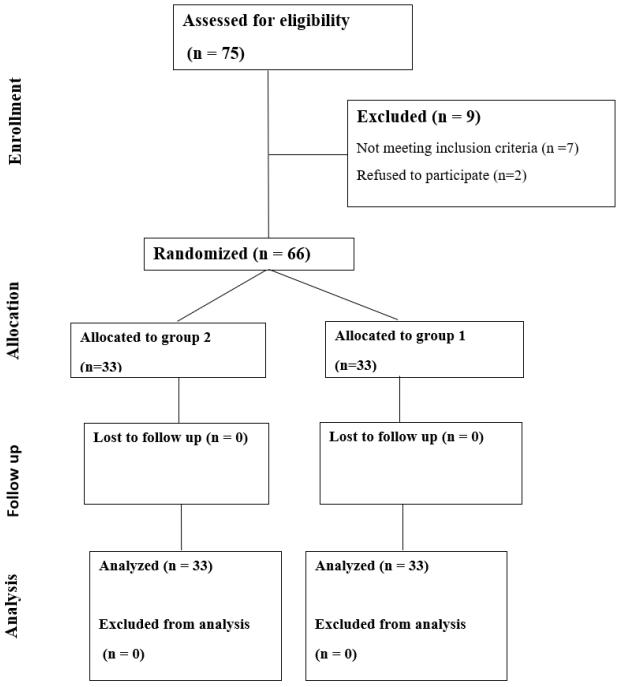

Figure 1. CONSORT flow diagram.

Table 1. Postoperative recovery using the Modified Aldrete's score.

	GROUP 1 N= (33)	GROUP 2 N= (33)	P VALUE
0 MINUTES	7 (6-8)	9 (8-9)	0.001*
5 MINUTES	7 (7-9)	9 (9-9)	0.001*
10 MINUTES	8 (7-9)	10 (9-10)	0.001*
15 MINUTES	9 (9-10)	10 (9-10)	0.925
30 MINUTES	10 (10-10)	10 (10-10)	0.748

Data presented as median (min-max)
*significant p value < 0.05

The comparison of the two groups in terms of heart rate showed that heart rate measurements were consistently lower in the DEX arm than in the fentanyl group for the whole evaluation period. A significant distinction was observed at 5 and 10 minutes and during colonoscopy removal. It is worth noting that none of the participants in either group experienced bradycardia, which is defined as a heart rate below 50 beats per minute (Table 2).

Table 2. Comparison between the study groups regarding heart rate.

HEART RATE (BEAT/MIN)	GROUP 1 N= (33)	GROUP 2 N= (33)	P VALUE
DURING THE PROCEDURE			
BASELINE	75.4±6.3	78.4±8.6	0.258
5 MINUTES	73.1±5.7	64.3±4.8	≤0.001*
10 MINUTES	71.5±4.6	67.3±4.3	≤0.001*
15 MINUTES	68.6±4.5	65.1±3.5	0.388
COLONOSCOPY WITHDRAWAL	73.5±3.9	63.1±.3.7	≤0.001*
AFTER THE PROCEDURE			
30 MIN	76.4±5.3	71.5±5.1	0.417
2 HOURS	75.1±4.8	73.6±5.3	0.115
4 HOURS	74.5±3.7	73.4±6.1	0.528

Data presented as mean ± SD

*significant p value < 0.05

The DEX group exhibited a statistically significant decline in mean blood pressure compared to the fentanyl group immediately after anesthetic induction and 15 minutes into the surgery (75.3 vs. 81.5 and 71.6 vs. 84.7 mmHg, respectively). No hypotension (mean blood pressure less than 60 mmHg) occurred in either of the study groups. Following the colonoscopy procedure, the average blood pressure was comparable in both groups, and the comparison did not yield any statistically significant differences (Table 3).

Table 3. Comparison between the study groups regarding mean blood pressure.

MBP (MMHG)	GROUP 1 N= (33)	GROUP 2 N= (33)	P VALUE
DURING THE PROCEDURE			
BASELINE	81.5±8.1	75.3±9.6	0.025*
5 MINUTES	77.3±9.7	73.5±8.3	0.521
10 MINUTES	74.5±8.5	73.0±6.4	0.436
15 MINUTES	84.7± 8.3	71.6± 5.5	≤0.001*
COLONOSCOPY WITHDRAWAL	77.6±10.2	75.3±8.4	0.622
AFTER THE PROCEDURE			
30 MINUTES	76.5±7.3	74.5±4.1	0.163
2 HOURS	74.1±6.8	73.8±5.3	0.183
4 HOURS	75.5±6.7	73.2±6.1	0.470

Data presented as mean ± SD;

*significant p value < 0.05

Following the administration of anesthetics, the fentanyl group encountered a drop in oxygen saturation, with a mean value of 94.7% at 15 minutes. The DEX group showed no significant deviation from the initial measurement over the first 15 minutes, with SpO2 levels measuring at 97.6%. The contrast between the two groups yielded statistically significant results during the initial 15-minute period (Table 4).

Following the operation, all patients in both groups experienced a recovery of SpO2 readings that closely approximated the initial baseline value.

Table 4. Comparison between the study groups regarding oxygen saturation.

SPO2 (%)	GROUP 1 N= (33)	GROUP 2 N= (33)	P VALUE
DURING THE PROCEDURE			
BASELINE	96.8±2.1	97.3±1.5	0.271
5 MINUTES	95.3±2.5	97.1±1.3	0.021*
10 MINUTES	94.5±1.1	96.8±2.4	0.035*
15 MINUTES	94.7±1.3	97.6±1.5	≤0.001*
COLONOSCOPY WITHDRAWAL	95.6±1.2	97.3±1.4	0.192
AFTER THE PROCEDURE			
30 MINUTES	97.2±1.3	97.5±1.1	0.751
2 HOURS	97.1±1.0	97.0±1.3	0.103
4 HOURS	97.0±1.7	97.2±1.1	0.290

Data presented as mean ± SD

*significant p value < 0.05

No significant disparity was observed in the analgesic parameters. The fentanyl group exhibited decreased pain intensity contrasted with the DEX arm, while the disparity was not significant. Furthermore, four subjects in the fentanyl arm necessitated intraoperative fentanyl rescue analgesia, with an average fentanyl consumption of 271.5 mcg. Three patients in the DEX group required the administration of additional fentanyl, with a cumulative dosage of 224 mcg (Table 5).

The study arms did not show any significant distinction in terms of complications. The fentanyl group experienced nausea in four cases, but the DEX group only had one occurrence, resulting in a significant difference (Figure 2). Surgeon and subject satisfaction levels were not significantly distinct between the groups studied. (Figure 3).

Table 5. Intraoperative fentanyl rescue analgesia (1mcg/kg)

	GROUP 1 N= (33)	GROUP 2 N= (33)	P VALUE
NUMBER OF PATIENTS REQUIRED RESCUE ANALGESIA	4 (12.1)	3 (9.1)	0.912
TIME TO FIRST REQUEST OF ANALGESIA (MINUTES)	35.7±12.5	42.8±15.4	0.205
CUMULATIVE FENTANYL CONSUMPTION (MCG)	271.5±22.7	224±18.4	0.193

Data presented as mean ± SD, number (%)

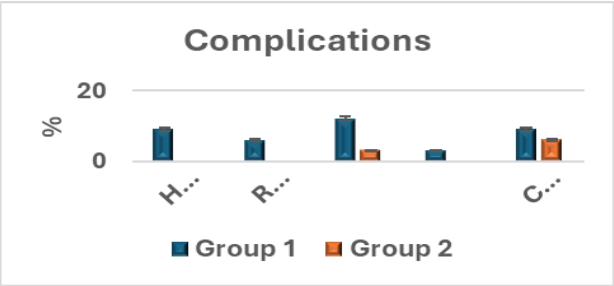

Figure 2. Comparison between the two groups regarding complication.

Figure 3. Grading of patient satisfaction in the two study groups.

4. Discussion

Colonoscopy is a frequently employed procedure for diagnosing, screening, treating, and monitoring various colorectal illnesses. Typically, the operation is characterized by discomfort and unpleasant sensations. Therefore, it requires an appropriate sedation-analgesia pharmaceutical combination to ensure maximum pain relief and patient participation while also preventing any negative consequences.[7]

Our findings revealed that patients in the dexmedetomidine group had considerably lower levels of sedation, as measured by the Modified Ramsay Sedation Scale (MRS), compared to those in the fentanyl group. Furthermore, dexmedetomidine exhibited equivalent efficacy to fentanyl, as indicated by comparable MRS scores two hours after colonoscopy.

Moreover, this research demonstrated that subjects in the DEX group had a more rapid recuperation from anesthesia in comparison to the fentanyl group. Study arms did not display significant distinction concerning complications. The fentanyl group experienced nausea in four cases, but the DEX group only had one occurrence, resulting in a significant distinction among the two arms. The diminished occurrence of vomiting and nausea can be attributed to the declined dose of propofol in those receiving dexmedetomidine. DEX is a sedative agent closely resembling natural sleep, making it easier for participants to adjust from sleep to consciousness. This allows patients to be responsive and communicative when they are triggered. This may explain why colonoscopists report higher satisfaction levels and why endoscopies are smoother procedures with DEX administration.[8]

Moreover, DEX, a potent α2-adrenoceptor agonist, predominantly targets the central pre- and postsynaptic α2-receptors in the locus coeruleus. This specific action grants DEX a distinct tranquil effect that differentiates it from traditional sedatives.[9] Importantly, DEX has negligible respiratory depressant effects and reduced physiological stress response to surgical triggers compared to GABA receptor agonists like propofol and benzodiazepines.[10]

Supportingly, Kavousi and colleagues designed a randomized trial on 70 candidates for colonoscopy. The purpose of the study was to contrast the effects of the intravenous administration of dexmedetomidine with a combination of propofol and fentanyl with respect to sedation-analgesia and hemodynamic changes. According to the findings, the DEX group exhibited decreased heart rate, compared to the propofol (P) group (72.51±16.7 vs. 81.56±15.71 p=0.001). The P group exhibited a notable prevalence of apnea. In contrast to our findings, the P group demonstrated a substantially higher level of satisfaction than the D group, with a satisfaction rate of 77% compared to 43%. The disparity can be ascribed to the inclusion of fentanyl in both groups.[11]

In addition, Rajaei and his colleagues conducted a study to examine the hypnotic effect and speed of recovery of dexmedetomidine and fentanyl in 80 individuals undergoing elective colonoscopy.[12] The researchers found no statistically significant distinctions between the two arms regarding age, gender, and sedation rate. The mean preliminary dosage of propofol in the fentanyl arm was 72±14 mg, but in the dexmedetomidine arm, it was 7±0.24 mg (p=0.000). The recuperation time in the fentanyl arm was 4.38±2.38 minutes, but in the dexmedetomidine arm, it was 2.63±1.22 minutes (p=0.000). The level of pain experienced after the colonoscopy procedure was quantified as 2.30±0.69 in the group that received fentanyl and 1.98±0.7 in the group that received dexmedetomidine. The disparity in pain levels between the two groups was significant, with a p-value of 0.039. These findings conformed with our conclusions.

This finding correlates with an updated meta-analysis executed in 2023 by Tang and colleagues. The meta-analysis encompassed 40 papers involving 2,955 patients. Their findings indicated that DEX exhibits similar efficacy to other sedatives with comparable sedation scores and patient satisfaction levels while achieving greater satisfaction among endoscopists.[13]

The findings of this study revealed that a

significant decline in the risk of hypoxia accompanies DEX sedation. This aligns with the conclusions drawn in a previous study accomplished by Liu W et al. and is also supported by the pharmacological properties of DEX.[14] Nevertheless, it contradicts the findings of other studies (Zhang et al., 2016; Nishizawa et al., 2017) where no significant difference in hypoxia risk was observed.[10, 15]

In addition, the double-masked clinical trial, led by Amri and colleagues, involved 80 patients to examine the effects of dexmedetomidine and fentanyl in elective colonoscopy. The researchers determined that dexmedetomidine exhibited hypnotic and analgesic properties without causing notable respiratory concerns.[6]

Our study revealed that heart rate recordings in the DEX arm were consistently less than in the fentanyl arm for the whole evaluation period. A significant distinction was observed at 5 and 10 minutes and during colonoscopy removal. Crucially, none of the participants in either group experienced bradycardia, defined as a heart rate below 50 beats per minute. Furthermore, the average blood pressure significantly declined in the DEX arm, contrasted with the fentanyl arm immediately after the administration of anesthetic and 15 minutes into the surgery.

Furthermore, our findings indicate that the fentanyl group exhibited reduced pain intensity compared to the dexmedetomidine group. However, the difference between the two groups was not significant. Nevertheless, the DEX group experienced a longer duration of time prior to considering their first request for analgesia compared to the fentanyl group. No significant disparity was observed in the analgesic parameters.

In agreement with our results, Amri and colleagues demonstrated a significant decline in heart rate among individuals in the DEX arm, contrasted with the fentanyl arm ($P < 0.05$).[6] None of the patients in the fentanyl group experienced serious bradycardia. However, one patient in the dexmedetomidine group did experience severe bradycardia, which was successfully alleviated with atropine. Furthermore, the mean blood pressure (MBP) in both groups did not exhibit any significant distinctions at 0, 5, and 10 minutes or during colonoscopy removal. However, The p-value reached statistical significance (less than 0.05) by the fifteenth minute.

Furthermore, Wu et al. completed a study on 60 patients, divided into two arms, to demonstrate the implications of dexmedetomidine and midazolam during endoscopy. The findings indicated that the dexmedetomidine group exhibited a declined pain intensity and enhanced SpO2. The researchers established that DEX is efficacious and safe.[16]

In addition, the study published by Kaygusuz et al. was on a sample of 24 patients undergoing colonoscopy. Results indicate that a combination of dexmedetomidine, low-dose fentanyl, and midazolam may be an effective and safe alternative to propofol.[17]

Incorporating fentanyl into the procedure can heighten the likelihood of bradycardia, which is already a concern given the minimal pain intensity experienced during colonoscopy and the sedative and analgesic properties of dexmedetomidine. Dere et al. conducted a trial in order to contrast the effects of dexmedetomidine, administered at a dose of 1 mcg/kg by infusion 10 minutes prior to colonoscopy, with midazolam, administered at a dose of 0.05 mg/kg, on 60 patients. The study focused on evaluating the impact of both medications on hemodynamic parameters, respiratory function, and analgesic properties. Prior to colonoscopy, a dose of fentanyl at a concentration of 1 mcg/kg was introduced. The assessed factors comprised heart rate, mean blood pressure, SpO2 levels, respiratory rate, pain intensity, and patient satisfaction. The midazolam group exhibited greater SpO2 and heart rate levels than the dexmedetomidine group. The two groups had no significant difference in the average blood pressure and pain severity. The dexmedetomidine group exhibited reduced patient satisfaction.[18]

Indeed, the results of this study did not align with our findings, as both sets of participants were administered fentanyl. The patient satisfaction levels were comparable between the two groups in our study, potentially attributed to the inclusion of propofol among other medications.

Moreover, another study investigated the impact of dexmedetomidine on colonoscopy procedures in the geriatric population. The study involved 50 patients between 60 and 70 classified as ASA classes 1 to 4. These patients were randomly assigned to DEX or midazolam. A 0.5 mg/kg dosage of Mepredidin was administered during the preliminary sedation and before commencing the procedure. If needed, an extra dose of 0.25 mg/kg was provided. In the dexmedetomidine arm, there was a higher occurrence of hypotension and bradycardia. However, the reported degree of pain was lower, and there was a noticeable decline in the amount of meperidine required in the dexmedetomidine group.[19]

While our investigation yielded comparable results regarding analgesia, it is important to note that meperidine was administered instead of fentanyl, which differed from our study.

On the contrary, the research executed by Amri and his colleagues showed that the average and standard deviation of pain intensity (measured using VAS) were lower in the dexmedetomidine arm contrasted with the fentanyl arm. This distinction was significant ($P < 0.05$). Furthermore, it is worth noting that nine individuals receiving dexmedetomidine and 40 patients receiving fentanyl required an additional dose of propofol ($P < 0.05$) due to insufficient sedation and pain relief.[6]

The primary advantage of the current investigation depends on the effectiveness of a double-blind, randomized clinical design in minimizing bias and ensuring the reliability of the results. An evident limitation of this study is the time-consuming nature of administering dexmedetomidine compared to fentanyl to achieve optimal analgesic effects, which results in a delay in the colonoscopy procedure. One further limitation of the current study is its limited sample size.

4. Conclusion

The dexmedetomidine group experienced a diminished magnitude of pain throughout colonoscopy compared to the fentanyl group, with a non-significant difference. Dexmedetomidine had faster recovery from anesthesia than fentanyl. Dexmedetomidine was comparable to fentanyl regarding the modified Ramsey Sedation score but with a higher patient and colonoscopist satisfaction level. The coadministration of dexmedetomidine and propofol yielded superior analgesic and sedative outcomes, together with a higher degree of recovery quality, in comparison to the use of fentanyl and propofol for colonoscopy.

In light of the prevalent occurrence of bradycardia and hypotension in our study and other investigations, we suggest investigating the impact of dexmedetomidine and ketamine (which carry a reduced risk of bradycardia) in colonoscopy operations.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

Funding

No Funds : Yes

Conflicts of interest

There are no conflicts of interest.

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