Dexmedetomidine - Oxycodone Combination for Conscious Sedation During Colonoscopy in Obese Patients: A Randomised Controlled Trial

Xinran Wang

Nanjing Medical University

Zhen Zhang

Suqian People's Hospital

Manman Zhang

Xuzhou Central Hospital

Meiyan Zhou

Xuzhou Central Hospital

Sun Han

Xuzhou Central Hospital

Rui Zhang

Suqian People's Hospital

Niall Ahmad

Imperial College London

Rongxia Shi

Xuzhou Central Hospital

Yangzi Zhu (✉ zhuyz@188.com)

Xuzhou Central Hospital <https://orcid.org/0000-0002-4709-4652>

Research Article

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Abstract

Background: The objective of this trial was to investigate the effectiveness and safety of dexmedetomidine plus oxycodone for conscious sedation during colonoscopy in obese patients.

Methods: A total of 138 patients undergoing colonoscopy were randomly assigned into one of two groups: group Dex+oxy received sedation with dexmedetomidine plus oxycodone; while group Pro+suf received anaesthesia with propofol plus sufentanil. Parameters including blood pressure, heart rate, respiration, blood oxygen saturation, injection pain, and recovery were recorded for both groups.

Results: The incidence of hypoxaemia was significantly reduced in group Dex+oxy compared with group Pro+suf (4.9% vs 20.3%, $P = 0.011$). Blood pressure was significantly increased, and heart rate was reduced in group Dex+oxy compared with group Pro+suf ($P < 0.05$). Moreover, the caecal insertion time, recovery time to orientation, and recovery time to walking were significantly reduced in group Dex+oxy compared with group Pro+suf ($P < 0.05$). Endoscopist satisfaction scores were significantly higher in group Dex+oxy compared with group Pro+suf ($P = 0.042$).

Conclusion: Dexmedetomidine plus oxycodone provides effective sedation with minimal adverse effects for obese patients, while also reducing colonoscopy operation difficulty by allowing obese patients to reposition. Thus, dexmedetomidine plus oxycodone could be used safely as a conscious sedation method for colonoscopy in obese patients.

Trial registration The protocol was registered at www.chictr.org.cn (ChiCTR1800017283, 21/07/2018)

Background

The prevalence of obesity in adults has increased rapidly in China over several decades. An estimated 85 million adults aged 18–69 years in China were obese in 2018 [1, 2]. Obesity and being overweight (defined as having a body mass index [BMI] $\geq 25\text{kg/m}^2$) have been associated with several diseases including colorectal cancer [3]. Early colonoscopy is an effective way to prevent morbidity and mortality from colorectal cancer [4]. However, colonoscopy and sedation can be challenging in obese patients.

Evidence suggests that a raised BMI can lead to difficulties in achieving caecal intubation, and prolongs caecal intubation times during colonoscopy [5, 6]. Additionally, obesity is an independent predictor of inadequate bowel preparation during colonoscopy [7], which indirectly contributes to difficult caecal intubation. Moreover, during colonoscopy in obese patients, repositioning and abdominal compression are often performed to facilitate the advancement of the endoscope [8], and sedation makes it more difficult to reposition an obese patient.

Colonoscopy, while useful for diagnosing and treating colonic diseases, may cause discomfort to patients, such as abdominal pain, anxiety, and fear [9, 10]. With advancements in anaesthesia, painless colonoscopy has become a reality. Propofol is the most common intravenous anaesthetic used during

painless colonoscopy [11]. It has a short half-life and rapidly induces anaesthesia [12]. However, it significantly suppresses both respiratory and circulatory systems with poor analgesic effect [13, 14]. This is a major challenge for the anaesthetist.

Dexmedetomidine is a selective α_2 adrenoreceptor agonist that provides anxiolysis and sedation with minimal respiratory depression [15–18]. Conscious sedation with dexmedetomidine allows patients to be awakened and repositioned during colonoscopy [18]. Additionally, oxycodone, a kappa-opioid agonist, demonstrates superior efficacy in targeting visceral pain [19, 20], and can therefore be used in conjunction with dexmedetomidine during colonoscopy.

The aim of this study was to investigate the sedation effects of dexmedetomidine plus oxycodone alongside the effects on respiration and colonoscopy operation, in order to seek a more suitable sedation method for colonoscopy in obese patients.

Methods

Participants

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and was registered at www.chictr.org.cn (ChiCTR1800017283, 21/07/2018). This study was approved by the Ethics Committee of Suqian People's Hospital and Xuzhou Central Hospital. Written informed consent was obtained from all patients who underwent colonic endoscopy. Inclusion criteria: American Society of Anesthesiologists (ASA) class I or II; body mass index (BMI) 30 to 35; age between 30 to 60 years; and elective colonoscopy. Exclusion criteria: difficult airway (the presence of predictors of difficult mask ventilation and difficult intubation, such as altered dentition, Ankylosing Spondylitis, Pierre-Robin syndrome, Mallampati scores $\geq$ III, et al.); grade 3 hypertension; coronary heart disease; bradycardia (heart rate falls below 60); neurological or mental illness; decompensated liver or kidney disease; or alcoholism (drink at least 3 standard drinks a day or 5 standard drinks at least once a week). The patients were randomly assigned into one of two groups (allocation ratio was 1:1) by computer-generated random numbers before the endoscopy procedure. Group Dex+oxy received dexmedetomidine plus oxycodone, and group Pro+suf received anaesthesia with propofol plus sufentanil.

Anaesthesia method and outcome measure

On the day before colonoscopy, all the participants were limited to a clear liquid diet for dinner. Patients were instructed to take the polyethylene glycol electrolyte with 1 L water at 8–9 pm. On the next day they were encouraged to follow the same regimen 5 to 6 hours before the colonoscopy. Once the patient was in the procedure room, supplementary oxygen was administered (2 L/min) via a nasal cannula. Blood pressure, heart rate, respiration, and blood oxygen saturation were all monitored, as well as pain from the drug injection. Group Dex+oxy received 0.1 mg/kg intravenous oxycodone hydrochloride and 0.6 μ g/kg dexmedetomidine in 10 minutes followed by a continuous pump infusion of 0.2 μ g/kg/h dexmedetomidine. Group Pro+suf received 0.1 μ g/kg intravenous sufentanil and 1 mg/kg intravenous

propofol. Additional doses (20–30 mg) of propofol were administered if the patient started to move. Colonoscopy began once the eyelash reflex disappeared.

During the procedure, heart rate (HR), respiration, and pulse oxygen saturation (SpO_2) were continuously monitored. The respiratory rate was recorded using the end-tidal CO_2 waveform. Hypoxemia was defined as $\text{SpO}_2 < 90\%$. Blood pressure was monitored every 2 minutes. Hypotension was defined as mean arterial pressure (MAP) < 70 mmHg. Bradycardia was defined as $\text{HR} < 60$ beats/minute. MAP, SpO_2 and HR were recorded in both groups before sedation or anaesthesia (T1), when the endoscope was inserted into the anus (T2), when the endoscope reached the splenic flexure (T3), when the endoscope reached the hepatic flexure (T4), when the endoscope reached the ileocaecal area (T5) and at the end of the procedure (T6).

Airway manoeuvres (jaw thrust, chin lift) and bag-mask ventilation would be performed when SpO_2 was below 90% or when the end-tidal CO_2 waveform disappeared. Ephedrine 3 mg was administered when systolic blood pressure (SBP) was under 80 mmHg or had a greater than 30% reduction from baseline measurement. When the heart rate decreased to < 50 beats/minute, the procedure was stopped and intravenous atropine 0.3-0.5 mg was administered. Biopsies or polypectomies were only performed after reaching the ileocaecal area.

The recovery time was measured from the end of the procedure to patients reaching a Ramsay Sedation Scale (RSS) score of 2. The discharge time was also recorded from the end of endoscopy to achieving a Steward Recovery Score (SRS) of 6. Patients were asked about drug injection pain and any other discomfort. Endoscopist and patient satisfaction surveys were performed and satisfaction scores were determined (between 1-4) [21].

Statistical analysis

Previous studies showed a 20-30% hypoxemia rate amongst all-comers under propofol-based monitored anaesthesia, without endotracheal intubation, during endoscopic procedures [22, 23]. Our institutional experience showed a hypoxaemia rate of less than 5% amongst obese patients sedated with dexmedetomidine plus oxycodone during colonoscopy. We assumed a 25% hypoxemia rate in obese patients sedated with propofol plus sufentanil. Hence, to detect a reduction in hypoxaemia rate from 25–5%, 100 patients would be needed to achieve a statistical power of 90% ($\alpha = 0.05$, $\beta = 0.1$).

SPSS 23.0 (SPSS, Chicago, IL, USA) was used for statistical analysis. All quantitative data was presented as the mean $\pm$ SD of independent experiments. Qualitative variables were statistically analysed with chi-square or Fisher's exact tests. Independent-samples t test or Mann–Whitney U test were used for other quantitative variables. The statistical significance level was set at 0.05.

Results

Patient characteristics

A total of 138 patients were enrolled in the study, of whom, 18 were withdrawn from the study due to poor intestinal preparation. The remaining 120 patients successfully completed colonoscopy under sedation with oxycodone hydrochloride plus dexmedetomidine or propofol plus sufentanil. The flow of patients through the study and detailed reasons for exclusion are provided in Figure 1. The basic demographic and clinical characteristics of the two groups are presented in Table 1.

Table 1
Demographic and Clinical Characteristics

Admission characteristics	Dex+oxy (N=61)	Pro+suf (N=59)	P value
Age (years)	47.5 ± 6.9	48.2 ± 7.1	0.582
BMI (kg/m ²)	33.3 ± 1.50	33.0 ± 1.53	0.265
Sex (M/F)	36/25	34/25	0.876
Hypertension	10 (16.4%)	9 (15.3%)	0.865
Diabetes mellitus	7 (11.5%)	8 (13.5%)	0.730
STOP-BANG score	3.4 ± 1.4	3.3 ± 1.2	0.238
Dex+oxy, dexmedetomidine + oxycodone; Pro+suf, propofol + sufentanil; BMI, body mass index; Values are mean ± SD or number (percentages).			

Respiration and haemodynamic parameters

Mean arterial pressure (MAP) was reduced in group Pro+suf compared with group Dex+oxy when the endoscope was inserted into the anus, following induction of anaesthesia (T2) ($P < 0.05$) (Fig. 2A). At four time points (T2-T6), from induction of anaesthesia to when the endoscope reached the ileocecal area, heart rate was reduced in group Dex+oxy compared with group Pro+suf ($P < 0.05$) (Fig. 2B). At three time points (T2-T4), SpO₂ was reduced in group Pro+suf compared with group Dex+oxy ($P < 0.05$) (Fig. 2C).

Adverse reactions

The incidence of hypoxaemia, hypotension, and drug injection pain were significantly increased in group Pro+suf compared to group Dex+oxy ($P < 0.05$). The number of times airway intervention was required (jaw thrust or bag-mask ventilation) in group Dex+oxy was lower than that in group Pro+suf ($P < 0.05$). (Table 2)

Table 2
Sedation-related adverse events

	Dex+oxy (N=61)	Pro+suf (N=59)	P value
Injection pain	0 (0%)	16 (27.1%)	<0.001
Hypoxemia	3 (4.9%)	12 (20.3%)	0.011
Hypotension	0 (0%)	8 (13.6%)	0.003
Somatic movement	4 (6.6%)	2 (3.4%)	0.426
Bradycardia	13(21.3)	7(11.9)	0.165
Chin lift	6 (9.8%)	12 (20.3%)	0.107
Jaw thrust	1 (1.6%)	9 (15.3%)	0.006
Bag-mask ventilation	0 (0%)	4 (6.8%)	0.038
Nausea and vomiting	3(4.9%)	2(3.4%)	0.676
Ephedrine application	0 (0%)	2(3.4%)	0.147
Atropine application	3(4.9%)	1(1.7%)	0.325
Data presented as number (percentages)			

Secondary outcome

The recovery time and the discharge time were significantly reduced in group Dex+oxy compared with group Pro+suf ($P < 0.05$). Endoscopist satisfaction scores were higher in group Dex+oxy ($P < 0.05$) and no statistical differences were found in terms of patient satisfaction between the two groups (Table 3). The caecal insertion time was shorter for patients in group Dex+oxy than patients in group Pro+suf ($P < 0.05$). The endoscopist did not perform any biopsies or polypectomies prior to the endoscope reaching the ileocecal area.

Table 3
CIT, recovery and discharge time, satisfaction of patients and operator

	Dex+oxy (N=61)	Pro+suf (N=59)	P value
CIT, (min)	6.2 ± 3.5	10.2 ± 5.3	0.001
Recover time, (min)	1.4 ± 0.8	8.5 ± 2.6	<0.001
Discharge time, (min)	9.6 ± 2.8	14.2 ± 5.6	0.012
Satisfaction of patient	3.7 ± 0.4	3.9 ± 0.3	0.653
Satisfaction of operator	3.8 ± 0.2	3.1 ± 0.2	0.042
CIT, caecal insertion time; Data presented as mean ± SD			

Discussion

This study represents the first prospective, randomised controlled trial comparing sedation with dexmedetomidine plus oxycodone versus anaesthesia with propofol plus sufentanil, during colonoscopy in obese patients. We found that sedation with dexmedetomidine plus oxycodone is associated with a lower incidence of sedation-related adverse events. Furthermore, sedation with dexmedetomidine plus oxycodone facilitated difficult colonoscopies in obese patients due to relatively free body positioning.

Obesity is a risk factor for sedation related respiratory depression during colonoscopy. Propofol has potent sedative and hypnotic effects and has been widely used in colonoscopy. However, propofol is associated with marked respiratory depression, especially for obese patients [24, 25]. Sufentanil, a μ -opioid receptor agonist, may also induce respiratory depression [26–28]. In our study, we found sedation with propofol plus sufentanil was associated with a significantly higher incidence of hypoxaemia necessitating airway intervention. Dexmedetomidine, an α_2 -adrenoceptor agonist that mimics natural sleep in humans given its sedative effect, has been widely used to induce anaesthesia and to sedate patients in intensive care [29–32]. Oxycodone is a dual μ and κ -opioid receptor agonist with good analgesic effects on visceral pain and less adverse effects, such as gastrointestinal motility suppression or respiratory depression [33, 34]. This study demonstrated that dexmedetomidine plus oxycodone hydrochloride exhibited good sedative effects with little respiratory depression.

Haemodynamic stability is an important factor to ensure patient safety during anaesthesia, especially in elderly patients with underlying diseases [35]. This study showed that dexmedetomidine plus oxycodone hydrochloride caused a slight reduction in heart rate with minimal effects on blood pressure, which has important clinical implications in patients with cardiovascular and cerebrovascular diseases.

Haemodynamic stability ensures tissue perfusion of vital organs, such as the heart and brain. Moreover, a slight decrease in heart rate reduces myocardial oxygen consumption, which may protect the myocardium [36–38].

Colonoscopy is especially challenging in obese patients [6, 39]. Patients often need to reposition during the procedure to facilitate the advancement of the endoscope. However, it can be difficult for the endoscopist and support staff to reposition an obese patient who is deeply sedated [8, 40]. Conscious sedation with dexmedetomidine and oxycodone meant that patients could be awakened and could be repositioned, facilitating difficult colonoscopy, improving patient compliance, and reducing the need for support staff to move the patient. This study revealed that the caecal insertion time was shorter and endoscopist satisfaction scores were higher when sedating with dexmedetomidine plus oxycodone.

There are limitations to this study. First, the entire experiment could not be performed in a double-blind manner. The endoscopist would notice that certain patients could be awakened, and although there is an inherent risk of bias toward the intervention group, we hoped to reduce this bias by using a more objective visibility scoring system rather than a subjective report of visibility adequacy by the endoscopist. Second, patients undergoing conscious sedation may remember having the procedure, although, our study

demonstrated that conscious sedation does not significantly increase procedure-related discomfort. Third, the depth of sedation in the two groups was different. We don't know whether the difference in the incidence of respiratory depression pertained to the depth of sedation or the pharmacological properties of the drug itself. Finally, intravenous infusions of dexmedetomidine have been shown to result in bradycardia in our study as well as existing research [41, 42]. Hence, sedation with dexmedetomidine would be contraindicated in patients with bradycardia.

Conclusion

In summary, conscious sedation with dexmedetomidine plus oxycodone exhibits good sedative effects and minimal respiratory depression for colonoscopy. This sedation method is well accepted by patients and does not significantly increase procedure-related discomfort. For obese patients, sedation with dexmedetomidine plus oxycodone is worthy to be considered.

Abbreviations

BMI: body mass index; ASA: American Society of Anesthesiologists; SpO₂: pulse oxygen saturation; HR: Heart rate; MAP: mean arterial pressure; SBP: systolic blood pressure; CO₂: carbon dioxide; RSS: Ramsay Sedation Scale; SRS: Steward Recovery Score; CIT: caecal insertion time.

Declarations

Acknowledgment

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Authors' contribution

YZZ and RXS conceived and designed the experiments. XRW, ZZ, MMZ, MYZ, HS and RZ performed the experiments. XRW, ZZ, MMZ and NA analyzed the clinical data and wrote the manuscript. All authors reviewed the manuscript and approved the final draft that was submitted.

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Availability of data and materials

The datasets in the study are included in the article, further inquiries can be directed to the corresponding author.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Suqian People's Hospital and Xuzhou Central Hospital (the Clinical College of Xuzhou Medical University). Written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interest

The authors declare that they have no competing interests.

Author details

¹Grade 2017, Department of Clinical Medicine, Kangda College of Nanjing Medical University, Lianyungang, China. ²Department of Anesthesiology, Suqian People's Hospital of Nanjing Drum Tower Hospital Group, Suqian, China. ³Department of Gastroenterology, Xuzhou Central Hospital, Xuzhou, China. ⁴Department of Anesthesiology, Xuzhou Central Hospital, Xuzhou, China. ⁵Department of Gastroenterology, Suqian People's Hospital of Nanjing Drum Tower Hospital Group, Suqian, China. ⁶Division of Anaesthetics, Pain Medicine and Intensive Care, Department of Surgery and Cancer, Faculty of Medicine, Imperial College London, Chelsea and Westminster Hospital, London, UK. ⁷ Department of Endoscopy Center, Xuzhou Central Hospital, Xuzhou, China. ⁸Xuzhou clinical school, Xuzhou Medical University, Xuzhou, China.

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Figures

Figure 1

Enrolment flowchart of patients through the study.

Figure 2

(A) The changes of blood pressure (MAP, mean arterial pressure) in two groups. (B) The changes of heart rate (HR) in two groups. (C) The changes of pulse oxygen saturation (SpO₂) in two groups. Dex+oxy, dexmedetomidine + oxycodone; Pro+suf, propofol + sufentanil; *P < 0.05 versus group Pro+suf. T1, before anesthesia; T2, the endoscope inserted into anus after induction of anaesthesia; T3, the endoscope reached the splenic flexure; T4, the endoscope reached the hepatic flexure of colon; T5, the endoscope reached the ileocecal area; T6, end of endoscopy.

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