Comparing the pain of propofol via different combinations of fentanyl, sufentanil or remifentanil in gastrointestinal endoscopy[1]

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ABSTRACT

PURPOSE: To evaluate the pain on injection of propofol via different combinations of fentanyl, sufentanil or remifentanil in gastrointestinal endoscopy.

METHODS: Total 439 patients were randomly allocated into 6 groups. Propofol & fentanil (PF) group received 1 μg/kg fentanyl, propofol & sufentanil (PS) group received 0.1 μg/kg sufentanil and propofol & remifentanyl (PR) group received 1 μg/kg remifentanyl prior to administration of 1-2 mg/kg of propofol. The propofol & half-fentanil (Pf) group, propofol & half-sufentanil (Ps) group and propofol & half-remifentanyl (Pr) group were given 0.5 μg/kg fentanyl, 0.05 μg/kg sufentanil and 0.5 μg/kg remifentanyl, respectively and later administrated 1-2 mg/kg propofol. All patients were monitored for the blood pressure (MAP), heart rate (HR), and oxygen saturation (SpO_2). Additionally, the pain intensity was assessed using a 4-point verbal rating scale (VRS) by professional doctors.

RESULTS: The incidence of pain due to propofol injection in Ps group (33.8%) was significantly lower than other 5 groups. The heart rate (HR) and mean arterial pressure (MAP) were maintained within the normal limits in all six groups and there was no hypotension or bradycardia encountered during the study period.

CONCLUSION: Propofol and sufentanil group was the most suitable program for painless gastroscopy.

Key words: Gastrointestinal Endoscopy. Propofol. Fentanyl. Sufentanil. Remifentanil.

Introduction

Gastrointestinal endoscopy, an invasive examination method, is one of the most common interventional medical procedures carried out worldwide. And usually, sedation is administrated to the patients scheduling to undergo gastrointestinal endoscopy for the purpose of analgesia, amnesia, controlling the behavior of patient during the procedure, well completing the endoscopy and prompt patient recovery to the pretreatment level of consciousness [1].

Propofol is a short-acting, intravenously administered hypnotic agent, which slows the channel-closing time and also acts as a sodium channel blocker [2] through activating GABA receptor [3]. Due to the high lipid solubility and short half-life, the onset of action of propofol is almost instantaneous and the recovery is rapid that make it into a desired sedative agent for short duration procedures such as gastrointestinal endoscopy [4]. Propofol appears to be an attractive endoscopic sedation among gastroenterologists and mow has been used extensively for gastrointestinal endoscopy [5]. It often has been administrated as a single agent. However, propofol injection frequently causes local pain or discomfort that sometimes induces distress to patients [6, 7]. Novel approach to propofol administration in combination with opioids has been proposed to improve sedation and analgesia [8-11]. Fentanyl is a potent, synthetic opioid analgesic with a rapid onset and short duration of action, and is commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with a benzodiazepine [12]. Sufentanil is a powerful synthetic opioid drug, approximately 5 to 10 times more potent than fentanyl [13]. Remifentanil, another opioid medicine, is used for sedation as well as combined with other medications for use in general anesthesia [14, 15]. Besides, when used alone, relatively large doses of propofol may be required to achieve adequate comfort which may result in dose-related side effects, such as hypotension or respiratory depression [16, 17]. Drug combinations can decrease the adverse reactions by reducing the dosage of drugs [18].

Studies on side effects of drug combination of propofol were not enough, and the anesthesia mechanism was not very clear. So we conducted a double blinded and random control study to compare the clinical efficacy and safety of anesthesia for gastrointestinal endoscopy using propofol via different combinations of fentanyl, sufentanil or remifentanil and to choose a more suitable sedation approach for gastrointestinal endoscopy.

Methods

The study was approved by the institutional review board. From March, 2011 to April, 2013, 439 American Society of Anesthesiologists physical status I or II patients, aged 20-65 years, who scheduled to receive a gastrointestinal endoscopy examination were included (Table 1).

TABLE 1 - Demographic data.

	PF (n=100)	PS (n=89)	PR (n=16)	Pf (n=90)	Ps (n=80)	Pr (n=64)
Sex(M/F)	45/55	48/41	7/9	46/44	44/36	37/27
Age(yr)	44.8 (13.7)	45.6 (14.4)	45.9 (12.7)	45.9 (13.4)	46.9 (14.2)	47.5 (14.3)
Weight	62.4 (9.1)	62.4 (8.7)	59.7 (9.4)	61.1 (10.4)	62.4 (7.5)	63.2 (6.4)
Height	157.8 (8.2)	165.3 (8.8)	163.1 (7.6)	164.6 (6.8)	165.3 (5.8)	164.9 (7.0)

PF: Propofol & sufentanil, PS: propofol & sufentanil, PR: propofol & remifentanyl, Pf:propofol & half-sufentanil, Ps: propofol & half-sufentanil, Pr: propofol & half-remifentanyl.
Values are shown as mean (SD) or number of patients. There were no significant differences between groups.

Gastrointestinal endoscopy and drug administration

All patients were allocated randomly into 6 groups using a computer generated randomization list manipulated by a statistician. Before examination no patient received diet and pre-anesthetic medications. On arriving at the operating room, the patients were monitored for the blood pressure (MAP), heart rate (HR) and oxygen saturation (SpO_2) using a monitoring device (Dash 3000). The patients maintained left-lateral lie and received oxygen insufflations at a rate of 2 L/min. The patients in PF group (propofol & fentanyl), PS group (propofol & sufentanil) or PR group (propofol & remifentanyl) respectively received the fentanyl of 1 μg/kg, sufentanil of 0.1 μg/kg or remifentanyl of 1 μg/kg intravenously (diluted with normal saline) for 30 s and 60 s and later were given the propofol of 1-2 mg/kg for 60 s. The patients in Pf group (propofol & half-fentanil), Ps group (propofol & half-sufentanil) or Pr group (propofol & half-remifentanyl) were given the fentanyl of 0.5 μg/kg, sufentanil of 0.05 μg/kg and remifentanyl of 0.5 μg/kg, respectively over a 30 s period and later were given the propofol of 1-2 mg/kg intravenously over a 60 s period. There was a 15-30 s period between the administration of opioid and propofol. The patients received the gastroscopy after the eyelash reflex vanished. The patients with cough or body movement were given additional propofol of 0.5-1 mg/kg.

Assessment of pain intensity using 4-point verbal rating scale

Immediately after injected with the propofol, the patients were asked about pain at the injection site and the

pain intensity was assessed using a 4-point verbal rating scale (VRS) by an anesthetist blinded to the drug administration. This VRS assessment was developed by McCrirrick and Hunter10 and has been previously applied (by the present investigators) to evaluate the pain intensity on injection of propofol. The 0 represents no pain (no reaction to the injection); The 1 represents mild pain (a minor verbal/facial response or motor reaction to the injection); The 2 represents moderate pain (a clear verbal/facial response or motor reaction to the injection); and The 3 represents severe pain (the patient both complained of pain and withdrew their arm) [19].

Statistical analysis

Data were presented by mean ± standard deviations and statistical software SPSS18.0 [20] was applied. A Fisher's exact test [21] was used to calculate the between-group differences in the incidence of microemulsion-induced pain, and a Kruskal-Wallis test [22] was used to assess the differences in the mean pain-intensity scores. $P < 0.05$ was considered statistically significant.

Results

Changes of MAP, HR, and SpO_2

The heart rate (HR), mean arterial pressure (MAP) and SpO_2 were maintained within the normal limits in six groups. There was no hypotension or bradycardia encountered during the study (Table 2).

The parameters comparison of painless gastroscopy of propofol

In Table 3, the doses of propofol in another five groups were similar except PR group (Table 3). The patients in the PR

TABLE 2 - Changes of MAP, HR, and SpO_2 at different time point.

	Group	Before gastroscope	Gastroscope over a throat	Gastroscope	After gastroscope
MAP (mmHg)	PF	87.52±10.31	79.15±10.15	78.64±8.52	89.51±11.63
	PS	88.34±9.83	77.03±8.39	78.64±8.85	88.74±8.73
	PR	89.28±10.02	76.19±7.89	77.53±7.84	87.16±9.62
	Pf	87.28±9.37	78.43±9.52	78.94±8.85	86.74±8.84
	Ps	88.83±8.25	78.06±11.13	79.56±10.64	89.28±8.48
	Pr	87.56±9.69	76.95±8.52	77.36±8.84	89.53±9.46
HR (min^{-1})	PF	79.52±9.65	76.76±7.42	75.26±8.36	78.73±7.83
	PS	80.45±10.53	78.63±8.83	77.63±9.26	79.62±9.73
	PR	78.62±6.26	75.63±7.74	75.26±7.36	76.84±7.26
	Pf	81.62±9.57	79.33±8.46	78.73±7.47	80.67±8.95
	Ps	79.63±9.63	76.63±7.26	75.73±7.84	78.94±7.95
	Pr	79.73±8.63	77.62±6.87	76.73±9.63	79.26±7.37
SpO_2 (100%)	PF	99.50± 0.63	99.00± 1.15	99.10± 1.18	99.12± 1.20
	PS	99.30 ± 0.52	98.80± 1.19	98.90±1.21	98.92± 1.22
	PR	99.46± 0.45	98.76±1.30	98.12±1.28	99.02±1.03
	Pf	99.34±0.46	98.78±1.24	99.12±1.10	99.04±1.20
	Ps	99.73±0.74	98.84±1.16	98.88±1.06	98.78±1.08
	Pr	99.25±0.42	98.64±1.20	98.90±1.02	98.58±1.22

PF: Propofol & sufentanil, PS: propofol & sufentanil, PR: propofol & remifentanyl, Pf: propofol & half-sufentanil, Ps: propofol & half-sufentanil, Pr: propofol & half-remifentanyl. MAP: the blood pressure, HR: heart rate, SpO2: oxygen saturation.
The differences between two groups aren't significant enough ($p > 0.05$) indicates no significant differences).

TABLE 3 - The parameters of six groups during the anesthesia in gastrointestinal endoscopy.

	Dose of propofol	Times of body movement (ave)	Eyelashreflex (times)	Manipulate time (min)	Revival time (min)
PF	96.3±5.5	0.030±0.003	64.9±4.5	122.4±8.6	94.6±9.4
PS	92.3±4.1	0.068±0.004	67.7±4.3	137.2±7.3	91.8±7.4
PR	110.7±4.3*	0.867±0.006*	80.2±3.2*	169.0±11.3*	96.4±4.3
Pf	91.6±5.3	0.057±0.014	64.8±3.5	132.1±10.5	93.2±6.5
Ps	95.8±5.4	0*	58.6±3.3	137.8±9.5	92.2±7.4
Pr	89.9±4.7	0.079±0.003	63.8±4.1	178.2±11.8	96.5±5.4

PF: Propofol & sufentanil, PS: propofol & sufentanil, PR: propofol & remifentanyl,
Pf: propofol & half-sufentanil, Ps: propofol & half-sufentanil, Pr: propofol & half-remifentanyl.
*, $p<0.05$ indicates significant differences.

group appeared respiratory and HR depression, and needed the respiratory support and assistance of atropine, which significantly affect the safety of outpatient, so this program was not suitable for clinical gastrointestinal endoscopy. Differences were observed in times of eyelashreflex, manipulate time and recovery time, but not significant. It was important to point out that there was no body movement in Ps group, which indicated the better anesthesia effect of Ps group than other groups.

Incidence and severity of pain on a propofol injection

The incidence of pain from Ps group (33.8%) was significantly lower than other five groups (47.0%, 41.6%, 43.8%, 42.2%, and 43.8%). The incidence of moderate pain was only 2.5%, and no case of severe pain was observed in all six groups (Table 4).

TABLE 4 - Incidence and severity of pain in six groups.

Severity of pain	PF (100)	PS (89)	PR (16)	Pf (90)	Ps (80)	Pr (64)
Incidence of pain	47.0%	41.6%	43.8%	42.2%	33.8%*	43.8%
0 (No pain)	53	52	9	52	53	36
1 (mild pain)	39	32	2	32	25	21
2 (moderate pain)	8	5	5	6	2	7
3 (severe pain)	0	0	0	0	0	0

PF: Propofol & sufentanil, PS: propofol & sufentanil, PR: propofol & remifentanyl,
Pf: propofol & half-sufentanil, Ps: propofol & half-sufentanil, Pr: propofol & half-remifentanyl.
The values are shown as the number of patients (%). *, $p < 0.05$ compared to the PF group.

Discussion

Action mechanism and significance of combination of propofol and opioids

Propofol-induced pain has been ranked by American anesthesiologists as the seventh most important problem of current clinical anesthesiology [23]. The mechanism by which propofol causes pain on injection is not fully understood. Site of injection, injection speed and carrier fluids [24], dilutions [25], temperatures [19], and concomitant therapies have been investigated, according to which clinical strategies for the prevention of propofol injection pain have been suggested with varying degrees of success [26]. Intravenous administration of local analgesic is a common pretreatment for reducing such pain. Opioids, psychoactive chemicals, are characterized as analgesic agents due to their effects on decreasing perception of pain and reaction to pain as well as increasing pain tolerance. Opioids work via binding to opioid receptors, which are found principally in the central and peripheral nervous system and the gastrointestinal tract [27]. They are frequently used to treat acute pain and alleviate sever, chronic pain. Our study provided a reasonable anesthesia method for gastrointestinal endoscopy using propofol in combination with opioids to reduce the pain on injection of propofol and less drug dose to reduce anesthesia risk and complications such as arrhythmias and then save medical expenses, which has a certain degree of social and economic benefit.

Comparison of anesthesia effect of propofol via different combinations of fentanyl, sufentanil or remifentanil

Pretreatment with opioids has been reported to reduce the incidence and severity of pain during a propofol injection with opioids. Fentanyl, sufentanil and remifentanil appear to be a very titratable opioid providing profound intraoperative analgesia [28-30]. In the report by Han [15], combination of a pretreatment with remifentanil and premixture of lidocaine and microemulsion propofol displayed effective function in reducing the incidence of pain on an injection of microemulsion propofol [31]. It was suggested that in combination with propofol 2 mg/kg, an appropriate dose of remifentanil was 2 μg/kg [32]. This scheme achieved good anesthetic effect, but always brought some side effects, such as respiratory and HR depression and desaturation [33]. Similarly, in current study, the patients in the PR group appeared respiratory and HR depression, and need the respiratory support and assistance of atropine. Therefore, PR was not a desirable strategy for sedation during gastrointestinal endoscopy.

In other five groups, the side effects, such as respiratory and HR depression, were not occurred.. Recent study found that patients who received fentanyl 100 μg, preceded by manual venous occlusion for 1 minute, had significantly less pain on injection than

those who received placebo, but fentanyl 50 μg was ineffective for reducing such pain [34]. So in present study, we increased the amount of fentanyl, and the effect was acceptable. It should be noted that there was no body movement in Ps group, and times of eyelashreflex, manipulate time and revival time were lower when compared to other 4 groups, which mean that the anesthesia effect of Ps group was the best. Additionally, the incidence of pain in Ps group (34.5%) was significantly lower than other five groups. Sufentanil is a powerful synthetic opioid analgesic drug, approximately 5 to 10 times more potent than fentanyl. The half-life ($t_{1/2}$) of sufentanil is 2.1 min, and the plasma protein binding rate is 92.5%, which is higher than fentanyl (44%). Since the small volume of distribution short period of terminal elimination and thus less accumulation, sufentanil has a good controllability [35]. Recent study demonstrated that the patients receiving sufentanil 0.2 μg/kg and propofol 1-2 mg/kg for induction of anesthesia achieved good anesthetic effect, but they produced depression in systolic and diastolic blood pressures during the anaesthesia [36]. So the dose of sufentanil in our study was reduced to 0.1 or 0.05 μg/kg, and this strategy produced desirable efficacy, especially when using the dosage of 0.05 μg/kg.

In conclusion, the program that 0.05 μg/kg sufentanil (diluted with normal saline) was administered intravenously for 30 s and 60 s later the propofol of 1-2 mg/kg were given for 60 s is the most suitable for gastrointestinal endoscopy.

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