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Research article

Effect of low dose ketamine versus dexmedetomidine on gag reflex during propofol based sedation during upper gastrointestinal endoscopy. A randomized controlled study

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ABSTRACT

Objective: The aim of this study is to evaluate the effect of dexmedetomidine versus low dose ketamine on incidence of gag reflex and the total amount of propofol consumed during (UGIE) in patient sedated with propofol.

Methods: This randomized, prospective, double blind study was approved by institutional ethics committee of El-Minia university hospital and carried out in the period ranged from March 2015 to January 2016. 75 male and female patients aged from 18 to 70 years old, ASA class I–II. The patients were randomly (by computer generated table) allocated into 3 equal groups: Group(I) (propofol group), Group(II): (propofol + ketamine group), Group(III): (propofol + dexmedetomidine group). Parameters assessed was - Gag reflex, depth of sedation, total dose of propofol, oxygen saturation(spo2), hemodynamic data, time to recovery, any side effects as:- emergence delirium, and ny need for airway assistance.

Results: Gag reflex In group(I) was 32% (8 patients) versus 20% (5 patients) in group(II) and 8% (2 patients) in group(III). Patients in group(I) were significantly required higher doses of propofol when compared to group(III) and group(II), while patients in group(II) were required higher doses of propofol than group(III) with significant statistically difference. The changes of HR were comparable between the studied groups except after 2 min of induction, there were significant reduction in mean values of HR in group(I) in comparison to group(II) and group(III). As regard MAP, there were significant elevation in group(II) when compared to group(I) (at 2, 4, 6 min) and group(III) (at 2, 4, 6, 8 min, otherwise there were no significant difference. Oxygen saturation was comparable in the studied groups at all set time and there was no significant difference in their values, only 8% of patients in group(II) versus 12% in group (III) and 20% in group(I) needed jaw thrust as airway assistance. Time to recovery in group(I) was (4.84 ± 0.89 min) which was significantly longer than both group(II) (4.16 ± 1.06 min) and group(III) (4.2 ± 1.04 min).

Conclusion: Dexmedetomidine with propofol in patients undergoing UGIE was safe and effectively, can reduce the incidence of gag reflex better than ketamine when added to propofol, with less propofol consumption and better in recovery time.

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1. Introduction

Upper gastrointestinal endoscopy (UGIE) is increasingly being performed under propofol sedation. Even under propofol sedation, UGIE is associated with gag reflex and retching in approximately 29% of patients [1]. Any further deepening of sedation to minimize gagging may cause respiratory depression and compromise hemodynamics, while continued gag reflex could affect the safety of the procedure. In a laboratory study, N-methyl-D-aspartate (NMDA) receptor antagonism has been shown to prevent gag reflex [2]. Ketamine, a phencyclidine derivative and NMDA receptor antagonist, is commonly used in sub-anesthetic doses as an adjunct for anesthesia technique. In a laboratory study, N-methyl-D-aspartate (NMDA) receptor antagonism has been shown to prevent gage reflex by abolish the coupling between loss of consciousness and upper airway dilator muscle dysfunction in a wide dose range [3] it is commonly used in sub-anesthetic doses as an adjunct for anesthesia technique [5]. Propofol is a preferred drug for sedation during UGIE [4]. Dexmedetomidine, a short-acting selective alpha-2 agonist, possesses anxiolytic, hypnotic, and analgesic properties

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[6]. It is approximately eightfold more selective for the alpha-2 adrenergic receptor than clonidine and is 1620-fold more potent as an alpha-2 adrenergic receptor agonist than as an alpha-1 adrenergic receptor agonist [7], it provide unique sedative activity not found in conventional sedatives and is thus unlikely to cause the restlessness or respiratory suppression seen with GABA receptor agonists such as propofol alone that minimize physical and emotional discomfort, and facilitate successful completion of the procedure without significant gag reflex [11]. Several randomized controlled trials (RCT) have evaluated the efficacy of dexmedetomidine in comparison with midazolam for gastrointestinal endoscopy [8]. Unfortunately, none of these trials enrolled a sufficient number of patients to produce an adequate power in order to detect meaningful differences. Many authors proposed that systematic pooling of all data from available studies might provide a better understanding the effects of dexmedetomidine [9].

The aim of this study is to evaluate the effect of dexmedetomidine versus low dose ketamine on incidence of gag reflex (primary outcome) and the total amount of propofol used during (UGIE) in patient sedated with propofol.

2. Patients and methods

This randomized, prospective, controlled, double blind study was approved by institutional ethics committee of El-Minia university hospital and carried out in the period ranged from March 2015 to January 2016. A written consent was obtained from 75 male and female patients aged from 18 to 70 years old from ASA class I - II patients, including patients with compensated hepatic cirrhosis undergoing upper GIT endoscopy. We excluded from our study Patients with major organ dysfunction specially patient with decompensated liver disease, also Closed angle glaucoma, any type of analgesics as opioids or corticosteroids preoperative or allergy to any type of studied drugs. A careful medical history was taken, general and local examination including chest, heart, abdomen, and neurological examination. Routine investigations including, liver function tests, complete blood picture, renal function tests, blood sugar, abdominal ultrasound to exclude any hepatic decomposition and electrocardiogram (ECG). The patients were randomly divided into three equal groups (25 of each) using a computer-generated sequence of random numbers and a sealed envelope technique. Study drugs were prepared by an anesthetist who did not participate in the procedure; this study was conducted in a double-blind manner (neither the administrator of the drug nor the patient know the nature of drugs given. Group(I): (propofol group), Patients receive 2 syringes one containing 5 ml normal saline followed by the second containing 50 mg propofol (deprivan, AstraZeneca, Egypt). Group(II): (propofol + ketamine group) 5 ml of normal saline containing 0.20 mg/kg ketamine (ketamine, liorad, Egypt) in the first syringe followed by the second syringe containing 50 mg propofol. Group: (III): (propofol + dexmedetomidine group) 5 ml volume of normal saline containing 0.5 mcg/kg dexmedetomidine (precede, hospira, Egypt) in the first syringe followed by the second syringe containing 50 mg propofol as bolus. Standard monitoring (i.e. ECG, heart rate (HR), pulse oximetry (SpO2), non-invasive arterial pressure measurement, and baseline parameters recorded using (Datex-omedah. GE healthcare co. U.S. A). 20F I.V cannula was inserted for administration of drugs and all patients were premedicated only with intravenous 50 mg ranitidine before start of sedation, Two ml of 2% lignocaine was slowly injected intravenously to prevent propofol induced pain, followed by the administration of content of the test syringes (either saline, ketamine or dexmedetomidine). Immediately after this injection a bolus of propofol (10 mg/ml) was given slowly over 1 min following which sedation was assessed and if needed further top up doses of propofol were given in 10 mg increments. Sedation was always maintained at Ramsay score of more than 4, Sedation levels were checked every 2–3 min by a light glabellar tap or loud noise according to Ramsay sedation score as shown at Table 1 [10]. Supplemental oxygen was given to all patients using nasal canula the sedation done by anesthesiologist who didn't know the contents the test syringes prepared by the senior author, also, data measured by assistant anesthesiologist who did not know the administered study drugs. **Measured data**: 1 – *Gag reflex*: Was recorded as "present or not" when a vomiting like response was elicited upon insertion of the endoscope. 2 – *Depth of sedation*: Assessed by Ramsay sedation score (Table 1), after 1 min of induction of sedation and allover the time of the procedure every 2 or 3 min. 3 – *Total dose of propofol* administered in each patient. 4 – *Oxygen saturation* (spo2). 5 – *Hemodynamic data*: HR and non invasive mean arterial blood pressure. Bradycardia (heart rate less than 50) and hypotension were defined as 20% decrease below base line values or mean arterial blood pressure less than 60 and if recorded treated by atropine 0.02 mg/kg or bolus dose of ephedrine 6 mg respective 6 – *Time to recovery*: From end of the procedure to Ramsay sedation score 2 (awake, cooperative, accepting ventilation, oriented and tranquil). 7 – *Any side effects* as:- emergence delirium: Patient talking irrelevant or disoriented upon recovery was labeled as having "emergence delirium". Any recall of the procedure, they were asked "do you remember anything about the endoscopy procedure performed on you. 8 – Any need for airway assistance. Also, other side effects of drugs used in the study if present as (nausea, vomiting, respiratory depression or hypersensitivity to any drug used.)

Table 1
Ramsay sedation scale [10].

1	Patient is anxious and agitated or restless, or both
2	Patient is co-operative, oriented, and tranquil
3	Patient responds to commands only
4	Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
5	Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
6	Patient exhibits no response

2.1. Statistical analysis

Based on prior study, the sample size was calculated to detect difference in incidence of gag reflex between the studied groups at power of 0.80, confidence interval of 95% and significance level of 0.05. Calculating for a 20% dropout rate, 25 patients in each group was appropriate to detect this difference. Data was analyzed using Statistical Package of Social Sciences (SPSS) software and expressed as mean ± standard deviation and median (minimum-maximum) for numerical data or as number and percent (%) for categorical data. Intergroup comparisons of continuous numerical variables were done using ANOVAtest for parametric data or kruskal-willis one way test for non-parametric data. Intragroup comparisons to baseline values were done using paired *t*-test for parametric data or Wilcoxon test for non-parametric data. The level of significance was fixed at a minimum of 0.05%.

3. Results

There were no significant differences in age, weight, sex distribution, ASA classification or duration of the procedure among the 3 groups (Table 2).

Gag reflex was recorded as present or not in all groups, there was significant reduction in the incidence of gage reflex in group (III) (8%) when compared with group(I) (32%) (p value: 0.034), also

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