Published online: 2019-09-26

Original Article

Comparison of dexmedetomidine, midazolam, and propofol as an optimal sedative for upper gastrointestinal endoscopy: A randomized controlled trial

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Abstract

Context: Midazolam and propofol are effective sedatives for use in upper gastrointestinal endoscopy (UGIE); however, their utility is limited when used alone. In this regard, dexmedetomidine seems to be a promising sedative. **Aims:** The aim was to compare the hemodynamic effects and sedation efficacy of these drugs in patients undergoing elective diagnostic UGIE. **Settings and Design:** Randomized control double-blind study was conducted at a teaching hospital. **Subjects and Methods:** Patients belonging to ASA Grade I or II, undergoing diagnostic elective UGIE were enrolled in the study and randomized into three groups; Group I received midazolam infusion, Group II received propofol infusion and Group III received dexmedetomidine infusion. Hemodynamic parameters and adverse events were recorded during the procedure (intra-operative period [IOP]). Both patient and endoscopist satisfaction were rated on visual analog scale (0 = no pain/least difficulty to 10 = worst pain/maximum difficulty). Recovery was recorded as time to achieve modified Aldrete score of 10/10. **Statistical Analysis:** Parametric test analysis of variance was applied to compare the means of three groups of continuous data. **Results:** Ninety patients were analyzed. Mean arterial pressure was significantly lower in the propofol group at IOP_2, IOP_4, IOP_8, and IOP_{10} compared with dexmedetomidine and midazolam group. The endoscopist satisfaction level was significantly higher in dexmedetomidine group as compared to propofol and midazolam (60%, 56.7%, 13.3%; $P < 0.001$). Significantly faster recovery was observed in dexmedetomidine group compared to midazolam and propofol group (7.7 ± 3.9, 18.3 ± 3.8, 12.7 ± 2.9 min; $P = 0.001$). **Conclusions:** Use of dexmedetomidine was associated with greater hemodynamic stability and faster recovery when compared to propofol and midazolam.

Key words

Dexmedetomidine, midazolam, propofol, sedative, upper gastrointestinal endoscopy

Introduction

The development of upper gastrointestinal endoscopy (UGIE) has greatly expanded the diagnostic and therapeutic capabilities of gastroenterologists. Routine UGIE is the standard practice to diagnose esophageal, gastric and duodenal diseases. This is an invasive procedure and the examination, usually, lasts for about 10 mins with very low complication rates. The procedure may be performed with or without conscious sedation using topical pharyngeal anesthesia alone. But, patient's tolerance to procedure and endoscopist's satisfaction increase when sedation is used along with topical pharyngeal anesthesia.[1] Moreover, judicious use of sedation can alleviate the sympathetic response (rise in heart rate and systolic blood pressure) to the procedure.[2] Numerous agents are available for moderate sedation in endoscopy. Sedation practices may vary from

Access this article online

Website: www.jdeonline.in

DOI: 10.4103/0976-5042.144826

Quick Response Code

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country to country and from hospital to hospital that could influence the endoscopists' attitude.[3] Furthermore, choice of a particular sedative agent depends on its availability, cost and experience of endoscopist and patient with that sedative agent.

The goals of sedation are analgesia, amnesia, immobility during the procedure, ability to complete the procedure and quick patient recovery to pre-procedure level of consciousness.[4] Midazolam and Propofol are the most widely used sedative medications during UGIE. Midazolam is favored due to its potent amnestic properties, anxiolytic effect and a short elimination half-life.[3] Dexmedetomidine, an α_2-agonist, has been used widely for sedoanalgesia in diagnostic and therapeutic procedures, and its use is progressively increasing.[5] However, the use of dexmedetomidine in adults undergoing UGIE has not been completely evaluated. Until date, no study has compared three anesthetic agents (solely) in diagnostic UGIE and data from Indian continent are scarce. This study aimed to compare the hemodynamic effects and to assess sedation efficacy of these drugs in patients undergoing elective UGIE.

Subjects and Methods

This randomized control double-blind study was conducted at a tertiary care level teaching hospital over a period of two years after obtaining Ethical Committee clearance and registration of trial (No. REF/2013/10/005800). The endoscopist, the investigator, and recovery room personnel remained blinded while the anesthesiologist was not blinded to the patient's sedation regimen. Adult patients aged 18-60 years and who belong to American Society of Anesthesiologists [ASA] physical status classification system class I or II, undergoing diagnostic elective UGIE were enrolled in the study. Exclusion criteria were systemic hypertension, bleeding diathesis, prior gastric surgeries, psychiatric diseases or long-term antipsychotic drug therapy, chronic use or addiction to opiates or sedatives, presence of neoplastic or other serious concomitant diseases, previous adverse reactions to any medication used in the present study, baseline systolic blood pressure <90 mmHg, allergy to eggs, history of sleep apnea and anticipated difficult intubation.

Randomization

After obtaining written informed consent, patients were randomized into one of the three groups using a computer-generated randomization list: Group I received an infusion of 0.03 mg/kg loading dose of Midazolam (Benzosed, Troikaa Pharmaceuticals Ltd.), followed by 0.06 mg/kg/h as continuous infusion. Group II received an infusion of 1 mg/kg loading dose of Propofol (Troypofol, Troikaa Pharmaceuticals Ltd.), followed by 3 mg/kg/h as a continuous infusion. Group III received an infusion of 1 μg/kg loading dose of dexmedetomidine (Dextomid, Neon Laboratories Ltd.) over 10 min, followed by 0.5 μg/kg/h as a continuous infusion. Inj. Fentanyl 25 μg was administered intravenously as rescue sedation for all the three groups as and when required. All medications in the syringe and the infusion lines were remained covered with white paper ensuring adequate blinding.

Procedure

Pre anesthetic check-up was conducted prior to procedure during which patients were explained about the visual analogue scale (VAS) and informed consents were obtained. All the patients were kept nil per oral 8-10 h prior to the procedure. Upon arrival to the endoscopy suite, monitoring (electrocardiography, pulse oximetry, NIBP) was started and continued until shifting out to the recovery area. The baseline values of HR, mean arterial pressure (MAP), oxygen saturation of hemoglobin (SpO_2) and respiratory rate (RR) were recorded. Topical pharyngeal anesthesia was administered by spraying metered dose of 10% lignocaine. Following peripheral IV access, patients were premedicated with injection glycopyrrolate 10 μg/kg. During the procedure, monitoring of HR, MAP, SpO_2 and RR was continued every 2 min for the first 10 min, thereafter every 5 min until end of the procedure. When the patient achieved a desired level of sedation level of 2-4 on observer assessment alertness/sedation scale, endoscope was introduced.[6] Time to reach the desired sedation level was also recorded. Occurrence of adverse events like hypertension, hypotension, desaturation, apnea, gagging and retching was also recorded during the procedure. All endoscopies were carried out by a single operator using a GIF-H180 gastroscope (Olympus®).

The Patients' satisfaction regarding discomfort (pain and gagging) during the procedure was assessed using the VAS in the recovery room. All patients were asked to place a vertical mark on a 10 cm straight line labeled only with descriptors at each end to represent procedural pain, (0 = no pain, 10 = worst pain imaginable). Endoscopist satisfaction regarding retching and difficulty during the procedure was assessed using VAS (0 = no retching/difficulty, to 10 = maximum retching/difficulty). Recovery from sedation was assessed using modified Aldrete score at 5 min after removal of the endoscope and every 5 min thereafter until a discharge score of 10/10 was reached.[7]

Statistical analysis

The data were entered in Epi Info 7 (Centers for Disease Control and Prevention Atlanta, GA) software and analyzed using SPSS (SPSS Inc., Chicago, Illinois, USA) 17.0 for Windows statistical software. Continuous data were expressed as mean and standard deviation. Dichotomous and categorical data were described using percentages. Analysis of variance was applied to compare the means of three groups of continuous data. Chi-square test and Fisher's exact test were applied to compare categorical and dichotomous data. To compare the means of two groups, Student's *t*-test with multiple comparisons was applied.

Results

We screened 103 patients for inclusion in the study as shown in the CONSORT flow diagram [Figure 1]. Ninety subjects were randomized into three groups of 30 each. There were no statistically significant differences between the groups with regard to age, gender, height, weight, ASA class, hemodynamic variables and requirement of fentanyl [Table 1]. The MAP was significantly lower in the propofol group at IOP_2, IOP_4, IOP_8, and IOP_{10} compared to dexmedetomidine and midazolam groups [Figure 2a]. There were no significant differences in mean RR and mean oxygen saturation among three groups [Figure 2b and c]. None of the patients developed desaturation or bronchospasm. Mean doses of midazolam, propofol and dexmedetomidine used were 7.8 mg ± 3.8 mg, 94.05 mg ± 6.1 mg, and 62.2 μg ± 5.4 μg respectively. The patient satisfaction level (measured by VAS) of grade 1 (highest level of satisfaction) was significantly higher in midazolam group as compared to dexmedetomidine group (93.3%, 40%; $P < 0.001$, *t*-test with multiple comparison), whereas no statistically significant differences in patient satisfaction were noted between (i) propofol and dexmedetomidine and (ii) propofol and midazolam ($P > 0.05$). The endoscopist satisfaction level of grade 1 (highest level of satisfaction) was significantly higher in the dexmedetomidine group than midazolam group (60%, 13.3%; $P < 0.001$, *t*-test with multiple comparisons). Similarly, propofol demonstrated significantly higher endoscopist satisfaction level as compared to midazolam (56.7% vs. 13.3%; $P < 0.001$, *t*-test with multiple comparisons). Recovery was significantly faster in the dexmedetomidine group than midazolam and propofol group (7.7 ± 3.9, 18.3 ± 3.8, 12.7 ± 2.9; $P < 0.001$). The incidence of adverse events (gag and discomfort) was not significantly different among three groups [Table 2].

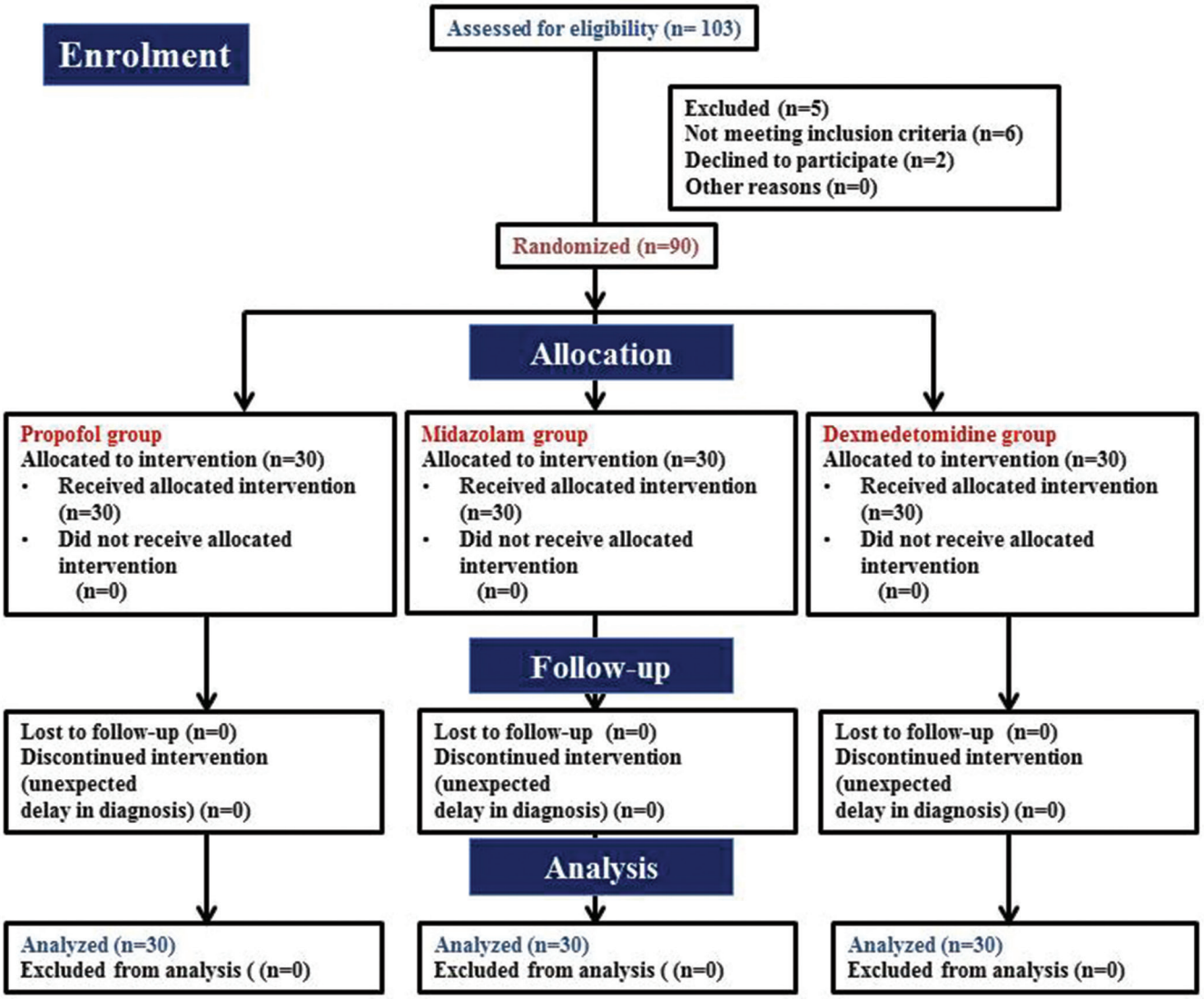

Figure 1: Consort flow chart

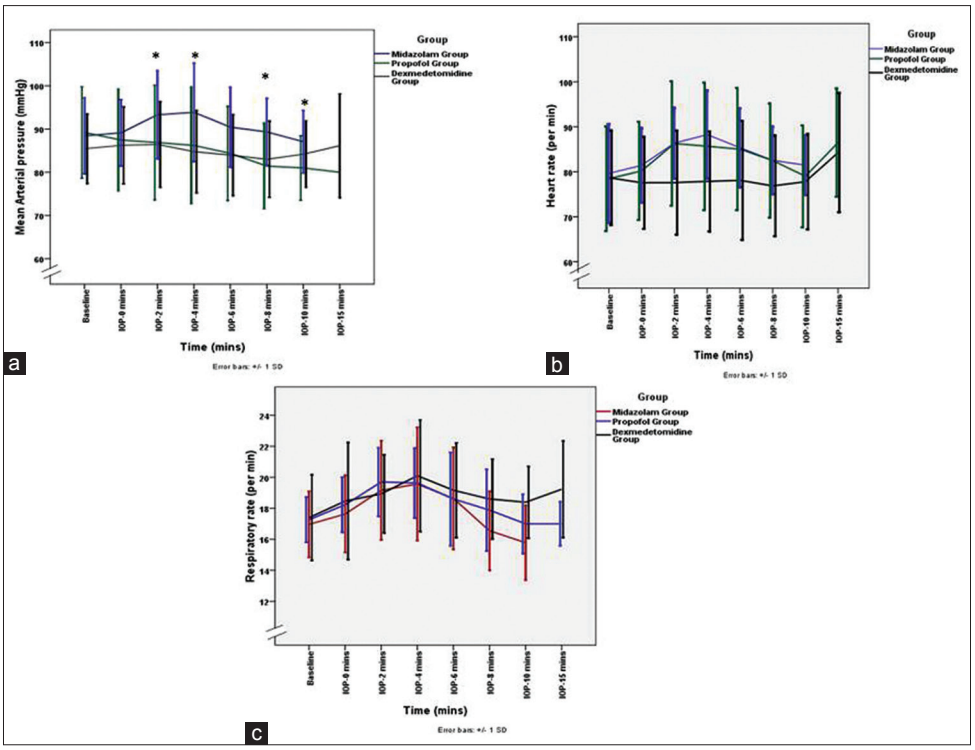

Figure 2: Hemodynamic changes (mean±standard deviation) in patients undergoing elective upper gastrointestinal endoscopy receiving midazolam, propofol and dexmedetomidine: (a) Mean arterial pressure, (b) Heart rate (c) Respiratory rate

Table 1: Subject and procedure characteristics

Characteristics	Sedation groups (*n*=30)			*P*
	MDZ group	PF group	DEX group	
Age (years)	33.8±11	34.8±10.1	36.8±9.6	0.52
Male/female (%)	18 (60)/12 (40)	17 (56.7)/13 (43.3)	19 (63.3)/11 (36.7)	0.87
Weight (kg)	59.9±11.9	57±11.1	62.4±12.2	0.21
Height (cm)	156.1±6.2	154.8±6.9	156.8±9.4	0.13
ASA class (I/II)	28 (93.3)/2 (6.7)	28 (93.3)/2 (6.7)	26 (86.7)/4 (13.3)	0.51
Baseline MAP (mmHg)	88.4±8.7	89.2±10.6	85.4±8.0	0.249
Baseline HR (beat/min)	79.6±10.9	78.4±11.6	78.7±10.5	0.908
Baseline RR (breath/min)	16.9±2.1	17.3±1.5	17.4±2.8	0.734
Baseline SpO_2 (100%)	99.9±0.2	99.9±0.3	100±0.0	0.164
Duration of procedure (min)	20±0	12±4.7	11±4	0.03*
Dose of fentanyl used for breakthrough sedation (mcg)	20±10.2	21.7±8.6	19.2±10.8	0.61
Willingness to undergo similar procedure in future, *n* (%)	24 (80)	24 (80)	29 (96.7)	0.11
Patient satisfaction of VAS 1/10 (%)	93.3	76.7	40	<0.001**
Endoscopist satisfaction of VAS 1/10 (%)	13.3	56.7	60	<0.001**
Time to achieve modified aldrete score of 10/10 (min)	18.3±3.8	12.7±2.9	7.7±3.9	0.001**

*Significant, **Highly significant, ANOVA test. ASA=American Society of Anesthesiologists, MAP=Mean arterial pressure, RR=Respiratory rate, HR=Heart rate, SpO2=Oxygen saturation of haemoglobin, VAS=Visual analogue scale, MDZ=Midazolam, PF=Propofol

Discussion

The aim of this study was to compare the efficacy and safety of dexmedetomidine with propofol or midazolam use as sole sedoanalgesic in patients undergoing UGIE. The present study revealed that the dexmedetomidine is safer as it is associated with least hemodynamic perturbations and is more effective (as rate of desired sedation achieved was higher) than midazolam and propofol. Dexmedetomidine use was also linked with the fastest recovery and higher level of endoscopist satisfaction as compared to midazolam [Table 3].

Each sedative agent has unique pharmacokinetic properties and pharmacodynamic effects. Selection of a particular sedative agent by an anesthesiologist or endoscopist depends on knowledge of pharmacological properties of the agent, familiarity and experience with its use. Dexmedetomidine is a relatively newer sedative as compared to other anesthetic

molecules.[8] It was approved by the Food and Drug Administration, at the end of 1999, for use in humans as a short-term medication (<24 h) for sedation/analgesia in the intensive care unit. Like other α-2 adrenoceptor agonists, dexmedetomidine provides sedation, hypnosis, anxiolysis, amnesia and analgesia. The hypnotic effect of dexmedetomidine is mediated by the hyperpolarization of noradrenergic neurons in the locus ceruleus of the brain stem (a small bilateral nucleus that contains many adrenergic receptors), which is a key site in modulating wakefulness. The locus ceruleus is also the site of origin for the descending medullo-spinal adrenergic pathway, which is known to be a key mechanism in regulating nociceptive neurotransmission. When these sites are stimulated, they decrease the firing of nociceptor neurons stimulated by peripheral A and C fibers and also inhibit the release of their neurotransmitters. Dexmedetomidine has a short onset of action (15 min) and is extensively metabolized in the liver through glucuronide conjugation and biotransformation by the cytochrome P450 enzyme system. There are no known active or toxic metabolites.

A bolus dose of 1 μg/kg results in an initial increase in blood pressure and a reflex drop in HR (due to stimulation of the α-2_b receptors in vascular smooth muscle). This initial response

Table 2: Adverse events during the procedure

Variables	Sedation groups (*n*=30) (%)			*P*
	MDZ group	PF group	DEX group	
Tachycardia[a]	15 (50)	10 (33.3)	9 (30)	0.231
Hypotension[b]	3 (10)	7 (23.3)	3 (10)	0.933
Bradycardia[c]	0 (0)	0 (0)	2 (6.6)	NA
Arrhythmias	0 (0)	1 (3.3)	0 (0)	NA
Gag and discomfort	19 (63.3)	13 (43.3)	11 (36.7)	0.099

Data are presented as *n* (%), [a]HR>100 beats min or an increase of >30 beats min from baseline, [b]Hypotension (MAP drop by >20% of baseline), [c]HR of <60/min minor a decrease of <15/min from baseline

Table 3: Review of studies comparing various sedatives in patients undergoing UGIE

Author	Country, year of publication	Study design, subjects	Drugs compared	Main findings	Conclusions
Demiraran *et al*.[10]	Turkey, 2007	Prospective randomized study, 50 patients undergoing UGIE	MDZ and DEX	Retching and endoscopist satisfaction were significantly different in patients receiving DEX versus those receiving MDZ (88.8±6.5 vs. 73.5±16.4, *P*<0.05; and 20.6±4.4 vs. 45.2±6.0; *P*<0.001). In the MDZ group, the number of patients who had adverse effects was higher than the DEX group (*P*<0.05)	DEX may be a good alternative to MDZ to sedate patients for upper endoscopy
Vázquez-Reta *et al*.[11]	Mexico, 2011	Double blind RCT, 40 patients undergoing UGIE	MDZ and DEX	The DEX group had a shorter recovery time (7.1 vs. 15.8 min, *P*<0.05) and satisfaction (9.9 vs. 9.0, *P*<0.05). Adverse effects occurred in similar proportions in both groups	MDZ and DEX are suitable for endoscopic procedures of upper digestive tract. DEX offers shorter recovery time and better patient's satisfaction
Sethi *et al*.[12]	India, 2014	Open-label RCT, 60 patients undergoing ERCP*	MDZ and DEX	Patients receiving DEX had lower HR and facial pain score at 5, 10 and 15 min following the initiation of sedation (*P*<0.05). There was no statistically significant difference in BP and respiratory rate. The procedure elicited a gag response in 29 (97%) and 7 (23%) subjects in MDZ group and dexmeditomidine group respectively (*P*<0.05). Modified Aldrete score of 9-10 at 5 min during recovery was achieved in 27 (90%) subjects in dexmeditomidine group in contrast to 5 (17%) in MDZ group (*P*<0.05). DEX showed higher patient and surgeon satisfaction scores (*P*<0.05)	DEX can be a superior alternative to MDZ for conscious sedation in ERCP
Muller *et al*.[13]	Brazil, 2008	Randomized, blind, double-dummy clinical trial, total 26 patients undergoing ERCP	DEX alone and propofol plus fentanyl	The RR was 2.71 (95% CI, 1.31-5.61) and the number of patients that NNT was 1.85 (95% CI, 1.19-4.21) to observe one additional patient with drowsiness 15 min after sedation in the DEX group. Greater reduction in blood pressure, a lower heart rate, and greater sedation after the procedure in DEX group	DEX was associated with greater hemodynamic instability and a prolonged recovery
Takimoto *et al*.[14]	Japan, 2011	Randomized study involving 90 patients undergoing ESD of gastric cancer	DEX, propofol and MDZ	None of the DEX-sedated patients showed a significant reduction of the oxygen saturation level. The rate of effective sedation was significantly higher in the DEX group compared with the MDZ or PF group. No DEX-sedated patient developed major surgical complications	Sedation with DEX is effective and safe for patients with gastric tumors who are undergoing ESD

ERCP=Endoscopic retrograde cholangiopancreatography, DEX=Dexmedetomidine, BP=Blood pressure, RR=Relative risk, CI=Confidence interval, NNT=Needed to be treated, MDZ=Midazolam, PF=Propofol, GI=Gastrointestinal, UGIE=Upper gastrointestinal endoscopy, RCT=Randomized controlled trial, ESD=Endoscopic submucosal dissection

lasts for 5-10 min that is followed by a slight decrease in blood pressure due to the inhibition of central sympathetic outflow. Despite profound sedative properties, dexmedetomidine is associated with only limited respiratory effects leading to a wide safety margin.[8]

The most important and most frequent side effect is bradycardia which can be managed with atropine, ephedrine, and volume infusion. Other notable side effects are hypertension, hypotension, nausea, atrial fibrillation, and hypoxia. Most of the adverse events associated with dexmedetomidine use occur during or shortly after loading dose. However, low bolus dosing, titrated maintenance rate of drug infusion, adequate volume repletion and careful patient selection and adequate monitoring may attenuate adverse cardiac side effects.

Hence, many clinicians might have qualms regarding safety profile of dexmedetomidine in endoscopic procedures mainly owing to its known adverse hemodynamic effects (particularly bradycardia and hypotension).[9] Prior to initiation of this study, the investigators had similar concerns and therefore the use of dexmedetomidine was restricted. Propofol or midazolam along with ketamine was the commonest sedative regime used in different combination of doses at our institution.

In the present study, both dexmedetomidine and midazolam maintained stable hemodynamics throughout the procedure. Nevertheless, propofol group showed a significant drop in MAPs at various instances during UGIE. Seven patients developed hypotensive episodes that were treated with 100-200 mL of fluid blouses. This finding could be due to its narrow therapeutic window and also due to overdosing as duration was slightly longer in this group of patients. However, there was no statistically significant intergroup variability in other hemodynamic parameters (HR, SpO_2 and RR). There was no event of desaturation or apnea as only low doses of fentanyl were used as rescue analgesia. However, patients in the dexmedetomidine group required higher but statistically insignificant dose of fentanyl (P = 0.266). Contrary to our study, Muller *et al.* recorded greater hemodynamic instability (greater reduction in blood pressure and lower HR) associated with dexmedetomidine use, the reason for which could be due to inclusion of ASA class III patients. Another reason could be a larger dose of dexmedetomidine used due to prolonged procedural time as compared to our study (24 min vs. 10 min).[13]

Rate of desired sedation level was significantly higher in the dexmedetomidine group as compared to other two groups. Similarly, Takimoto *et al.* reported significantly higher rate of effective sedation in the dexmedetomidine group compared with the midazolam or propofol groups undergoing endoscopic mucosal resection of gastric tumors.[14]

Endoscopist satisfaction was significantly higher in patients receiving dexmedetomidine due to decreased rate of movement and gag reflex during procedure. Contrastingly, patient satisfaction seemed to be significantly higher in the midazolam group. This contradictory finding can be explained by amnestic property of midazolam as patients were interviewed within 1 h of completion of outpatient procedure. Similar observations were made by Demiraran *et al.* who noted higher level of endoscopist satisfaction in the dexmedetomidine group as compared to the midazolam group (VAS 88.8 vs. 73.5; P = 0.029).[10] A recent study from India also noted higher patient and endoscopist satisfaction scores in the dexmedetomidine group as compared to the midazolam group ($P < 0.05$).[12] Significantly faster recovery was observed in the dexmedetomidine group that could be due to shorter duration of the procedure and low dose infusion. This result is in line with those reported in studies by Vázquez-Reta *et al.* and Takimoto *et al.*[11,14]

Similar to our finding, randomized controlled trial from Mexico done by Vázquez-Reta *et al*. reported no difference in adverse events between midazolam and dexmedetomidine group in UGIE.[11] Though, all sedative drugs were safe to use during a UGIE, the importance of vigilant monitoring by a trained nurse or anesthetist cannot be ignored. Sedative-induced-hypotension can be prevented by pre-hydration with 100-200 mL intravenous fluid just prior to administration of UGIE.

There are some limitations in our study: Single center with small sample size which included stable ASA class I or II patients, therefore, our findings have external validity and cannot be extrapolated to the general population. In our study, the endoscopic procedures were simple, diagnostic and of short duration. Lengthy procedures are associated with more discomfort and retching as topical anesthetic applied once at the beginning of the procedure is short-lived. Therefore, future studies may be directed to study the comparative effectiveness of these agents involving patients undergoing lengthy procedures. We could not study the cost benefits ratio of these sedatives given the fact that dexmedetomidine is a relatively expensive drug, and affordability may limit its use. However, we believe that due to its wide safety profile in recommended doses, it can be used even by trained nurses and endoscopists as well, which may cut overall procedure cost per patient. Further studies are needed to address this issue. The robust design (randomized and double-blind) and consistency in data collection by single investigator eliminating the possibility of selection biases form the strengths of this study.

Dexmedetomidine as sole sedative is superior to midazolam and propofol in terms of safety and recovery time. The use of propofol was associated with hypotensive episodes that can be prevented by pre-hydration. All sedatives were similar with regard to adverse events.

Conclusion

Use of dexmedetomidine was associated with greater hemodynamic stability and faster recovery as compared to propofol and midazolam. Endoscopists expressed a higher level of satisfaction with dexmedetomidine compared with other sedatives in this study. Multi-centric large clinical trials are required to confirm findings of this study so as to make dexmedetomidine first choice for conscious sedation among contemporary endoscopists.

Acknowledgement

We sincerely thank to Professor Thomas Alexander, Department of Gastroenterology, PIMS hospital, for his valuable suggestions at various steps of study and manuscript review.

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How to cite this article: Samson S, George SK, Vinoth B, Khan MS, Akila B. Comparison of dexmedetomidine, midazolam, and propofol as an optimal sedative for upper gastrointestinal endoscopy: A randomized controlled trial. J Dig Endosc 2014;5:51-7.

Source of Support: Nil, **Conflict of Interest:** None declared.