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Case Report

Dexmedetomidine as a Sole Sedative Agent versus Propofol for Sedation during Upper and Lower Gastrointestinal Endoscopies

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Abstract

Introduction and objectives: Diagnostic and therapeutic procedures recently are done in gastroenterology setup as a part of fast-track concept. A major volume of gastrointestinal procedures are performed routinely on daycare basis under sedation as upper and lower GIT endoscopy. Many anesthetic agents used to provide sedation for these procures. Propofol, opioids, and midazolam form the backbone of the various regimes employed in the endoscopic suites all over the world. Dexmedetomidine is a pharmacologically active selective α 2-adrenergic receptor agonist. It was approved it in the intensive care unit (ICU) for sedation and analgesia for the duration of less than 24 hours. The aim of this study was to study efficacy and safety of Dexmedetomidine efficacy as sole sedating agent versus propofol for sedation during upper and lower GIT endoscopy.

Methods: This randomized controlled trial was carried out on 60 patients of either sex, aged 21-70 years of age undergoing upper and lower GIT endoscopy, with ASA I-II. Patients were randomly assigned into two groups, (30 patients in each group).

Dex group: Sedation was induced by loading dose of (dexmedetomidine 1μg/kg) followed by infusion of (dexmedetomidine 0.8μg/kg /h)

Propofol group: Sedation was initially started by bolus dose of 0.5mg/kg propofol IV Then, infusion was started at the rate of 50μg /kg/min. Upper and lower GIT endoscopies were carried out in the usual standard manner for all patients, then patients were discharged to PACU after attaining an Aldrete Recovery Scale Score of 9-10 Time taken to achieve this score was recorded. The patient's vital signs, Respiratory complications, VAS score for pain measurement, PONV, and any other adverse events were recorded.

Results: There was significant decrease in (HR and MAP) but not respiration rate (RR) and SpO2, in (Dex group) during the procedure and early post-operative (P. value 0.000**). But during the remaining of post-operative periods (HR and MAP) were comparable. VAS pain scores in both groups were decreased in comparable manner at all measured time points. But complications (atthythmia, air way obstruction, nausea, and vomiting) was significantly increased in Propofol group (P. value 0.001**). Mean time to achieve RSS 3-4 was 6 (±1.5) min in Dex group versus 9 (±1.9) min in Propofol group (P<0.005) and to achieve an Aldrete Recovery Scale Score of 9-10 was 8 (±2.1) min in Dex group versus 6 10 (±1.6) min in Propofol group (P<0.029).

Conclusion: In conclusion, there is evidence to support dexmedetomidine as a potential sole sedative agent in small diagnostic and therapeutic procedures like GIT endoscopies, our study support these evidences and although dexmedetomidine resulted in longer onset and recovery, more side effects but sufficient levels of sedation and analgesia are good advantages to use it as sole sedating agent.

Keywords: Dexmedetomidine; Sedation; Propofol; GIT endoscopy

Background and Objectives

Sedation level can be divided into minimal, conscious, deep, and general anesthesia. A sedative decreases the level of consciousness, allows a patient to withstand and tolerate a painful procedure (whether or not in combination with a local anesthetic), and minimizes discomfort and memory of the procedure. Minimal-to-moderate sedation is generally sufficient to maintain spontaneous respiration and protect airway reflexes [1-3]. Diagnostic and many therapeutic procedures recently are done in gastroenterology setup as a part of fast-track concept. A major volume of gastrointestinal procedures are performed routinely on daycare basis under sedation as upper and lower GIT endoscopy [4].

Criteria of an ideal sedative agent include; rapid onset has a predictable clinical effect and should be easily titrable [5]. Respiratory and hemodynamic stability are two factors of

paramount importance for procedural sedation. Many anesthetic agents used to provide sedation. Propofol, opioids, and midazolam form the backbone of the various regimes employed in the endoscopic suites all over the world [6-8].

Propofol, the most commonly used sedating agent, is a potent hypnotic agent with rapid onset of action and rapid recovery. But dose dependent cardiac and respiratory depression with inadequate analgesic action; represent the common adverse effects observed with it [9] Dexmedetomidine (DEX) -dextro-isomer of medetomidine- is a pharmacologically active selective α 2-adrenergic receptor agonist. It was introduced in the year 1999, when the US Food and Drug Administration approved it in the intensive care unit (ICU) for sedation and analgesia for the duration of less than 24 hours [10-12]. The aim of this study was to study efficacy and safety of Dexmedetomidine efficacy as sole sedating agent versus propofol for sedation during upper and lower GIT endoscopy.

Patients and Methods

After approval of local ethical committee of Assiut University and written informed consent from patients, this randomized controlled trial (RCT) was carried out on 60 patients of either sex, aged 21-70 years of age undergoing upper and lower GIT endoscopy, with American Society of Anaesthesiologist (ASA) Grade I, II. Patients who had ASA physical status Grade III, VI, baseline SpO_2 <90%, patients who had difficulty in communication, who refused the study, patients allergic to the studied medications, morbidly obese patients, patients with chronic obstructive pulmonary disease, complicated airway, and pregnant patients were excluded.

Patients mostly presented by; haematemsis, bleeding per rectum, melena and chronic diarrhea. One day before endoscopy, data were collected as; demographic data, medical, physical fitness and routine laboratory investigations. On the arrival of patient in endoscopy unit, IV access was inserted and secured and 0.03mg/kg midazolam was given as sedation and Ringer Lactate drip was started. During endoscopy, vital parameters such as (HR, mean arterial pressure MAP and oxygen saturation SPO_2) were recorded as baseline and every 5min until the completion of the procedure.

Patients were randomly assigned into two groups, (30 patients in each group), as following; opaque sealed envelopes containing a computer generated randomization schedule; the opaque envelopes were sequentially numbered and were opened immediately before application of anesthetic plan.

Dex group (no. =30 patients)

Sedation was induced by loading dose of (dexmedetomidine 1μg/kg slowly infused over 5 minutes) followed by infusion of (dexmedetomidine 0.8-1.2μg/kg /h).

Propofol group (no. =30 patients)

Sedation was initially started by bolus dose of 0.5mg/kg propofol IV over 3 minutes then, infusion was started at the rate of 50-100μg/kg/min. The level of sedation was assessed at 1-3min intervals in both group, and the infusion rate was adjusted accordingly to achieve a Ramsay Sedation Scale (RSS) score of 5 (Table 1) [13]. Upper and lower endoscopies were carried out in the usual standard manner for all patients and after routine preparations. Infusion was discontinued at the end of the procedure, and the recovery time was recorded and calculated as the time from discontinuation of infusion of the study drug till achievement of RSS score of 3 then patients were discharged to PACU after attaining an Aldrete Recovery Scale Score of 9-10 (Table 2) [14]. Time taken to achieve this score was also recorded.

Table 1: Ramsay sedation scale.

Sedation Level	Description
1	Patient is anxious, agitated or restless, or both
2	Patient is cooperative, oriented, and tranquil
3	Patient responds only to commands
4	Patient responds to light glabellar tap or loud auditory stimulus
5	Patient has a sluggish response to light glabellar tap or loud auditory stimulus
6	No response

Table 2: The modified aldrete scoring system.

Activity able to move voluntarily or on command	
4 extremities	2
2 extremities	1
0 extremities	0
Respiration	
Able to deep breath and cough freely	2
Dyspnea, shallow or limited breathing	1
Apneic	0
Circulation	
BP + 20mm of preanesthetic level	2
BP + 20-50mm of pre anesthesia level	1
BP + 50mm of pre anesthesia level	0
Consciousness	
Fully awake	2
Arousable on calling	1
Not responding	0
O2 Saturation	
Able to maintain 0-, saturation > 92% on room air	2
Needs 0, inhalation to maintain 02 saturation > 90%	1
02 saturation < 90% even with supplementation	0

Any respiratory depression (desaturation (SpO_2 dropped to <90% or cessation of respiration for more than 15 seconds), were

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recorded, and managed by supporting the airway and ventilation. Also hypotension was defined as systolic blood pressure <85mmHg and was treated with IV fluid plus IV ephedrine 0.1mg/kg. Bradycardia was defined as HR slower than 50 beats/min and was treated by atropine 0.01mg/kg. All patients were followed up for 12 hours for the following parameters; VAS scores for pain measurement, which was recorded at 0, 1, 2, 4, 6, and 12 hours. Any other adverse events (e.g. nausea and vomiting, arrhythmia, airway obstruction and laryngeal spasm) were recorded and were managed accordingly. The patient's vital signs were assessed at regular intervals.

Statistical analysis

Data analysis: Statistical analysis was carried out using SPSS® version 21 software. Normality distribution of continuous data was tested. Data were expressed as number, percentage, mean and standard deviation. Chi-square test was used in order to compare qualitative variable among studied groups. Independent t- test was used to compare quantitative variables between the two studied groups. P Value <0.05 was considered statistically significantly. Sample size estimation: The sample size included all eligible patients admitted to the GIT endoscopy unit from August 2017 to March 2018 who were consecutively enrolled to detect a 20% improvement in Achievement of modified Aldrete score of 9-10 (average standard deviation 0.8cm) with a power of 0.8. To account for the multiple outcomes and dropouts we increased the sample size to 24 patients per group.

Results

This study involved two groups of patients who underwent diagnostic and therapeutic upper or lower GIT endoscopy, DEX group (n=30) and the Propofol group (n=30). The demographic data, the patient's characteristics and baseline vital signs between the two groups were statistically insignificant (Table 3). There was significant decrease in (HR and MAP) but not respiration rate (RR) and SpO_2, in (Dex group) during the procedure and early post operative (P. value 0.000**) (Figure 1-3). But during the remaining of post operative periods (HR and MAP) were comparable (Table 4).

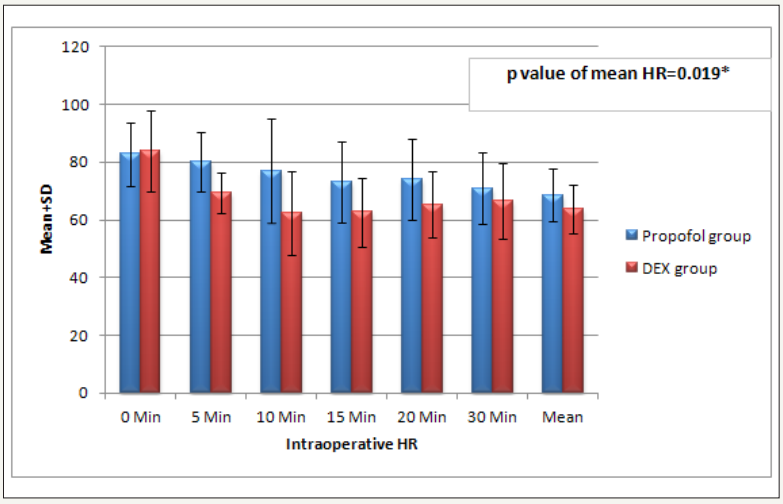

Figure 1: Intra-operative heart rate (HR) (beat/ min) data are expressed as mean ± SD. At 0 and 1, hours MAP= mean arterial pressure (mmhg), HR=heart rate (beat per minutes). h=hour interval Group D: Dexmedetomidine group P. value < 0.05 considered statistically significant. There was significant difference in intra operative periods being decreased in group Dex in comparison to Propofol group.

Table 3: Demographic data of the studied groups Data expressed as (Mean±SD) and number (%) DEX group: Dexmedetomidine group. P. value<0.05 considered statistically significant. There was no significant difference between both groups.

	DEX Group (n=30)	Propofol Group (n=30)	P Value
Age: mean±SD	46.73±5.61 (29-71)	43.73±6.07 (24-73)	0.191
Gender, M/F	21-Sep	19-Nov	0.592
BMI, kg/m 2: mean±SD	22.1±3.3	23.9±1.5	0.066
ASA, n (%)			
I	19 (63.3%)	18 (60.0%)	0.501
II	11 (36.6%)	12 (40.0%)	
Operative duration (minutes), mean±SD and rang	17.64±1.7	15.41±1.68	0.196
	(9.5-34)	(8.3-37.5)	

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Type of endoscopy:			
Upper endoscopy	24 (80.0%)	25 (83.3. %)	0.795
Lower endoscopy	6 (20.0%)	5 (16.6 %)	0.998

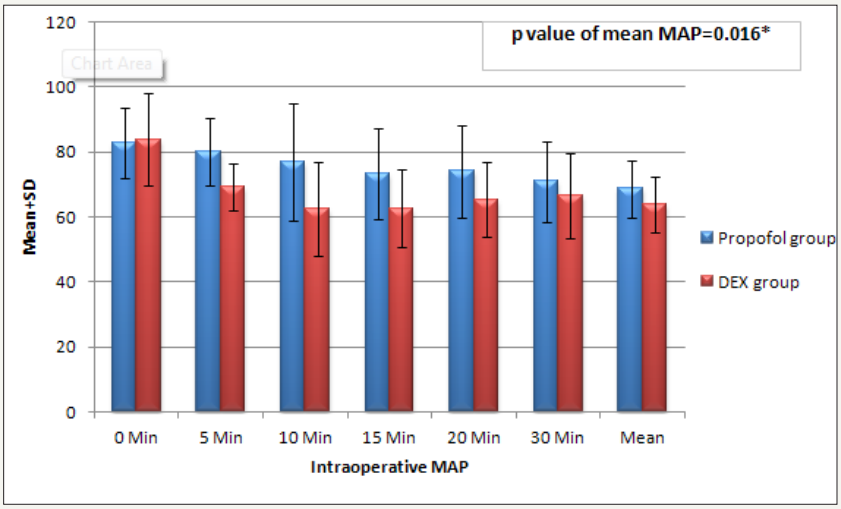

Figure 2: Intra-operative mean arterial pressure (MAP) mmHg Data are expressed as mean±SD. At 0 and 1, hours MAP= mean arterial pressure (mmhg), HR=heart rate (beat per minutes). h=hour interval Group D: Dexmedetomidine group P. value < 0.05 considered statistically significant. There was significant difference in intra operative periods being decreased in group Dex in comparison to Propofol group.

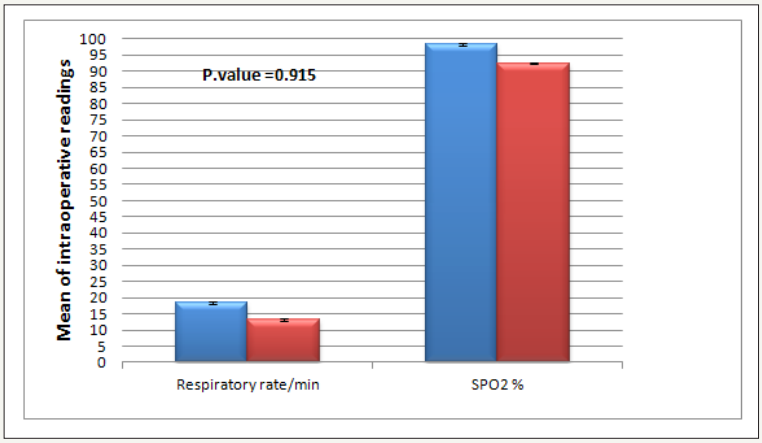

Figure 3: Intra-operative respiratory rate and saturation O2 Data expressed as (Mean±SD) and number (%) Dex group: Dexmedetomidine group. There was no significant difference between the two groups.

Table 4: Post-operative MAP and HR Data are expressed as mean±SD. At 0 and 1, hours MAP= mean arterial pressure (mmhg), HR=heart rate (beat per minutes). h=hour interval Group D: Dexmedetomidine group P. value < 0.05 considered statistically significant. There was significant difference in early post operative periods being decreased in group Dex in comparison to Propofol group.

MAP (mm Hg)	Propofol Group (n=30)	Dex Group (n=30)	P Value
0 h	77.67±12.2 (62-98)	64.07±7 (52 - 77)	0.000*
1 h	81.47±10.4 (62 - 100)	64.3±10.2 (56 - 90)	0.001*
2 h	75.9±10.6 (58 - 94)	69.5±9.3 (68 - 95)	0.117
4 h	74.73±11.9 (60 - 100)	69.7±7.2 (60 - 82)	0.13

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6 h	70.2±13.3 (62 - 108)	71.2±8.5 (59 - 86)	0.918
12 h	71.13±8.6 (62 - 98)	70.93±4.5 (65 - 82)	0.904
HR (bpm)			
0 h	73.9±18.02(56 - 120)	64.7±12.3 (57 – 110)	0.001*
1 h	76.3 ±10.37(65 - 98)	66.4±7.6 (65 - 89)	0.005*
2 h	75.8±11.0(56 - 94)	70.9±11.0 (57 - 97)	0.126
4 h	73.27±13.96(58 - 110)	71.7±14.1 (56 - 108)	0.912
6 h	76.7±14.14(59 - 108)	73.3±16.7 (52 - 98)	0.861
12 h	77.93±11.4 (55 - 100)	70.3±11.5 (55 - 100)	0.452

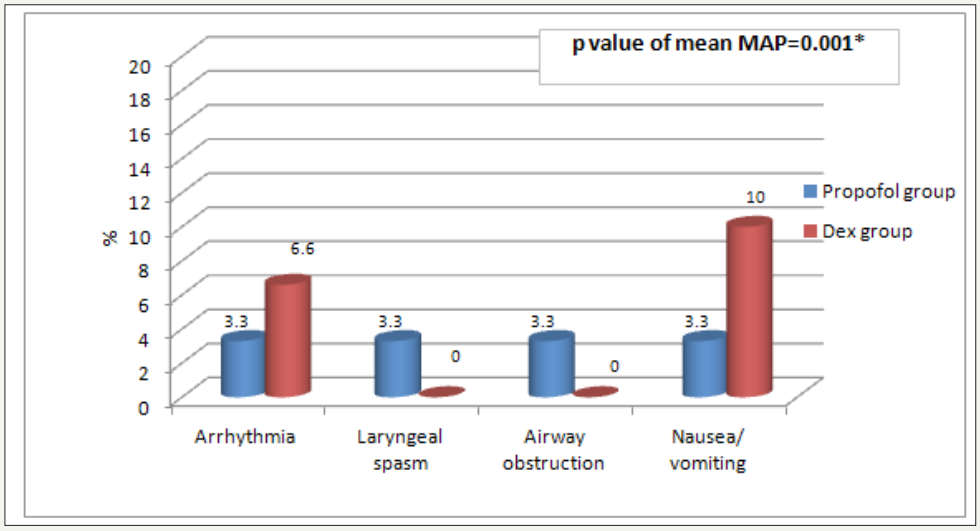

Figure 4: Post endoscopy complications Data are expressed as percentage, P. value<0.05 considered statistically significant, Dex group: Dexmedetomidine. There was significant difference between the two groups.

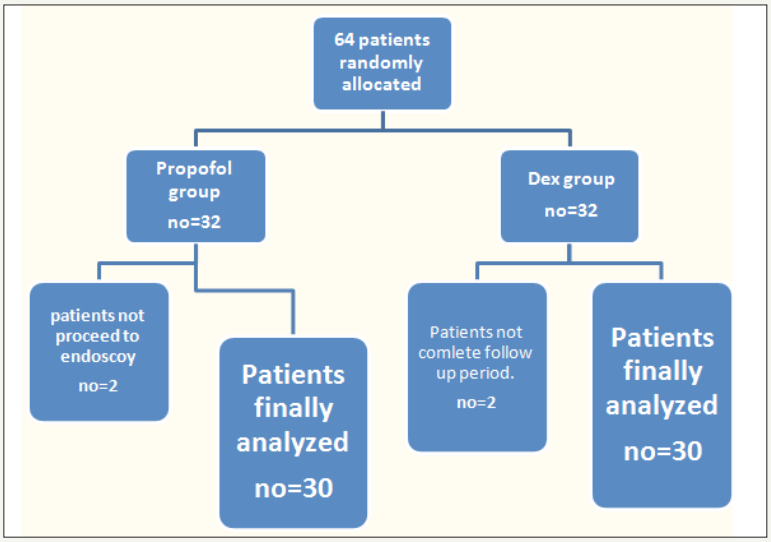

Figure 5: Flow diagram of patients through the study.

VAS pain scores in both groups were decreased in comparable manner at all measured time points (Table 5). Complications (laryngeal spasm and air way obstruction,) were significantly increased in Propofol group but nausea, vomiting and arrhythmia were decreased in Propofol group (P. value 0.001**) (Figure 4). Mean time to achieve RSS 3-4 was 9 (±1.9) min in Dex group versus 6 (±1.5) min in propofol group (P<0.005) as time of onset of action of Dex was 2 minutes and to achieve an Aldrete Recovery Scale Score of 9-10 was 10 (±1.6) min in Dex group versus 8 (±2.1) min in Propofol group (P<0.029) (Table 6) (Figure 5).

Table 5: Pain VAS scores during the postoperative 12 hours Data are expressed as median (range) VAS=visual analogue scale, h=hour. P. value<0.05 considered statistically significant. Dex group Dexmedetomidine group P. value<0.05 considered statistically significant. There was no significant difference between the two groups.

VAS scores	Propofol Group (n=30)	Dex Group (n=30)	p value
0 h	0	0	0
1 h	2 (1-4)	1.5 (2-4)	0.822
2 h	2 (1-3)	2 (1-4)	0.512
4 h	2 (1-3)	1 (1-3)	0.946
6 h	1 (1-2)	1.5 (1-2)	0.354
12 h	1 (1-2)	1 (1-2)	0.734

Table 6: Time to achieve; desired RSS of 3, and an Aldrete Recovery Scale Score of 9-s10 Data are expressed as mean ± SD, P. value<0.05 considered statistically significant. Dex group: Dexmedetomidine group. There was significant difference between the two groups regarding Time to achieve; desired RSS of 3.

	Propofol Group (n=30)	Dex Group (n=30)	P.value
	Mean±SD	Mean±SD	
Time to achieve desired RSS of 3 (Minutes)	6 (±1.5)	9 (±1.9)	0.005*
Time to achieve an Aldrete Recovery Scale Score of 9-10 (Minutes)	8 (±2.1)	10 (±1.6)	0.209
Total drug dosage Range ±mean	120-180 (145) mg	110-165 (125) µg	-

Discussion

During procedures like gastro-endoscopies, sedation is very important to enhance the comfort level of the patients, relief their anxiety associated with the procedure and facilitates patient cooperation and comfort level [15]. This prospective randomized controlled trial aimed to compare the efficacy and safety of IV dexmedetomidine versus propofol, for sedation during gastro-endoscopies. The dose regimens of both drugs used in our study were similar to that used by many previous studies [16,17] was used in our study continuous infusion technique to maintain a steady state sedation level. Our results were as following, dexmedetomidine provides good level of sedation, tolerable side effects with longer recovery without significant decreased in hemodynamic parameters when compared to Propofol and both agents provide comparable levels of analgesia.

Dexmedetomidine was compared to propofol in many previous studies; as Anterior segment ophthalmic surgery, Fibreoptic nasotracheal intubation, Minor oral surgery and Septoplasty. All these procedures are minor and the results were In favor of propofol regaring level of pain by VAS and patients satisfaction [18-21]. Propofol which is a phenol derivative, with short duration of action administered as sedative and hypnotic agent. It has been used frequently over the past two decades as a sedative agent for endoscopic procedures. But unfortunately, propofol may cause deep sedation and dangerous side effects that need cardiopulmonary support [22].

But with the use of dexmedetomidine, hemodynamics was less aeffected by the stressful periods during the procedure. Which is considered beneficial effect especially for the elderly patients undergoing painful procedures who could be potentially hypertensive or ischemic [23]. And also the analgesic effects of dexmedetomidine which is mediated by α2 - alpha 2 adrenergic receptors present on the neurons of superficial dorsal horn in lamina II, by inhibiting the release of nociceptive transmitters, namely substance P and glutamate [24].

Against our results, a previous study in which dexmedetomidine was used a sole agent for sedation during minor procedures as ERCP versus propofol and the results were, less satisfactory sedation than propofol, as most of the patients needed additional sedatives to achieve a sufficient sedation level [25]. We can attribute these findings due to the use of dexmedetomidine as a sole agent with a relatively small dose similar to those employed in intensive care for sedation and in anesthesia as an adjunct agent.

But confirming our study, a study compared dexmedetomidine versus propofol during electrophysiology study and demonstrated comparable sedation level with either drug. And mean arterial blood pressure and respiratory rates values were significantly better at 5, 15min in dexmedetomidine group [26]. We can explain the occurrence of hypotension and bradychardia, observed in group dexmedetomidine because of dexmedetomidine is a highly selective α-2 adrenergic agonist with sedative and analgesic properties. It causes sympatholysis and affects hemodynamic stability [27].

Sympatholysis occurs due to the activation of postsynaptic α2 adrenergic receptors that results in hypotension, and Bradycardia thus helps in attenuating the stress response leading to ideal sedation [28]. Although there is a higher incidence of side effects as PONV and air way obstruction in the propofol group compared to dexmedetomidine group, this procedures may be associated with more respiratory complications especially during endoscopic insertion and throughout procedure due to either deep sedation or even light sedation in presence of secretions and endoscopic manipulations [29]. Regarding drug combinations, another study compared dexmedetomidine/fentanyl versus propofol/nalbuphine in plastic surgery found that though HR, SBP and DBP decreased intraoperatively in both groups but these decreases were more evident in the dexmedetomidine group [30].

In conclusion, there is evidence to support dexmedetomidine as a potential sole sedative agent in small diagnostic and therapeutic procedures like GIT endoscopies, our study support these

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