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Original Research Article

Conscious Sedation in Upper Gastrointestinal Endoscopy with Dexmedetomidine versus Midazolam: A Comparative Study from Tertiary Care Centre, Maharashtra

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Abstract:

Background: Administering sedation during endoscopic therapy is crucial due to the significant amount of time it takes. Despite being less intrusive and time-consuming compared to endoscopic treatment, endoscopic examination typically causes patients to suffer pain and discomfort in the absence of sedation. Conscious sedation is often achieved by the administration of a narcotic and/or a benzodiazepine. Midazolam, with the briefest half-life among traditional benzodiazepines, is commonly provided either on its own or in conjunction with opioids like fentanyl or pethidine in several countries. Dexmedetomidine is a potent alpha2-adrenoreceptor agonist that specifically targets these receptors, resulting in sedation, pain relief, and reduced saliva production. Dexmedetomidine provides cardiovascular stability, exerts low impact on respiration, and has negligible effects on cognitive functions.

Objective: To compare Dexmedetomidine and Midazolam for a conscious sedation in patients undergoing Upper Gastrointestinal Endoscopy.

Methodology: The present study was carried out at Department of Anesthesiology at MIMER Medical College, Talegaon Dabhade involving the patients undergoing diagnostic and therapeutic upper gastro intestinal endoscopy procedure. A total of 44 patients were randomly divided in to two groups, 22 each group; Group M received Inj. Midazolam IV and group D received Inj. Dexmedetomedine IV by computer generated random number table.

Results: Mean time to achieve sedation i.e. Ramsay sedation grade 3-4 was 8.91 mins for Dexmedetomidine and 8.82 mins for Midazolam, with no difference between study groups (p=0.797). Mean Ramsay sedation score at baseline, after 5 min, after 10 min, after 15 min, after 20 min, after 25 min, after 30 min, after 35 min, after 40 min, after 45 min, after 50 min, after 55 min, after 60 min was recorded. We observed that the mean scores were comparable between the groups during the initial phase of the procedure. However, the mean sedation score was significantly higher in the dexmedetomidine group compared to the midazolam group during the latter part of the procedure i.e at 55 minutes and 60 minutes time interval, indicating that sedation was more effectively maintained with dexmedetomidine group. Additional sedation was required in 5 cases managed by midazolam as compared to only 1 case managed by dexmedetomidine (22.7% vs. 4.5%; p – 0.03).

Conclusion: Present study observed that both Dexmedetomidine in a dose of 1 mcg/kg/iv bolus over 10 min followed by infusion 0f 0.2 mcg/kg/hr and Midazolam in a dose of 0.06 mg/kg required similar amount of time to achieve sedation, however, the sedation was sustained more effectively with Dexmedetomidine, and additional sedatives were required more often in patients that were sedated with Midazolam.

Keywords: Sedation, upper gastrointestinal endoscopy, dexmedetomidine, midazolam etc.

Introduction

Upper gastrointestinal endoscopy (GI) is a commonly conducted technique used for both diagnosis and treatment purposes. The recent progress in gastrointestinal endoscopy is as excellent. Gastrointestinal endoscopy is used for both diagnosing gastrointestinal tract cancers, such as stomach, oesophagus, and colon cancers, and treating gastrointestinal diseases, such as endoscopic submucosal dissection and endoscopic retrograde cholangiopancreatography. The demand for endoscopic therapy for gastrointestinal

disorders has been steadily rising due to its less intrusive nature compared to surgery. [1]
Administering sedation during endoscopic therapy is crucial due to the significant amount of time it takes. Despite being less intrusive and time-consuming compared to endoscopic treatment, endoscopic examination typically causes patients to suffer pain and discomfort in the absence of sedation. [2]

Typically, endoscopic procedures are carried out with the patient under moderate sedation and analgesia, also referred to as "Conscious Sedation." This level of sedation allows the patient to respond purposefully to verbal or tactile stimulation, while ensuring that both their breathing and cardiovascular function are maintained. Patients who have been administered sedatives have a greater inclination to endure a repeated operation, if it is deemed necessary. [1]

Conscious sedation is often achieved by the administration of a narcotic and/or a benzodiazepine. [2] Midazolam, with the briefest half-life among traditional benzodiazepines, is commonly provided either on its own or in conjunction with opioids like fentanyl or pethidine in several countries. It amplifies the impact of gamma-aminobutyric acid, an inhibitory neurotransmitter in the central nervous system, at its receptor. Thus, the desired outcomes of inducing hypnosis, promoting relaxation, reducing anxiety, causing amnesia, preventing seizures, and relaxing muscles are attained. Midazolam has the shortest active duration (2-6 hours) of all conventional benzodiazepines. It is metabolised by the liver. Severe adverse effects, such as respiratory depression, hypotension, and bradycardia, may develop depending on the dose. There is no discomfort in the blood vessels during intravenous injection. [3]

Several clinical trials have been carried out to investigate the efficacy of midazolam for sedation during endoscopic procedures. A randomised controlled experiment comparing endoscopies with either midazolam or a placebo demonstrated that the midazolam group exhibited greater rates of procedural success, patient satisfaction, and compliance with re-examination. There was no notable disparity in the occurrence of severe hypoxaemia between the two groups. [4,5]

Dexmedetomidine is a potent alpha2-adrenoreceptor agonist that specifically targets these receptors, resulting in sedation, pain relief, and reduced saliva production. Dexmedetomidine provides cardiovascular stability, exerts low impact on respiration, and has negligible effects on cognitive functions. The average distribution half-life and the average terminal half-life of dexmedetomidine are 8.6 minutes and 3.14 hours, respectively. Dexmedetomidine undergoes hepatic metabolism and is eliminated mostly by urine (95%) and faeces (4%). [6,7]

In comparison to clonidine, dexmedetomidine exhibits greater selectivity for alpha2-adrenoreceptors and functions as a complete agonist in the majority of pharmacological test models. Possible benefits of this treatment may include reduced need for additional anaesthetics and painkillers, a lessened stress response, potential protection against heart muscle ischaemia, and little impact on breathing. [8,9] In addition, dexmedetomidine reduces salivary secretion by exerting sympatholytic and vagomimetic actions. Administering a little amount of this medication to individuals who are in good health induces sedation, which may be readily restored with verbal prompts. [10] It has been utilised to administer secure sedation and pain relief in order to enhance patient tolerance during mechanical ventilation and fiberoptic intubation. [11]

Only a small number of studies have examined these two medications for sedation in patients undergoing upper gastrointestinal (GI) endoscopy. [12-14] In research conducted by Demiraran et al [12], it was shown that dexmedetomidine was equally efficient as midazolam in sedating patients during upper gastroscopy. Furthermore, dexmedetomidine was found to be superior to midazolam in terms of satisfaction reported by the endoscopist.

Research conducted by Wu W. et al [13] and Samson S. et al [14] has also found that dexmedetomidine might serve as a viable substitute for midazolam in sedating patients undergoing upper endoscopy.

The objective of this study was to evaluate the two most often prescribed medicines for conscious sedation during upper gastrointestinal endoscopy.

Objective: To compare Dexmedetomidine and Midazolam for a conscious sedation in patients undergoing Upper Gastrointestinal Endoscopy

Materials and Method

Study Area: Department of Anesthesiology in tertiary health care centre in western Maharashtra.

Study Population: All the patients undergoing diagnostic and therapeutic upper gastro intestinal endoscopy procedure by applying inclusion and exclusion criteria

Study Design: Observational and Comparative study

Inclusion Criteria

1. Patients Aged 18 to 60 years

2. American Society of Anesthesiologists physical status (ASA) classification of grade I and II
3. Patients undergoing diagnostic and therapeutic upper gastro intestinal endoscopy.

Exclusion Criteria

1. Patients with renal and hepatic diseases.
2. Patients on beta-blockers and patients with any heart block or other significant rhythm changes on ECG.
3. Patients with prior gastrectomy.
4. Chronic use or addiction to opioids or sedatives.
5. Previous adverse reactions to any medication used in the present study.
6. Pregnant women.

Sample size and sampling procedure: A total of 44 patients were randomly divided in to two groups, 22 each group; Group M received Inj. Midazolam IV and group D received Inj. Dexmedetomedine IV by computer generated random number table.

Data collection procedure:

Patients aged 18 to 60 years and Patients with American society of anaesthesiologist's physical status of classification grade I and II were enrolled in this study after approval of institutional ethical committee. Patients undergoing upper gastrointestinal endoscopy were considered for study.

Written and informed valid consent was taken. Thorough preoperative evaluation was done for significant past history or any related clinical history, systemic and general examination and routine laboratory test such as complete hemogram, BT/CT, PT-INR, Blood sugar- fasting and post prandial, urine routine and microscopy, LFT and RFT, ECG and C x-ray were done. Then they were divided in to two groups, group Midazolam (M) receiving Midazolam intravenous and group Dexmedetomedine (D) receiving Dexmedetomedine intravenous for sedation. Preoperative vitals of the patient were monitored, IV access (20G) established. Before induction of sedation all patients received 4 squirts of 10% topical lignocaine spray for pharyngeal anaesthesia. Group M received single dose of 0.06mg/kg Intravenous (IV) Midazolam and additional doses of 0.5 mg till Ramsay sedation score (RSS) reached 3-4. Group D received loading dose of Dexmedetomidine 1 mcg/kg IV over 10 minutes followed by 0.2mcg/kg/hour infusion via syringe infusion pump until Ramsay sedation scale (RSS) reached 3-4. Time to achieve Ramsay sedation scale (RSS) of 3-4 was recorded. Vital parameters such as Heart rate (HR), Mean Arterial Pressure (MAP) and SpO2 were monitored. During the endoscopic procedure any rescue sedative doses of Midazolam or Dexmedetomedine was kept ready and the same was recorded. All endoscopic procedures were performed by same endoscopist. If adverse reaction occurred, it was informed to ethical committee.

Statistical Analysis: All the data was noted down in a pre-designed study proforma. Qualitative data was represented in the form of frequency and percentage. Association between qualitative variables was assessed by Chi-Square test. Quantitative data was represented using Mean ± SD.

Analysis of Quantitative data between the two groups was done using unpaired t-test if data passed 'Normality test' and by Mann-Whitney Test if data failed 'Normality test'. A p-value < 0.05 was taken as level of significance. Results were graphically represented where deemed necessary. SPSS Version 26.0 was used for most analysis and Microsoft Excel 2021 for graphical representation.

Results

The study involved 44 patients who were assigned in to two groups for sedation: **Group D**: consist of 22 patients receiving inj. dexmedetomidine 1mcg /kg /iv loading dose over 10 min followed by 0.2 mcg/kg /hr/iv maintenance dose until Ramsay sedation score 3-4 achieved. **Group M**: consist of 22 patients receiving single dose of 0.06mg/kg Intravenous (IV) Midazolam and additional doses of 0.5 mg till Ramsay sedation score (RSS) reached 3-4.

Table 1: Distribution according to age and gender

Variables	Group	N	Mean	SD	p- value
Age (yrs)	Dexmedetomidine	22	55	8.02	0.11, Not significant
	Midazolam	22	58.55	11.34	

Mean age of Dexmetomidine group was 55.00 and Midazolam group was 58.55, mean age of the study cases was 56.78 years with no difference between study groups (p-0.11).

Table 2: Distribution according to gender

Gender	Group		Total
	Dexmedetomidine	Midazolam	
Female	9	9	18
	40.90%	40.90%	40.90%

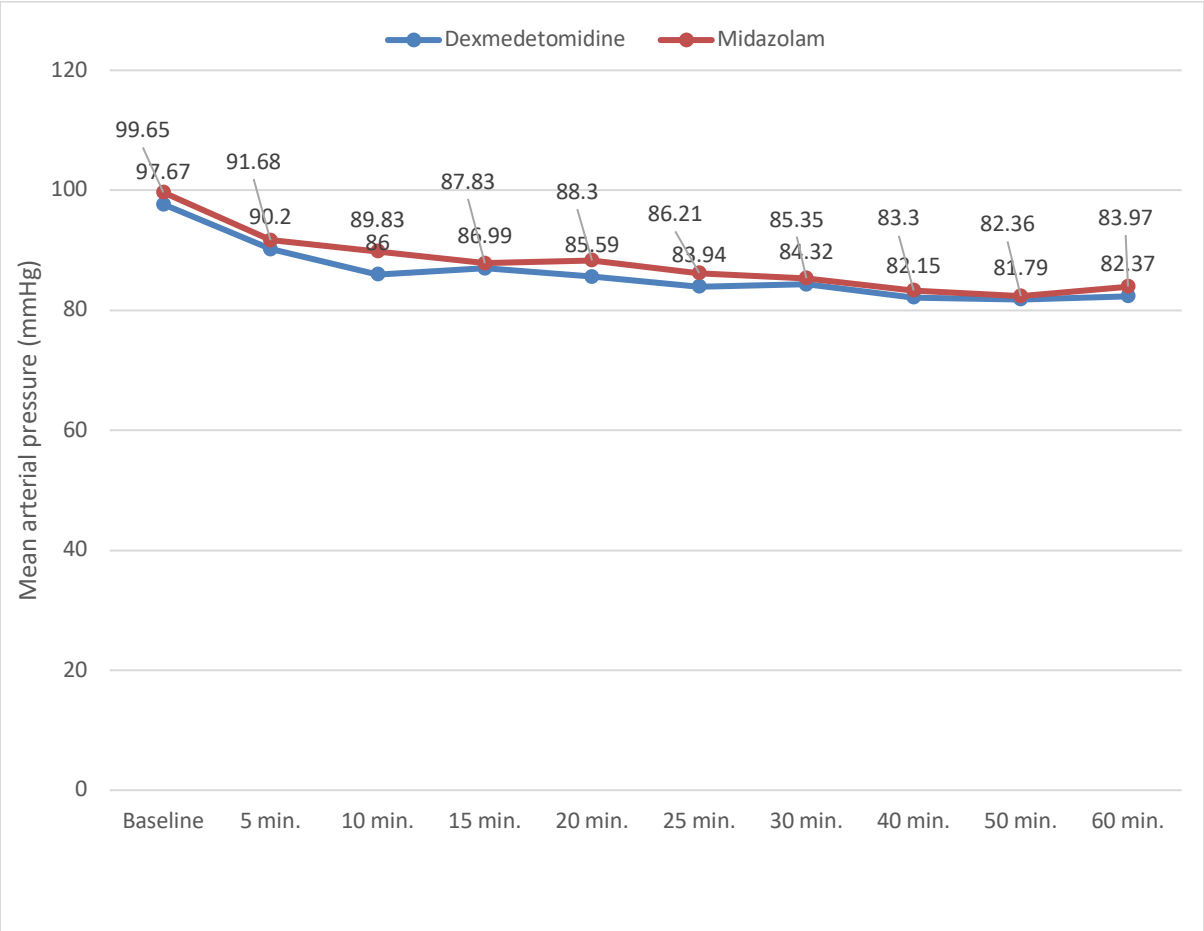
Male	13	13	26
	59.10%	59.10%	59.10%
Total	22	22	44
	100.00%	100.00%	100.00%
p value = 1.0			

Out of the 44 cases, 59.1% were males and 40.9% were females with no difference between study groups (p-1.0).

Table 3: Mean comparison of time required for sedation

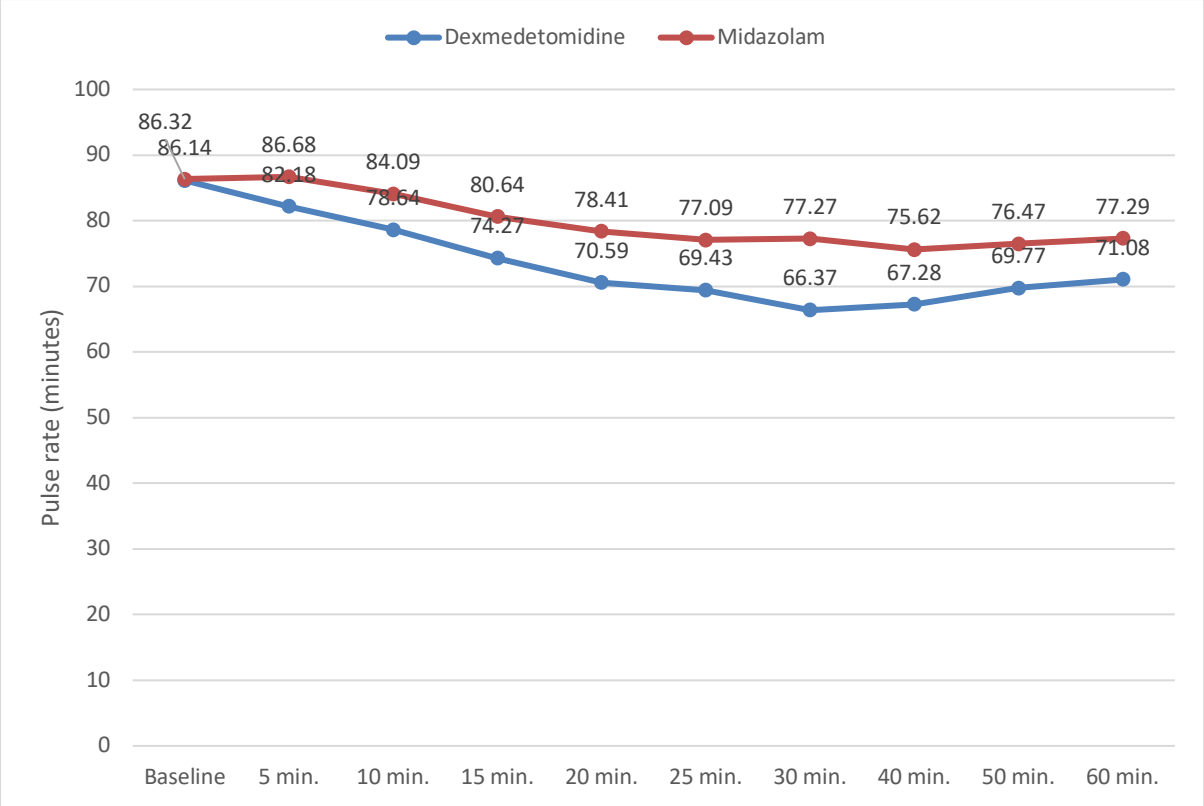
Variables	Group	N	Mean	SD	p- value
Time required for sedation (RSS score3-4)	Dexmedetomidine	22	8.91	1.19	**0.797, Not significant**
	Midazolam	22	8.82	1.14	

Mean time to achieve sedation i.e. Ramsay sedation grade 3-4 was 8.91 mins for Dexmedetomidine and 8.82 mins for Midazolam, with no difference between study groups (p=0.797).



Graph 1: Line diagram showing comparison of mean arterial pressure at different time intervals between two groups

Mean of mean arterial blood pressure at baseline, after 5 min, after 10 min, after 15 min, after 20 min, after 25 min, after 30 min, after 40 min, after 50 min, after 60 min was recorded and it was observed that both groups were similar in baseline mean arterial pressure (p=0.50), and the mean changes in arterial pressure were comparable throughout the follow-up period (p>0.05).



Graph 2: Comparison of mean pulse rate at different time intervals between two groups

Mean pulse rate at baseline, after 5 min, after 10 min, after 15 min, after 20 min, after 25 min, after 30 min, after 40 min, after 50 min, after 60 min was recorded and it was observed that both groups had similar baseline pulse rates (p=0.97), and the mean changes in pulse rate were comparable throughout the follow-up period (p>0.05).

Table 4: Comparison of mean Ramsay sedation score at different time intervals between two groups

Ramsay Sedation Score	Group	N	Mean	SD	p- value
5 min.	Dexmedetomidine	22	4.48	0.53	0.36
	Midazolam	22	4.34	0.51	
10 min.	Dexmedetomidine	22	4.2	0.44	0.07
	Midazolam	22	4.01	0.22	
15 min.	Dexmedetomidine	22	3.79	0.38	0.05
	Midazolam	22	3.53	0.49	
20 min.	Dexmedetomidine	22	3.53	0.49	0.54
	Midazolam	22	3.44	0.49	
25 min.	Dexmedetomidine	22	3.2	0.73	0.96
	Midazolam	22	3.19	0.78	
30 min.	Dexmedetomidine	22	3.57	0.49	0.57
	Midazolam	22	3.65	0.46	
35 min.	Dexmedetomidine	22	3.77	0.25	0.95
	Midazolam	22	3.76	0.36	
40 min.	Dexmedetomidine	22	3.96	0.01	0.3
	Midazolam	22	3.87	0.42	
45 min.	Dexmedetomidine	22	3.9	0.21	0.29
	Midazolam	22	3.76	0.57	
50 min.	Dexmedetomidine	22	3.84	0.41	0.39
	Midazolam	22	3.65	0.91	
55 min.	Dexmedetomidine	22	3.73	0.6	<0.05
	Midazolam	22	3.23	0.87	
60 min.	Dexmedetomidine	22	3.61	0.99	<0.01
	Midazolam	22	2.8	0.99	

Mean Ramsay sedation score at baseline, after 5 min, after 10 min, after 15 min, after 20 min, after

25 min, after 30 min, after 35 min, after 40 min, after 45 min, after 50 min, after 55 min, after 60 min was recorded.

We observed that the mean scores were comparable between the groups during the initial phase of the procedure. However, the mean sedation score was significantly higher in the dexmedetomidine group compared to the midazolam group during the later part of the procedure i.e at 55 minutes and 60 minutes time interval, indicating that sedation was more effectively maintained with dexmedetomidine group.

Table 5: Comparison of study groups as per additional sedation required

Additional Sedation	Group		Total
	Dexmedetomidine	Midazolam	
No	21	17	38
	95.50%	77.30%	86.40%
Yes	1	5	6
	4.50%	22.70%	13.60%
Total	22	22	44
	100.00%	100.00%	100.00%
p value =0.03			

Additional sedation was required in 5 cases managed by midazolam as compared to only 1 case managed by dexmedetomidine (22.7% vs. 4.5%; p – 0.03).

Discussion

Sedation Characteristics

In our study the average time it took to achieve sedation, specifically a Ramsay sedation score of 3-4, was 8.91 minutes for dexmedetomidine and 8.82 minutes for midazolam; There was no significant difference between the two research groups (p=0.797). The mean Ramsay sedation ratings were similar between the groups throughout the early part of the surgery. The average sedation score was notably greater in the dexmedetomidine group compared to the midazolam group towards the end of the operation, indicating that sedation was more effectively maintained in cases treated with dexmedetomidine.

A study by Dere K et al [15] reported similar findings, using comparable doses of dexmedetomidine and midazolam. However, they administered fentanyl at a dose of 1 mcg/kg in both groups prior to the procedure. Despite not using fentanyl in our study, we observed similar results. Nidhi Jain et al [16] conducted a study comparing the effects of Dexmedetomidine and Midazolam in patients undergoing upper gastrointestinal endoscopy (UGIE), following a similar dosing protocol. Their study, however, included the administration of fentanyl at 1 mcg/kg in both groups and used only a loading dose of dexmedetomidine. They observed that the Midazolam group (Group M) achieved a Ramsay Sedation Score (RSS) of 3-4 more quickly than the Dexmedetomidine group (Group D). Unlike our study, which continuously monitored RSS throughout the procedure, their study did not. Our findings suggest that dexmedetomidine maintained sedation longer than midazolam, likely due to the use of dexmedetomidine infusion. Wu et al [13] compared dexmedetomidine or midazolam for conscious sedation and found dexmedetomidine has superior sedative profile as compared to midazolam. This study has limitations, Firstly the retrospective design, which introduces the possibility of bias in data collection.

Demiraran Y et al [12] also compared these medications in patient undergoing esophagogastroduodenoscopy (EGD) procedure. They used dexmedetomidine in dose of an intravenous infusion of 1 μg/kg administered using a syringe infusion pump over a period of 10 minutes This was followed by a continuous infusion at a rate of 0.2 μg/kg/h dexmedetomidine (n=25) and midazolam in a dose of 0.07 mg/kg dose (total dose of 5 mg) and found that dexmedetomidine is superior in terms of sedation. In our study we got similar results but we used inj. midazolam in dose of 0.06mg/kg to avoid side effects associated with high dose of midazolam which found in their study.

Takimoto et al [17] conducted a comparison of these medications along with propofol in patients with stomach tumours who were having endoscopic mucosal excision. They used inj dexmedetomidine with an initial infusion of 3.0 μg/kg /hr over 5 minutes, followed by a continuous infusion at a rate of 0.4 μg/kg/hr or propofol (n = 30), or midazolam (n = 30). Within each group, a dosage of 1 mg of midazolam was administered intravenously as required. They found dexmedetomidine group had a considerably greater rate of effective sedation compared to the midazolam group comparable with our study but they used the different dosing protocol than our study. In a meta-analysis conducted by Fan Zhang et al [18] randomized controlled trials (RCTs) that compared the sedative and clinical effectiveness of dexmedetomidine and midazolam in patients undergoing endoscopy were analysed across various databases. Findings suggest

that dexmedetomidine could be a viable alternative to midazolam for sedation during endoscopy. They maintained that further high-quality, well-designed studies are necessary to validate this conclusion. (SMD, 0.64; 95% CI, 0.35–0.93; P<0.0001), these findings are aligned with our study.

Ghomeishi A et al [19] studies these medications in patients undergoing elective endo sonography. They used dexmedetomidine in a dose of dexmedetomidine 1 µg/kg over 25 minutes, along with propofol (0.5 mg/kg) and fentanyl (1 µg/kg) at the start of the procedure and midazolam in a dose of 0.03 mg/kg with propofol (0.5 mg/kg) and fentanyl (1 µg/kg). They Found that the dexmedetomidine group had substantially higher RSS ratings during sedation compared to the midazolam group (P = 0.02). Though findings are similar to our study dosing protocol of our study is different than their study as we have not used propofol and fentanyl.

The primary benefit of dexmedetomidine for endoscopy is its powerful sedative effect. The findings of our study demonstrated superior sedation in the dexmedetomidine group compared to the midazolam group. Out of the instances treated by midazolam, 5 required more sedation (0.5 mg midazolam as rescue dose), whereas only 1 case managed by dexmedetomidine required additional sedation (by increasing maintenance infusion rate). There is a difference of 22.7% vs 4.5%. The p-value for this difference is 0.03. The results demonstrated that dexmedetomidine had a more potent sedative effect in comparison to midazolam.

Conclusion

Present study observed that both Dexmedetomidine in a dose of 1 mcg/kg/iv bolus over 10 min followed by infusion 0f 0.2 mcg/kg/hr and Midazolam in a dose of 0.06 mg/kg required similar amount of time to achieve sedation, however, the sedation was sustained more effectively with Dexmedetomidine, and additional sedatives were required more often in patients that were sedated with Midazolam.

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