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Comparison of Dexmedetomidine Versus Midazolam in Providing Sedation for Endoscopy

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Abstract

Background: To minimize patient discomfort, anxiety and pain and to improve patient cooperation throughout the procedure and ease the performance of the procedure by the endoscopists conscious sedation is required. The main objective of this study is to explore and compare the safety and efficacy of dexmedetomidine versus midazolam in providing sedation aimed at endoscopy. *Materials & Methods:* A randomized, prospective study was directed in Pushpagiri institute of medical sciences Thirunalla Totally 60 patients were enrolled in this study & they were separated in two groups: Group M: Inj.Fentanyl 1 mcg/kg + Inj.Midazolam 0.04 mcg/kg. Group D: Inj.Fentanyl 1 mcg/kg + Inj. Dexmedetomidine 1 mcg/kg. Participants of either sex, aged 18-60 years of age undergoing diagnostic and therapeutic Endoscopy, with American Society of Anaesthesiologist (ASA) Grade I and II. *Results:* The mean arterial pressure was significantly lower at time-points 2 and 3 compared with time-point 1 in participants of midazolam group ($p < 0.05$). SpO_2 and RSS scores were significantly higher in the dexmedetomidine group as compared to midazolam group at time-points 2 and 3. Participants in the dexmedetomidine group rated their overall satisfaction with the procedure higher as compared to midazolam group ($p < 0.05$). A total of 6 patients (dexmedetomidine group n = 1; midazolam group n = 5) believed that they required either more or less sedation than they acknowledged. No patient reported feeling any severe pain during the process. The amnesic effect was corresponding in both groups, with no patient reporting any recall of intra-procedure events. There were no clinically significant complications in either group. *Conclusion:* Our results are suggestive of that dexmedetomidine has a good safety outline and is an effective sedative for use in endoscopy. We conclude that Dexemeditamedine has Good, Effective, Safety, Awake analgesia but satisfactory throughout procedure due to hypotension and bradycardia due to alpha 2 agonist action compared to midazolam group.

Keywords: Dexmedetomidine; Midazolam; Endoscopy

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Introduction

The signs for endoscopy have increased extremely as it has matured from a purely diagnostic procedure toward a therapeutic subspecialty. There has been a substantial progress in practice of sedation and analgesia through endoscopic procedure. The most widely used form of sedation is the mixture of a benzodiazepine, which has anxiolytic, amnesic, and sedative properties, through an opioid, providing analgesia, synergistic sedation with benzodiazepines and extra amnesia.

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Intravenous benzodiazepines are acknowledged to reduce patient uneasiness and increase tolerance to upper gastrointestinal endoscopy. Sedated patients seem to be more eager to undergo a repeat procedure if required. However, these sedatives regularly cause significant oxygen desaturation and, sporadically, a cardiopulmonary complication, but seldom death [1,2].

Objectives

- To equate respiratory, haemodynamic and recovery profile of both drugs.
- To evaluate the degree of comfort practiced by patients and the utility of the drug to endoscopist.

Materials & Methods

A randomized, prospective study was conducted in Pushpagiri institute of medical sciences Thirunalla Totally 60 patients were included in this study & they were divided in two groups:

1. Group-M: 30 patients
2. Group-D: 30 patients

Treatment

Group M: Inj.Fentanyl 1 mcg/kg + Inj.Midazolam 0.04 mcg/kg.

Group D: Inj.Fentanyl 1 mcg/kg + Inj. Dexmedetomidine 1 mcg/kg.

Scales used: Ramsey sedation scale, Wilcoxon test and t-test (paired).

Inclusion criteria

Patientsof either sex, aged 18-60 years of age undergoing diagnostic and therapeutic Endoscopy, with American Society of Anaesthesiologist (ASA) Grade I and II.

Exclusion criteria

- Those Patients who had ASA physical status Grade III and higher, baseline SpO_2 < 90%.
- Mechanically ventilated patients.
- Patients with comorbid conditions such as type 1 & 2 diabetes mellitus, hypertension (HTN) orhepatic or renal insufficiency to see the clean effect of both the drugs and to avoid any collaboration with any concurrent drug intake, which could have changed the results.
- Patients who had difficulty in statement (due to language problemor deafness).
- Patients with history of operative intervention within the past 72h, because we wanted to record their Ramsay Sedation Scale (RSS) and MAS which might not have been possible in these subsets of patients.
- Those Patients with any known allergy to these drugs.
- Pregnant patients.

Outcomes

Primary outcomes

- Variations in the respiratory rate, heart rate (HR), non-invasive blood pressure (BP) and oxygen saturation throughout ERCP and recovery.
- Attainment of modified Aldrete score (MAS) of 9-10 at 5 min after completion of the procedure during retrieval.

Secondary outcomes

- Complications during Endoscopy.
- Complications during recovery.

Results

A randomized, prospective study was conducted in Pushpagiri institute of medical sciences Thirunalla Totally 60 patients were included in this study & they were divided in two groups: Group M: Inj.Fentanyl 1 mcg/kg + Inj.Midazolam 0.04 mcg/kg. Group D: Inj.Fentanyl 1 mcg/kg + Inj. Dexmedetomidine 1 mcg/kg. Patientsof either sex, aged 18-60 years of age undergoing diagnostic and therapeutic Endoscopy, with AmericanSociety of Anaesthesiologist (ASA) Grade I and II.

Recorded observations on clinical parameters at each time-point are shown in Table 2. In the midazolam group, mean arterial pressure was significantly lower at time-points 2 and 3 compared with time-point 1 ($p < 0.05$ for both comparisons). SpO_2 and RSS scores stood significantly higher in the dexmedetomidine group at time-points 2 and 3 ($P < 0.05$)

Table 1: Demographic and clinical features of participants included in the study and to compare the use of dexmedetomidine and midazolam for conscious sedation in upper gastrointestinal tract endoscopy ($n = 60$).

Characteristic	Dexmedetomidine Group n = 30	Midazolam Group n = 30
Sex, male/female	16/14	17/13
Age, years	35.3 + 10.6	36.6 + 11.4
Weight, kg	61.1 + 7.3	59.4 + 8.4
Time to full sedation, min	8.5 + 1.2	7.6 + 1.8
Time to full recovery, min	8.9 + 6.2	10.3 + 5.3

Data presented as *n* or mean ± SD

No statistically significant between-group differences ($p \geq 0.05$; Student's t-test).

Table 2: Pre-, intra- and post-procedure clinical parameters of participants enduring upper gastrointestinal endoscopy under conscious sedation with dexmedetomidine or midazolam.

	Dexmedetomidine Group n=30				Midazolam Group n=30			
	Time-point				Time-point			
Parameter	1	2	3	4	1	2	3	4
Heart rate, beats/min	80.4 ± 14.4	75.6 ± 12.6	72.5 ± 13.2	78.5 ± 10.7	82.4 ± 14.9	78.5 ± 15.3	74.1 ± 13.9	78.3 ± 10.7
Mean arterial pressure, mmHg	115.3 ± 12.5	108.5 ± 10.1	105.2 ± 9.3	110.8 ± 8.7	120.6 ± 12.3	100.5 ± 14.1a	98.7 ± 13.5a	110.3 ± 14.1
Pulse oximetry, Spo2	99.8 ± 0.4	98.4 ± 1.1b	98.3 ± 0.7b	99.7 ± 0.5	99.7 ± 0.4	91.4 ± 1.4	92.4 ± 1.2	99.3 ± 0.6
RSS Score	NR	4.2 ± 0.8b	4.5 ± 1.2b	NR	NR	3.2 ± 1.1	3.5 ± 1.5	NR
NRS Score	NR	2.3 ± 0.6	2.1±0.8	NR	NR	2.6±0.5	2.7±0.6	NR

Data Presented as mean ± SD.

Time Points: 1, before sedation; 2, full sedation, earlier endoscopy; 3, 5 minute after beginning of endoscopy; and 4, after conclusion of endoscopy and discontinuance of drugs.

[a]P<0.05 versus time- point 1 in same group [b]P<0.05 versus midazolam group; paired t-test and Wilcoxon test.

RSS, Ramsay sedation scale; NR, not recorded; NRS, numeric ration scale

According to data attained from questionnaires, patients in the dexmedetomidine group rated their complete approval with the procedure higher than those in the midazolam group (96.6% vs 83.3%, $p < 0.05$). A total of six patients (dexmedetomidine group n=1; midazolam group n=5) thought that they required either sedation than they usually received. No patient reported any severe pain during the procedure. The amnesic effect was alike in both groups, with no patient reporting any recollection of intra-procedure events.

Around eight patients required supplementary sedation and analgesia (dexmedetomidine group n=3; midazolam group n=5). None of the patient experienced rebound hypertension, tachycardia or acute reversal of sedative and analgesic possessions in either group. No patient required lengthy post-procedure monitoring, unintended admission or subsequent medical attention.

Discussion

Presently dexmedetomidine has been used as a substitute to midazolam in conscious sedation. It is a strong and highly selective α-2 adrenoceptor agonist with sympatholytic, sedative, analgesic and amnestic properties and has been designated as a useful and safe aide in many clinical applications.It is the most lately developed drug of this class. It delivers a unique 'conscious sedation' (patientsappear to be asleep, but are readily aroused) and analgesia, without respiratory depression. To our information, there is no study in the literature describing the effects of dexmetedomidine in upper endoscopy.

The present study related the sedatives dexmedetomidine and midazolam. Our recorded observations showed that patients in the dexmedetomidine group experienced improved peripheral oxygen saturation and RSS scores than those in the midazolam group. No patient seen clinically significant bradycardia in the present study. Also, there were no cases of rebound

hypertension or tachycardia following termination of either drug. Low total dose may elucidate the absence of respiratory and cardiovascular complications in our study, and the low early loading dose followed by continuous infusion of dexmedetomidine provided adequate, well controlled sedation. High doses of sedative drugs are probable to cause complications, especially in high-risk patients.

Mizuno et al. [3] observed that sedation with intravenous midazolam throughout upper gastrointestinal endoscopy was valuable to control the cardiovascular responses, and to induce amnesia. Though, they suggested that decrease in the SpO_2 should be monitored prudently. In the midazolam group, we detected apnea in one patient and decreased SpO_2 in two patients; no decline in respiratory and cardiovascular parameters was observed in the dexmedetomidine group.

Trevisani et al. [4] recommended that low-dose conscious sedation with midazolam could recover the tolerance to EGD, in agreement with a previous trial reporting a lower discomfort in sedated patients than in controls.

Sethi et al. [5] conducted open-label randomised controlled trial was to relate haemodynamic, respiratory and recovery outline of both dexmedetomidine and midazolam. In Group D, patients had lower HR and FPS at 5, 10 and 15 min subsequent the initiation of sedation ($p<0.05$). There was no significant difference in BP and respiratory rate. The procedure produced a gag response in 29 (97%) and 7 (23%) subjects in Group M and Group D respectively ($p<0.05$). MAS of 9-10 at 5 min during retrieval was achieved in 27 (90%) subjects in Group D in contrast to 5 (17%) in Group M ($p<0.05$). Dexmedetomidine presented higher patient and surgeon approval scores ($p<0.05$). Dexmedetomidine can be a higher alternative to midazolam for conscious sedation in ERCP.

Yavuzetal.[6]conductedaprospectiverandomised study which states that dexmedetomidine achieved as effectively and safely as midazolam when used as a sedative in upper gastroscopy; it was greater to midazolam with respect to retching, rate of side effects and endoscopist satisfaction. It was decided that dexmedetomidine may be a good substitute to midazolam to sedate patients for upper endoscopy.

Conclusion

Our results suggested that dexmedetomidine has a good safety profile and is an effective sedative for use in endoscopy. Dexmedetomidine can be a superior alternative to midazolam for conscious sedation.

References

1. Froehlich F, Schwizer W, Thorens J, Kohler M, Gonvers JJ, Fried M. Conscious sedation for gastroscopy: Patient tolerance and cardiorespiratory parameters. Gastroenterology. 1995;108:697–704.
2. Arrowsmith JB, Gerstman BB, Fleischer DE, Benjamin SB. Results of the American Society for Gastrointestinal Endoscopy/US Food and Drug Administration collaborative study on complication rates and drug use during gastrointestinal endoscopy. GastrointestEndosc. 1991;37:421–7.
3. Mizuno J, Matsuki M, Gouda Y, Nishiyama T, Hanaoka K. Sedation with intravenous midazolam during upper gastrointestinal endoscopy – changes in hemodynamics, oxygen saturation and memory. Masui 2003;52:976-80.
4. Trevisani L, Sartori S, Gaudenzi P, et al. Upper gastrointestinal endoscopy: Are preparatory interventions or conscious sedation effective? A randomized trial. World J Gastroenterol. 2004;10: 3313-7.
5. Priyanka Sethi, Sadik Mohammed, Pradeep Kumar Bhatia, Neeraj Gupta. Dexmedetomidine versus midazolam for conscious sedation in endoscopic retrograde cholangiopancreatography: An open-label randomised controlled trial. Indian Journal of Anaesthesia. 2014;58(1):18-24.
6. Yavuz Demiraran, Esin Korkut, Ali Tamer, Ilknur Yorulmaz et al. The comparison of dexmedetomidine and midazolam used for sedation of patients during upper endoscopy: A prospective, randomized study. Can J Gastroenterol. 2007;21(1):25-29.