Original Article

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Efficacy of Nebulised Dexmedetomidine for Patients Comfort and Satisfaction during Diagnostic Upper Gastrointestinal Endoscopy: A Randomised Controlled Study

Anaesthesia Section

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ABSTRACT

Introduction: Diagnostic upper Gastrointestinal (GI) endoscopy is used to evaluate GI disorders. It causes patient discomfort because of its invasive nature. Conventional sedatives, although effective, have risks of respiratory depression and prolonged recovery, especially in high-risk patients. Dexmedetomidine, a selective α-2 adrenergic agonist, has been found to be an effective sedative with lesser respiratory side-effects.

Aim: To assess the efficacy of nebulised dexmedetomidine for patients comfort and satisfaction during diagnostic upper GI endoscopy.

Materials and Methods: The present randomised controlled trial was performed at Dr. D. Y. Patil Medical College Hospital And Research Centre, Pimpri, Pune, Maharashtra, India, from September 2024 to February 2025 on 64 patients aged 18-70 years, American Society of Anaesthesiologists (ASA) I and II, undergoing elective diagnostic upper GI endoscopy. Participants were randomly assigned into two groups- group D (dexmedetomidine) and group C (normal saline). Both groups underwent 15-minute preprocedure nebulisation with the respective drugs. Patient satisfaction was the primary outcome measured, and secondary outcomes measured were haemodynamic parameters, stress response, procedural ease, patient tolerance, and side-effects. Chi-square or Fishers exact test and independent t-tests or Mann-Whitney U test were used with a p-value <0.05 considered statistically significant.

Results: The demographic comparison between group D and group C revealed no statistically significant differences in age, gender distribution, or ASA status (p>0.05 for all variables. The mean age for group D was 38.5±13.8 and Group C was 41.9±12.8. group D demonstrated substantially better haemodynamic parameters compared to group C (p<0.05). Patient satisfaction was greater in group D (100%-very satisfied) than in group C (68.8%-very satisfied) (p<0.05). Endoscopists perceived ease of procedure and patient tolerance was greater in group D, with significantly less coughing (9.4% vs. 46.9%, p=0.001). Sedation scores were equal among the two groups.

Conclusion: Nebulised dexmedetomidine immensely increases patient comfort, satisfaction, and haemodynamic stability during diagnostic upper GI endoscopy. It lessens cardiovascular stress, limits side-effects such as coughing, and optimises procedural results, recommending it as a viable alternative to the standard sedatives used in GI endoscopy.

Keywords: Haemodynamic, Inhalation, Nebuliser, Sedation

INTRODUCTION

Diagnostic upper GI endoscopy is a standard examination used to assess a variety of GI disorders, including ulcers, cancers, and inflammation. Although it is essential for both the diagnosis and treatment of such disorders, it usually causes discomfort, anxiety for patients and psychological strain due to the invasive nature of the test [1]. Providing patient comfort and reducing discomfort during upper GI endoscopy is a significant issue in clinical practice. Traditionally, sedation has been utilised to curtail such discomfort and mitigate patient anxiety. The use of sedative drugs is most often accompanied by some risks like respiratory depression, extended recovery duration, and potential complications, especially in elderly or high-risk individuals. This makes it imperative that alternative sedative drugs be identified that would have sufficient sedative effects without carrying the risks posed by conventional medications [2,3]. Dexmedetomidine, an α-2 adrenergic agonist, is a sedative for procedures like endoscopy. It is recognised for its sedative, anxiolytic, and analgesic actions without inducing excessive respiratory depression [4]. Additionally, when used through the nebulised route, dexmedetomidine can potentially provide better anaesthetic action to the airways, also providing greater patient comfort during the procedure [5].

To address this gap, a comprehensive study was conducted (e.g., Sriramka B et al., Antony T et al., Gupta M et al.,) and have examined the use of dexmedetomidine for procedural sedation, there is limited research focused specifically on nebulised dexmedetomidine for diagnostic upper GI endoscopy [6-8]. They either use i.v. administration or focus on other procedures like bronchoscopy or intubation. Additionally, comprehensive data comparing patient comfort, satisfaction, haemodynamic stability, and procedural ease in this context remain sparse. The present study aimed to fill a gap in the existing literature, providing scientific evidence for the optimal use of effectiveness of nebulised dexmedetomidine as a premedication for upper GI endoscopy, aiming to provide a safer, more comfortable, and efficient alternative to traditional sedatives. It addresses a clinical need for sedation techniques that enhance patient experience without compromising safety, especially in outpatient and high-risk populations. The study aimed to determine if nebulised dexmedetomidine enhances the overall comfort and satisfaction of patients undergoing the procedure. It also aimed to assess the stress response of the patients to the procedure by monitoring haemodynamic parameters, ease of procedure for the endoscopist, patient comfort and satisfaction, and side-effects or adverse reactions with the use of nebulised dexmedetomidine.

MATERIALS AND METHODS

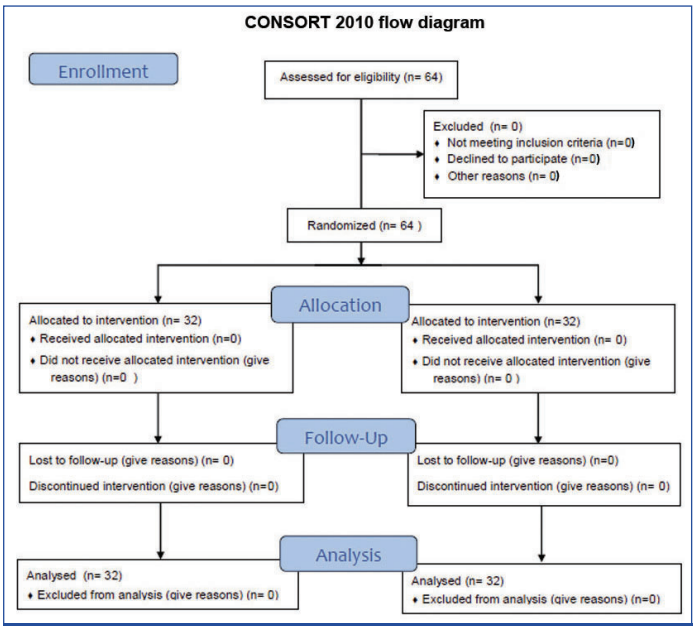
The present randomised controlled trial was conducted at the Department of Anaesthesiology, Dr DY Patil Medical College, Hospital & Research Centre, Pimpri, Pune, Maharashtra, India from September 2024 to February 2025. The study commenced following approval from the Institutional Ethics Sub-Committee (Research Protocol No : IESC/FP/19/2024 dated 15 April 2024) and registered with the Clinical Trial Registry - India (CTRI/2024/09/073834, https://www.ctri.nic.in). Study was carried out for six months. Written informed consent was obtained for participation and use of patient data for research and educational purposes. Preanaesthetic assessment and appropriate laboratory tests were done on all patients.

Sample size calculation: Comparing the means and standard deviations of postprocedure Systolic Blood Pressures (SBP) of 126±12.67 and 137.64±14.34, according to the study of Sriramka B et al., at a 95% confidence interval, and considering a 10% loss of the subjects, the sample size needed was calculated to be 64 (32 in each group) by WINPEPI version 3.85 software [6].

Inclusion and Exclusion criteria: The study included patients between 18 and 70 years of either gender, ASA grade I and II, and undergoing elective diagnostic upper GI endoscopy. Patients having uncontrolled hypertension or hypotension, psychiatric diseases, or who refused to be included in the study were excluded.

Study Procedure

The study protocol, alternative therapies, potential risks and benefits were explained to participants in detail. Written informed consent was obtained from those who voluntarily agreed to participate. Baseline investigations were conducted for all participants, including tests for Haemoglobin percentage (Hb%), Total Leucocyte Count (TLC), fasting and postprandial blood sugar levels, blood urea levels and serum creatinine. Additional assessments included a chest X-ray Posteroanterior (PA) and a routine Electrocardiogram (ECG) to evaluate the initial cardiorespiratory status. A total of 64 patients participated in the trial and were split into two groups of 32 individuals each at random. Patients were randomly allocated into two groups (group D and group C) using a computer-generated random number table [Table/Fig-1]. Group allocation was concealed using sequentially numbered, opaque, sealed envelopes, which were opened just before the induction of anaesthesia. The group assignment was concealed from the patient and the researcher.



[Table/Fig-1]: CONSORT flow chart.

In group D, nebulised dexmedetomidine was given to patients at a dose of 1 mcg/kg in 5 ml of normal saline (0.9%). In group C, normal saline (0.9 %) was given five millilitres [6]. Before the patients were transferred to the surgery room, they were nebulised for fifteen minutes in the preoperative room using an electrical compressor nebuliser. Before the endoscope was inserted, each patient received four puffs of 10% lidocaine spray. The primary outcome of the research was patient satisfaction, measured with a 0 to 10 Likert scale, with 0 "not satisfied at all" and 10 "very satisfied" [9] and patient comfort measured using numeric rating scale with 0 being-no discomfort and 10=worst imaginable discomfort [10]. Secondary outcomes were Endoscopist-assessed ease of procedure on a scale from 0 (most difficult) to 10 (very easy) which was counted as endoscopist reported outcome, patient tolerance to the procedure without any resistance or retching, and number of coughing spells counted by an assistant. Levels of sedation were quantified by the Ramsay Sedation Score, which had categories from anxiety or restlessness to no response to stimulus [6,11].

Demographic information, including age, sex, weight were recorded. SBP, DBP, and HR were measured before and after nebulisation, during the procedure, and postprocedure. The postoperative observation was done for 30 minutes postprocedure.

STATISTICAL ANALYSIS

Depending on the data distribution, either the Mann-Whitney U test or an unpaired Student's t-test was used to evaluate continuous variables between the two groups statistically. The Chi-square test or Fisher's-exact test, as applicable, was used to compare categorical data. A statistically significant result was defined as a p-value of less than 0.05 ($p<0.05$). Statistical Package for Social Sciences (SPSS) version 27 was utilised to analyse the data.

RESULTS

Thirty-two patients were studied in each group. No patient was excluded from the study analysis. There were no statistically significant differences in age, gender, or ASA status between group D and group C ($p>0.05$ for all variables). The groups appear to have been well-matched based on the similarity in baseline characteristics. The demographic data , HR, SBP and DBP are depicted in [Table/Fig-2,3].

Variables	group D (n=32)	group C (n=32)	p-value
Age (in years), Mean±SD	38.5±13.8	41.9±12.8	0.31
Gender, n (%)			
Male	22 (68.8%)	19 (59.4%)	0.43
Female	10 (31.2%)	13 (40.6%)	
ASA status, n (%)			
I	20 (62.5%)	16 (50%)	0.31
II	12 (37.5%)	16 (50%)	

[Table/Fig-2]: Comparison of demographic profile of patients among groups.

Parameters		group D (n=32)	group C (n=32)	p-value
Heart rate (beats/min)	Baseline	73.9±2.92	72.3±8.5	0.318
	Post nebulisation	74.22±5.4	74.13±8.6	0.962
	During procedure	86.8±10.9	82.7±6.6	0.07
	Postprocedure	78.9±8.6	85.2±8.02	0.004*
Systolic Blood Pressure (SBP) (mmHg)	Baseline	125.6±9.3	124.3±7.1	0.532
	Post nebulisation	125.7±10.8	125.6±7.1	0.95
	During procedure	125.7±13.6	130.6±6.9	0.07
	Postprocedure	121.06±11.3	133.6±6.7	<0.001*
Diastolic Blood Pressure (DBP) (mmHg)	Baseline	81.7±7.23	82.8±4.8	0.476
	Post nebulisation	77.9±8.3	83.8±5.3	0.08
	During procedure	80.2±9.5	85.06±4.9	0.004*
	Postprocedure	77.4±8.8	84.3±4.7	0.004*

[Table/Fig-3]: Comparison of heart rate, SBP, DBP of patients among groups.

All patients in group D (100%) reported being "very satisfied" and "no discomfort" with their experience. group C showed mixed results, with 68.8% of patients reporting being "very satisfied" and 31.2% reporting being "not satisfied" with "mild discomfort", and the scores differed significantly between the two groups (p<0.05). These are expressed in [Table/Fig-4].

Patient satisfaction/comfort scores	group D (n=32)	group C (n=32)	p-value
Not satisfied/ mild discomfort	0	10 (31.2%)	0.001
Very satisfied/ no discomfort	32 (100%)	22 (68.8%)	

[Table/Fig-4]: Comparison of patient satisfaction/comfort scores among groups. Statistical significance was indicated as p-value <0.001

group D demonstrated higher scores in endoscopist-reported outcomes (7.97±0.4 vs 6.97±1.4) and patient tolerance (7.97±0.4 vs 6.84±1.6) compared to group C. Significant differences were observed between group D and group C in both endoscopists' reported outcomes and patient tolerance (p<0.05). A comparison of these variables is expressed in [Table/Fig-5].

Variables (mean±SD)	group D (n=32)	group C (n=32)	p-value
Endoscopists reported outcome	7.97±0.4	6.97±1.4	<0.001
Patient tolerance	7.97±0.4	6.84±1.6	<0.001

[Table/Fig-5]: Comparison of different variables among groups. Statistical significance was indicated as p-value <0.001.

In group D, only 3 (9.4%) of the patients experienced coughing, while 29 (90.6%) reported no side-effects. In contrast, group C showed a higher incidence of coughing, affecting 15 (46.9%) of patients, with 17 (53.1%) reporting no side-effects, and the occurrence of side-effects differed significantly between the two groups (p<0.05) in [Table/Fig-6].

Side-effects	group D (n=32)	group C (n=32)	p-value
Coughing	3 (9.4%)	15 (46.9%)	0.001
Nil	29 (90.6%)	17 (53.1%)	

[Table/Fig-6]: Comparison of side-effects among groups. Statistical significance was indicated as p-value <0.001.

[Table/Fig-7] compares sedation scores between the two groups and presents an intriguing result. Both group D and group C showed identical outcomes, with 100% of patients in each group classified as "co-operative/oriented". No patients in either group were categorised as anxious, restless, or both. The p-value of one confirms the absence of any statistical difference between the groups in terms of sedation levels.

Sedation scores	group D (n=32)	group C (n=32)	p-value
Anxious	0	0	1
Restless	0	0	
Anxious/restless	0	0	
Cooperative/oriented	32 (100%)	32 (100%)	

[Table/Fig-7]: Comparison of sedation scores among groups.

This finding is particularly noteworthy as it suggests that while dexmedetomidine appears to offer cardiovascular benefits, it does not result in excessive sedation compared to the control intervention. This balance of maintaining patient alertness while potentially offering better haemodynamic control could be a significant advantage in endoscopic procedures, especially for patients who may be at risk from more profound sedation.

DISCUSSION

Sedatives play a crucial role in ensuring patient comfort throughout GI endoscopy procedures which are physically uncomfortable and anxiety-evoking because of the invasive nature of the test. Sedatives such as benzodiazepines, opioids, and barbiturates were used in endoscopic procedures. These medications are effective in reducing anxiety, discomfort, and pain. They also carry their risks and side-effects, such as respiratory depression, prolonged sedation, and prolonged recovery. These are especially challenging for geriatric patients, co-morbid disease patients, or high-risk patients receiving deep sedation for procedures [12,13]. To avoid these, the medical community has sought alternatives with more selective and safer effects. One such alternative is dexmedetomidine, an α-2 adrenergic agonist, which has sedation, analgesia, and anxiolysis property without causing respiratory depression and has proven to be an effective sedation for procedures such as GI endoscopy [14,15].

It is safer in outpatient surgery or in patients with respiratory impairment. Dexmedetomidine has been related to faster recovery time, wherein the patients get to return to baseline function quicker following the procedure [16,17].When given by nebuliser, dexmedetomidine has the advantage of anaesthetic action on the upper respiratory tract. This administration mode guarantees that the sedative action is focused on the location of the procedure and can maximise patient comfort with a reduction in systemic side-effects. Such a technique would be beneficial for procedures such as upper GI endoscopy, where manipulation of the airway can cause gagging or coughing, further contributing to patient discomfort [5].

The demographic analysis between group D and group C showed no statistically significant differences in baseline characteristics such as age, gender, and ASA status, which implies that the two groups were well-matched at the beginning of the study. A study conducted by Antony T et al., on effectiveness of nebulised dexmedetomidine as a premedication in flexible bronchoscopy in Indian patients -a prospective, randomised, double-blinded study and by Sriramka B et al., on nebulised dexmedetomidine for patient's comfort and satisfaction during diagnostic upper GI endoscopy: A double-blind randomised controlled study reported the same outcomes as the present study [6,7].

Postprocedure, group D's mean HR (78.9 bpm) was significantly lower than group C (85.2 bpm) with a p-value of 0.004, indicating dexmedetomidine's ability to stabilise HR in recovery. This is particularly beneficial for patients with cardiovascular disease or those at risk of tachycardia. These findings align with studies of Antony T et al., Gupta M et al., [7,8]. They found nebulisation of dexmedetomidine favours better haemodynamic response and stabilises heart rate.

SBP was significantly lower in group D (121.06 mmHg) compared to group C (133.6 mmHg, p<0.001) postprocedure. This suggests dexmedetomidine's role in blood pressure modulation, providing cardiovascular stability postprocedure, especially in patients at risk of hypertension or cardiovascular complications. DBP showed no significant differences at baseline or postnebulisation, but intra- and postprocedure values were lower in group D. At procedure time, group D's mean DBP was 80.2 mmHg vs. 85.06 mmHg in group C (p=0.004), and postprocedure, group D's DBP was 77.4 mmHg vs. 84.3 mmHg in group C (p=0.004). This supports dexmedetomidine's role in maintaining lower DBP and reducing cardiovascular stress, in line with studies by Gupta M et al., Gu W et al., Antony T et al., and Kumar NR et al., [7,8,18,19]. All these studies found that dexmedetomidine effectively controlled the postprocedure rise in SBP and DBP.

Patient satisfaction/comfort was also notably greater in group D, with 100% of patients responding as "very satisfied", with "no discomfort" with their experience. group C, on the other hand, yielded varying outcomes, with just 68.8% of patients responding as "very satisfied" and 31.2% as "dissatisfied". The satisfaction score difference between the two groups was significant statistically

(p<0.05), and it is a reflection of how dexmedetomidine makes the patient's overall experience during diagnostic upper GI endoscopy better. The finding corroborates other research works that have previously shown that the use of dexmedetomidine provides greater patient comfort in invasive procedures. These results are similar to the studies of Gupta M et al., and Bhalotra AR et al., [8,19,20].

Patient tolerance and Endoscopist-reported outcomes were also significantly greater in group D. The reported ease of procedure scores by the endoscopists were substantially greater in group D (7.97±0.4) than in group C (6.97±1.4) with a p-value of <0.001. Similarly, the tolerance of the patient towards the procedure was higher in group D (7.97±0.4) compared to group C (6.84±1.6), with the p-value being<0.001. These findings suggest that dexmedetomidine not only improved the comfort of the patients but also led to a more comfortable procedure for the endoscopists and, hence, a better experience for both groups, and are similar to the studies done by Bhalotra AR et al., Gu W et al., and Gupta M et al., [8,18,20].

On the side-effect aspect, group D experienced significantly fewer cases of coughing compared to group C. Only 9.4% of patients in group D coughed during the procedure, whereas 46.9% of patients in group C coughed, with the p-value being 0.001. The lower rate of coughing in group D may be due to the analgesic and sedative properties of dexmedetomidine, which may reduce airway irritation during endoscopy. This side-effect variability is an added advantage of dexmedetomidine in keeping patients comfortable during the procedure. Sedation scores were equivalent among groups since 100% of the patients in each of the groups were rated "cooperative/oriented". In contrast, no patients from either of the groups displayed being restless and/or anxious. The lack of significant differences in sedation levels (p=1) shows that even though dexmedetomidine has cardiovascular advantages and increased comfort, it does not cause undue sedation. These results are similar to the studies done by Gupta M et al., Gu W et al., Sriramka B et al., and Bhalotra AR et al., [6,8,18,20].

The results of this study confirm that nebulised dexmedetomidine significantly improves patient comfort, satisfaction, and haemodynamic stability after diagnostic upper GI endoscopy compared to nebulised saline. It effectively lowers cardiovascular stress, minimises coughing to the absolute minimum, and improves overall procedure results, suggesting that it could be a safe choice to standard sedatives for GI endoscopy.

Limitation(s)

The study was conducted at a single centre and the participants were classified as ASA Grade I and II without any risk factors that may limit the generalisability of the findings.

CONCLUSION(S)

This research demonstrates that nebulised dexmedetomidine significantly enhances patient comfort, satisfaction, and haemodynamic stability during diagnostic upper GI endoscopy compared to nebulised saline. The use of dexmedetomidine reduced HR, SBP, and DBP postprocedure, which may be helpful for cardiovascular stability, particularly in patients with risk factors for hypertension or cardiovascular complications. Patients nebulised with dexmedetomidine were more tolerant and satisfied with the procedure and less experienced with side-effects, such as coughing, than control patients. Both groups had equal levels of sedation, meaning that dexmedetomidine can be effective in sedation without leading to oversedation, so patients can stay alert but remain comfortable during the procedure. Overall, dexmedetomidine is an effective and safe option for optimising the patient experience in GI endoscopy, and its use can bring significant advantages over traditional sedatives. Further studies can affirm its role as an ideal sedative during endoscopic procedures, particularly in cardiovascular patients.

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