Clinical Communication

Nebulised dexmedetomidine for patient's comfort and satisfaction during diagnostic upper gastrointestinal endoscopy: A double-blind randomised controlled study

INTRODUCTION

Upper gastrointestinal endoscopy (UGE) is an uneasy and stressful event for most patients.[1] Various strategies and drugs have been used to provide patient comfort during UGE with variable effects and limitations.[2-5] Dexmedetomidine has been used in anaesthesia practice for sedation, given its beneficial effect in avoiding airway and respiratory compromise.[5,6] Nebulised dexmedetomidine has been studied in paediatric patients for sedation in daycare procedures.[7] It also alleviates the stress response to laryngoscopy and intubation.[5] Nevertheless, it has not been investigated in UGE procedures. We hypothesised that nebulised dexmedetomidine improves patients' comfort and satisfaction during UGE.

METHODS

This randomised controlled trial was approved by the institutional ethics committee (vide approval number DMR/IMS.SH/SOA/180466/2021 dated 12 February 2021) and registered with the Clinical Trial Registry – India (vide registration number CTRI/2021/06/034447, https://www.ctri.nic.in). The study was conducted from July to November 2021 per the principles of the Declaration of Helsinki, 2013. Written informed consent was obtained for participation and use of patient data for research and educational purposes. Patients 18–65 years, American Society of Anesthesiologists physical status I/II posted for diagnostic UGE, were included. Time of procedure >10 min, patients with uncontrolled hypertension/hypotension and psychiatric illness were excluded.

A computer-generated random sequence was performed, and group allocation was concealed in sequentially numbered opaque envelopes. The anaesthesia technician not involved in the study opened the envelope and prepared the drug accordingly. The investigator and the patient were blinded to the group allocation. Patients were randomly allocated into two groups: Group D received nebulised dexmedetomidine 1 μg/kg (Precedex, Abbot Laboratories, USA) diluted in normal saline (0.9%) to a volume of 5 ml and Group C received nebulised normal saline (0.9%) 5 ml. Drug nebulisation was provided with an electrical compressor nebuliser (Eco Smart, Saify Healthcare, Medi Devices, India). After nebulisation for 15 minutes in the preprocedure room, patients were shifted to the procedure room. All patients received four puffs of 10% lidocaine spray before insertion of the endoscope.

The primary outcome was the patient's satisfaction score (PSS) on a Likert scale of 0–10 (0 – not satisfied at all; 10 – very satisfied) as evaluated by the patient.[8] The secondary outcomes included endoscopist-reported outcomes - 'ease of procedure' (0 – most difficult; 10 –very easy) and 'patient tolerance to procedure' (0 – unbearable; 10 – none); an assistant blinded to the study drugs counted the number of coughing and retching episodes during the procedure. Demographic data (age, sex and weight) and anxiety scores (0 – not anxious; 10 – extremely anxious) were obtained before UGE. Systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate (HR) were noted before nebulisation, postnebulisation and after the procedure. The sedation was measured using the Ramsay sedation score (RSS).

The sample size was calculated by open epi software using the study by Yun Wu *et al*.,[9] which compared IV dexmedetomidine to propofol. Considering the mean±standard deviation PSS in the intervention and control group was 8.9 ± 1.4 and 9.6 ± 0.8 with a superiority margin of 0.15 and effect size of 0.52, power of 80%, confidence interval of 95% and an alpha error of 0.05, the sample size was calculated 45 in each group.

Statistical analysis was performed using International Business Machine Statistical Package for Social Sciences (SPSS, IBM, Chicago, USA) version 20. Continuous variables between the groups were analysed using an unpaired Student's *t* test or Mann–Whitney U test.

RESULTS

Forty-five patients were studied in each group. No patient was excluded from the study analysis. Groups were similar in age, sex, weight and preprocedure anxiety scores. PSS was similar in both groups. The

endoscopist's ease of performing the procedure and patient tolerance were better in Group D than in Group C [Table 1]. The HR, SBP and DBP are depicted in Table 1. Coughing was significantly less in Group D (11/45 vs 20/45 *P* value 0.04), although retching and RSS (<3) were similar. There were no episodes of bradycardia, hypotension or any other complications.

DISCUSSION

We observed that nebulised dexmedetomidine in a dose of 1 μg/kg had no benefit in increasing PSS in diagnostic UGE. However, it effectively controlled the postprocedure rise in SBP and DBP.

Patient cooperation is paramount for performing UGE. Retching and vomiting during endoscopy may be due to air insufflation that stimulates the vomiting centre and obscure the field of vision.[7] It not only causes discomfort to the patient but also hinders the smooth conduct of the procedure.

Dexmedetomidine has anxiolytic, amnesic, analgesic and sedative effects and does not cause respiratory depression. An intravenous bolus can cause bradycardia and hypotension.[10] Nebulisation is easier, provides higher bioavailability and maintains haemodynamic parameters better than the IV route.[7] It avoids transient nasal irritation, coughing and vocal cord irritation associated with intranasal administration.[11] Nebulised dexmedetomidine has a short half-life (6 min), an elimination half-life of 2 hours and good bioavailability through the large mucosal surface.[5] Nebulised dexmedetomidine is effective in diminishing the stress response to laryngoscopy and intubation.[5] We found SBP was better-controlled postnebulisation and postprocedure in our patients with nebulised dexmedetomidine. No patients developed bradycardia or hypotension. Abdel-Ghaffar *et al*.[12] found nebulised dexmedetomidine superior with respect to sedation, recovery and postoperative agitation compared to ketamine and midazolam in children.

The limitations of this study are that it is a single endoscopist, single-centric study. We used a low dose of dexmedetomidine (1 μg/kg) through the nebulisation route. The PSS showed no improvement statistically. Hence, a higher dose could be further investigated to anticipate any benefits.

CONCLUSION

Nebulised dexmedetomidine in a dose of 1 μg/kg does not improve patient satisfaction in UGE. It was effective in controlling the postprocedure rise in SBP and DBP. There was a significant improvement in endoscopist-reported ease of the procedure and patient tolerance with a lesser incidence of cough.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' Institution policy.

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Table 1: Comparison of outcome measures between the groups

Parameters		Group D (*n*=45)	Group C (*n*=45)	*P*
Patient satisfaction score		7 (5,8)	6 (5,7.5)	0.29
Endoscopists reported	• Ease of procedure	7 (6,9)	6 (5,7)	0.001
	• Patient tolerance for the procedure	7 (5.5,8)	5 (5,7)	0.004
	• Total procedure time (minutes)	7 (5,8)	6 (5,7.5)	0.29
Heart rate (beats/min)	• Baseline	78.49±11.63	78.24±15.34	0.93
	• Postnebulisation	80.18±10.37	79.96±15.05	0.94
	• Postprocedure	84.67±12.20	85.13±16.59	0.88
Systolic blood pressure (mmHg)	• Baseline	127.29±15.63	129.02±15.43	0.60
	• Postnebulisation	164.40±23.70	152.36±27.30	0.72
	• Postprocedure	126.00±12.67	137.64±14.34	0.001
Diastolic blood pressure (mmHg)	• Baseline	78.07±8.54	78.64±8.79	0.75
	• Postnebulisation	76.78±8.90	80.58±7.39	0.03
	• Postprocedure	77.96±8.90	81.93±8.87	0.04

Data are presented as median (IQR) or mean±SD. IQR – Interquartile range, SD – standard deviation

Conflicts of interest

There are no conflicts of interest.

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