

ORIGINAL ARTICLE

Satisfaction and safety using dexmedetomidine or propofol sedation during endoscopic oesophageal procedures

A randomised controlled trial

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BACKGROUND Dexmedetomidine possesses anxiolytic and hypnotic properties without respiratory side-effects, making it theoretically an ideal sedative agent for endoscopic procedures.

OBJECTIVE We aimed to compare satisfaction and safety among outpatients receiving sedation with dexmedetomidine or propofol for endoscopic oesophageal procedures.

DESIGN A randomised controlled study.

SETTING Endoscopic intervention suite at the Academic Medical Centre in Amsterdam, Netherlands.

PARTICIPANTS Patients aged at least 18 years, and American Society of Anesthesiologists' physical status 1 to 3.

INTERVENTION Total 63 patients were randomised to receive either dexmedetomidine (D) or propofol (P). Pain was treated with alfentanil in both groups.

MAIN OUTCOME MEASURES The primary outcomes were patients' and endoscopists' satisfaction levels measured by validated questionnaires (1 = very dissatisfied; 7 = highly satisfied). A secondary outcome was safety, determined by blood pressure, heart rate and oxygen saturation during

and after the procedure, and respiratory rate and noninvasive cardiac output during the procedure.

RESULTS Satisfaction of patients [median (IQR); group D, 5.0 (3.75 to 5.75) vs. group P, 6.25 (5.3 to 6.5)] and satisfaction of gastroenterologists [group D, 5.0 (4.4 to 5.8) vs. group P, 6.0 (5.4 to 6.0)] were lower in group D (both $P < 0.001$). More patients in group D would not recommend this form of sedation to one of their friends (group D, 15 of 32 vs. group P, 1 of 31; $P < 0.001$). Total 30 min after the procedure, heart rate [group D, 60 bpm (52 to 69) vs. group P, 70 bpm (60 to 81), $P = 0.031$] and SBP group D, 112 mmHg (92 to 132) vs. group P, 120 mmHg (108 to 132); $P = 0.013$] were significantly lower after dexmedetomidine sedation. There were no other differences in safety between groups.

CONCLUSION Compared with propofol, sedation with dexmedetomidine resulted in less satisfaction, and caused prolonged haemodynamic depression after endoscopic oesophageal procedures.

TRIAL REGISTRATION ISRCTN Register (ISRCTN 68599804).

Published online 2 March 2016

Introduction

Dexmedetomidine is a short-acting selective post-synaptic α_2 -agonist with anxiolytic and hypnotic properties.^{1,2} Patients receiving dexmedetomidine seem to be in a hypnotic state but are easily roused by verbal or tactile stimuli. Dexmedetomidine also decreases patients' requirements for other anaesthetics and analgesics while providing

haemodynamic stability (as a result of a diminished sympathetic response to stress) and no clinically important respiratory side-effects. However, although dexmedetomidine seems to be an alternative option for sedation during endoscopic outpatient procedures the sympatholysis it induces can cause hypotension and bradycardia.

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Propofol is a powerful sedative that has gained the role as the 'gold standard' for moderate to deep procedural sedation because of its rapid onset and offset of action, and the high level of satisfaction achieved among patients and gastroenterologists. Its most important disadvantage is the risk of rapidly induced deep sedation, with the possibility of respiratory depression or airway obstruction leading to hypoxaemia and cardiovascular depression.^{3,4}

Several trials have compared sedation with dexmedetomidine or propofol in various procedures, with contradictory results.^{5,6} No study has previously compared these two drugs in the setting of endoscopic oesophageal procedures under conscious sedation. The primary aim of the current study was to estimate the satisfaction of both patients and endoscopists when endoscopic oesophageal procedures were conducted during sedation with either dexmedetomidine or propofol. As a secondary outcome, we estimated the safety of sedation with regard to haemodynamic and respiratory effects.

Methods

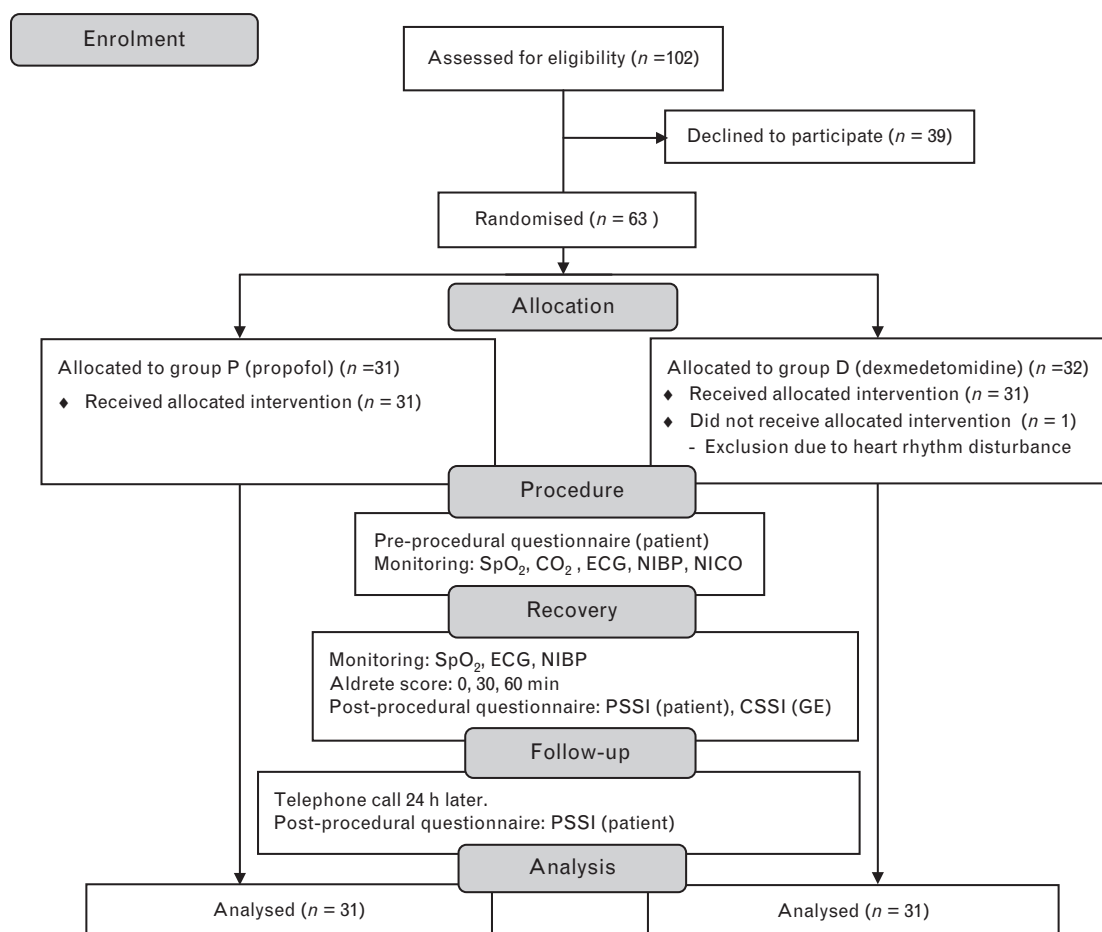
Ethical approval was obtained from the Medical Ethics Committee of the Academic Medical Centre (AMC), Amsterdam, Netherlands (Chairperson Dr M. Trip) (NL36861.018.11) on 12 January 2012.

All authors had access to the study data and reviewed and approved the final article.

A randomised controlled trial was performed. In the AMC endoscopic oesophageal procedures are routinely performed by two experienced endoscopists on Mondays and Fridays in one intervention suite at the Department of Gastroenterology and Hepatology. During the period between July 2012 and August 2013, all included patients were randomised, by computer selection, to receive either dexmedetomidine or propofol sedation in a 1:1 ratio. The study flow chart is shown in Fig. 1.

Our study focussed on elective endoscopic oesophageal procedures for treatment of Barrett's oesophagus (mapping, endoscopic resection and radiofrequency ablation).

Fig. 1



Study flow chart. CO₂, exhaled carbon dioxide concentration; CSSI, clinical satisfaction with sedation instrument; GE, gastroenterologist; NIBP, noninvasive blood pressure; NICO, noninvasive cardiac output; PSSI, patient satisfaction with sedation instrument; SpO₂, peripheral oxygen saturation.

Endoscopic resection of the mucosa is the cornerstone of endoscopic therapy for Barrett's oesophagus, allowing curative removal and histological staging of neoplasia. Radiofrequency ablation is used to eradicate all oesophageal metaplasia to prevent recurrences. All these procedures require easily arousable, conscious sedation.

All parties concerned (patient, endoscopist, endoscopy nurse and independent investigator), with the exception of the specialised anaesthesia nurse who administered the sedation, were blinded to the drug employed, as previously published in the study protocol.⁷

Patients scheduled for an elective endoscopic oesophageal procedure were considered for enrolment. Inclusion criteria were age at least 18 years, American Society of Anesthesiologists' physical status 1 to 3, and provision of informed consent. Exclusion criteria were known allergic reaction to planned medication, SBP less than 80 mmHg, heart rate (HR) less than 50 bpm, ejection fraction less than 30%, estimated glomerular filtration rate less than 15 ml min⁻¹ or impaired liver function (Child–Pugh Class A, B or C).

Endoscopic procedure and monitoring

No premedication was provided. An intravenous cannula was inserted and 500 ml of 0.9% saline was infused, followed by administration of glycopyrrolate 0.2 mg and lignocaine 50 mg. Five minutes before insertion of the endoscope, the pharynx was sprayed with 10% lignocaine spray (Xylocaine 10%, Astra, Netherlands).

During the procedure, oxygen was administered by nasal cannula at a flow rate of 2 l min⁻¹ and patients were constantly monitored for HR, oxygen saturation (SpO₂), ECG and exhaled carbon dioxide concentration, with noninvasive blood pressure (NIBP) measured at 5-min intervals. Noninvasive cardiac output (NICO) was measured continuously using Nexfin technology (Edwards Lifesciences, Irvine, California, USA) and stroke volume (SV) and systemic vascular resistance (SVR) were estimated. The Nexfin system provides beat-to-beat, continuous NIBP by measuring finger arterial pressure with a small cuff, thus eliminating the need for arterial cannulation. The resulting blood pressure (BP) waveform is used as the basis for the estimation of continuous NICO.

After the procedure, monitoring during recovery was limited to SpO₂, ECG and NIBP. Recovery from anaesthesia and the return of psychomotor fitness were assessed using the modified Aldrete Score⁸ on arrival in the recovery room, and 30 and 60 min after termination of the endoscopic procedure. This score is designed to assess patient recovery and describes the patient's motor activity, mechanical respiratory function, SpO₂, BP and consciousness. The total score is 10. Patients had to stay for at least 2 h in the recovery room although 'ready for discharge' was noted when the Aldrete Score was at least

9 or was similar to the preprocedural score. Patients had to be capable of walking without assistance before discharge.

Sedative intervention

Anaesthesia nurses, specialised in sedation, (with an anaesthesiologist as back-up) were responsible for sedation. Patients in group D were treated with dexmedetomidine (Dexdor: Orion corporation, Finland). Owing to the absence of precise pharmacokinetic/pharmacodynamic models for a dexmedetomidine target controlled infusion (TCI) system, we used the dosage recommended by the American Food and Drug Administration agency for bolus and continuous sedation with dexmedetomidine. We started with a loading dose of intravenous dexmedetomidine, 1 µg kg⁻¹ over 10 min followed by a maintenance infusion rate of 0.7 to 1 µg kg⁻¹ h⁻¹ continued throughout the procedure. In patients aged more than 65 years, the loading dose was reduced to 0.5 µg kg⁻¹. Patients in group P received the routine AMC sedation regimen using a propofol TCI system (Propofol 1% MCT Fresenius, Germany), starting with a targeted plasma concentration of 2.0 µg ml⁻¹.

Before the endoscopic procedure started, patients were assessed for level of sedation using the observer's assessment of alertness/sedation scale (OAA/S) aiming for a score between 2 and 4, referring to the patient's maximal lethargic response to their name spoken in normal tone. When OAA/S was more than 4, that is, the patient was too alert or agitated to tolerate the procedure, additional sedation was provided with an additional bolus dose of propofol 20 mg (group D) or a step up of the propofol TCI (group P).

Pain scores were assessed by the behavioural pain scale for nonintubated patients (BPS-NI).⁹ Patients with a BPS-NI of 7 or more pain scale were given an intravenous dose of alfentanil - 100 µg.

Outcome assessment

Before discharge and on the first day after the procedure (by telephone call), patients were asked to answer the two different parts of a questionnaire modified from the patient satisfaction with sedation instrument (PSSI).¹⁰ Directly after the procedure, the endoscopist was asked to rate his satisfaction using the clinical satisfaction with sedation instrument (CSSI).¹⁰ The complete PSSI includes 20 multiple choice type questions which are categorised into 4 sub scales four describing a patient's satisfaction, and the CSSI contains 21 questions compiled into three subscales describing the endoscopist's satisfaction. We focused on the PSSI subscores for global satisfaction, procedural recall and sedation side-effects, and within the CSSI to the corresponding issues among gastroenterologists: global satisfaction and recovery. Patients and endoscopists were asked to rate their satisfaction or dissatisfaction with the procedure ranging from

1 = very dissatisfied to 7 = highly satisfied. Patients were also asked if they would recommend the sedation regimen they had received to a friend.

Secondary outcomes were safety related, assessed by BP, HR and SpO₂ during and after the procedure, and respiratory rate and noninvasive cardiac output during the procedure. Bradycardia during and after the procedure was defined as HR 20% lower than baseline.

Statistical methods

Sample size calculation was based on patients' global satisfaction measured by the validated PSSI questionnaire.¹⁰ Within this questionnaire, the maximum number of points awarded is 7, ranging from 1 to 7. With a true difference of the mean of at least 0.5 points between two groups and to allow for a dropout rate of 20% per group, a sample size of 31 study participants per group was necessary to demonstrate a statistical significance for global patient satisfaction with α of 0.05 and $1-\beta$ of 80% with an anticipated effect size (Cohen's *d*) of 0.8.¹¹

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) software version 22.0 (SPSS Inc., Chicago, Illinois, USA). All data were checked for normal distribution using the Kolmogorov–Smirnov test and histograms. For normally distributed, continuous variables, an independent Student's *t*-test was used and the variables are presented as mean \pm standard deviation (SD). A *P* value < 0.05 was considered statistically significant. For categorical variables, cross tabulation and the Pearson's χ^2 test were applied and variables were categorized as number and/or percentage of the total. Nonnormally distributed data were compared using the Mann–Whitney U-test where appropriate, and data are presented as median [interquartile range (IQR)]. To compare measurements of HR, BP, SV, cardiac output and SVR between groups, the area under the curve (AUC) for each value was calculated over the different measurement time points during the procedure. The difference between the AUCs for the different groups was tested for statistical significance using the

Table 1 Patients' characteristics

	Dexmedetomidine	Propofol
Sex (female/male)	3 (10%)/28 (90%)	9 (29%)/22 (71%)
Age		
18 to 65 years	16 (52%)	12 (37%)
>65 to 80 years	14 (45%)	14 (44%)
>80 years	1 (3%)	6 (19%)
ASA		
1	10 (32%)	6 (19%)
2	20 (65%)	23 (72%)
3	1 (3%)	3 (9%)
BMI, kg m ⁻²	26 \pm 3	27 \pm 5
Heart disease/hypertension		
No	21 (71%)	23 (72%)
Yes	7 (23%)	4 (13%)
Serious	2 (6%)	5 (15%)
Lung disease		
No	26 (84%)	22 (69%)
Yes	4 (13%)	9 (28%)
Serious	1 (3%)	1 (3%)
Diabetes		
No	30 (97%)	28 (87%)
Yes	1 (3%)	4 (13%)

Data presented as mean \pm SD or *n* (%). ASA, American Society of Anesthesiologists' physical status.

Students *t*-test, because the AUC values were normally distributed.

Results

In total, 102 patients were eligible for enrolment, but 39 patients declined to participate. The remaining 63 patients were allocated randomly to receive either dexmedetomidine (group D, *n* = 32) or propofol (group P, *n* = 31). The groups were comparable in respect of demographic characteristics (Table 1) and endoscopic procedures, including the indication for endoscopy, type and length of procedure and results of pathology.

Patients in group D received dexmedetomidine $136 \pm 86 \mu\text{g}$ ($4.3 \pm 3 \mu\text{g min}^{-1}$) and alfentanil $302 \pm 324 \mu\text{g}$ ($8 \pm 5 \mu\text{g min}^{-1}$). Patients in group P received propofol $380 \pm 232 \text{ mg}$ ($16 \pm 11 \text{ mg min}^{-1}$) and alfentanil $259 \pm 265 \mu\text{g}$ ($10 \pm 8 \mu\text{g min}^{-1}$). There was no significant

Table 2 Patient satisfaction with sedation instrument scores

	Dexmedetomidine	Propofol	<i>P</i>
Global satisfaction	5.0 (3.75 to 5.75)	6.25 (5.3 to 6.5)	< 0.001
Overall satisfaction	5.0 (3.0 to 6.0)	6.0 (6.0 to 7.0)	< 0.001
Side-effects	5.0 (3.0 to 6.0)	6.0 (5.25 to 7.0)	< 0.004
Comparison with other forms of sedation	4.0 (2.0 to 6.0)	6.0 (4.0 to 6.75)	< 0.007
Satisfaction with sedation level	6.0 (3.0 to 7.0)	7.0 (6.0 to 7.0)	< 0.02
Sedation side-effect	5.25 (4.1 to 6.0)	5.8 (5.33 to 6.34)	< 0.007
Pain during procedure	6.0 (6.0 to 7.0)	7.0 (6.0 to 7.0)	NS
Nausea	7.0 (6.0 to 7.0)	6.75 (6.0 to 7.0)	NS
Length of time after procedure patients feel sedative effects	5.0 (3.0 to 6.0)	6.0 (5.0 to 7.0)	< 0.005
Drowsiness after procedure	4.0 (3.0 to 6.0)	6.0 (6.0 to 7.0)	< 0.001
Grogginess after procedure	4.0 (3.0 to 6.0)	6.0 (5.25 to 6.0)	< 0.03
Ease of recovery	5.0 (3.0 to 6.0)	6.0 (5.0 to 6.0)	< 0.02
Return to daily activities	5.0 (3.0 to 6.0)	6.0 (4.25 to 6.75)	< 0.04

Data presented as median (IQR). PSSI scores range from 1 (very dissatisfied) to 7 (highly satisfied).

Table 3 Clinical satisfaction with sedation instrument score

	Dexmedetomidine	Propofol	P
Global satisfaction	5.0 (4.4 to 5.8)	6.0 (5.4 to 6.0)	<0.001
Satisfaction with sedation	5.0 (5.0 to 6.0)	6.0 (6.0 to 6.0)	<0.001
Cooperation of patient	6.0 (5.0 to 6.0)	6.0 (5.0 to 6.0)	NS
Overall ease of procedure	5.0 (3.0 to 5.0)	6.0 (5.0 to 6.0)	<0.001
Comparison with other sedation forms	4.0 (3.0 to 5.0)	6.0 (5.0 to 6.0)	<0.001
Time to reach adequate sedation	3.0 (2.0 to 5.0)	6.0 (6.0 to 6.0)	<0.001
Stability of sedation level	6.0 (5.0 to 6.0)	6.0 (6.0 to 6.0)	<0.004

Data presented as median (IQR). CSSI scores range from 1 (very dissatisfied) to 7 (highly satisfied).

difference in alfentanil consumption ($P=0.57$) or pain experience ($P=0.29$) during the procedure.

Among the patients receiving dexmedetomidine, all but one required additional (5 ± 4) doses of propofol, and in one patient the dexmedetomidine infusion was discontinued and propofol TCI started because of persistent, new-onset bradycardia with HR less than 50 bpm. This patient was excluded from the final analysis.

Global satisfaction among patients [group D, 5.0 (3.75 to 5.75) vs. group P, 6.25 (5.3 to 6.5)] was significantly lower after dexmedetomidine sedation ($P<0.001$) (Table 2). After sedation with dexmedetomidine, significantly more patients indicated that they would not recommend this form of sedation to one of their friends (group D, 15 of 32 vs. group P, 1 of 31, $P<0.001$). Global satisfaction among gastroenterologists [group D, 5.0 (4.4 to 5.8) vs. group P, 6.0 (5.4 to 6.0)] was significantly lower after dexmedetomidine sedation ($P<0.001$) (Table 3).

The AUC for HR during endoscopy was significantly smaller in group D [difference of the mean value over time 6.69 (1.30 to 12.07), $P<0.01$] and episodes of bradycardia occurred significantly more often in this group (group D, 107 episodes vs. group P, 13 episodes, $P<0.001$). Both dexmedetomidine and propofol induced decreases in NIBP, NICO, SV and SVR during the procedure, with no significant differences between groups. Respiratory events were not significantly different between the two groups.

After the procedure, patients in group D had significantly lower values of HR and NIBP during the recovery period (Table 4). Three patients in group D with an Aldrete score at least 9 suffered syncope between 75 and 90 min

after the procedure, with serious bradycardia (25, 27 and 35 bpm) and unrecordable NIBP; all patients recovered after intravenous atropine 0.5 mg and 500 ml 0.9% saline.

The Aldrete scores 30 and 60 min after the end of sedation were significantly lower in group D (Fig. 2).

Discussion

Dexmedetomidine combined with alfentanil resulted in less satisfaction than propofol among patients and endoscopists, and was less safe in respect of haemodynamic effects compared with TCI propofol combined with alfentanil during and after endoscopic oesophageal procedures. Patients complained mainly about insufficient sedation during the procedure and a hangover of sedative side-effects (drowsiness and grogginess) after the procedure. Endoscopists complained about inadequately sedated patients making the procedure more difficult.

Other studies have compared dexmedetomidine with midazolam during procedural sedation for colonoscopy and upper gastrointestinal endoscopy; dexmedetomidine was shown to be superior to midazolam in respect of endoscopists' satisfaction and similar to midazolam in respect of patient's satisfaction.^{12,13} In contrast to the current study, satisfaction with sedation during the procedure was assessed in these studies, but not during the recovery period.

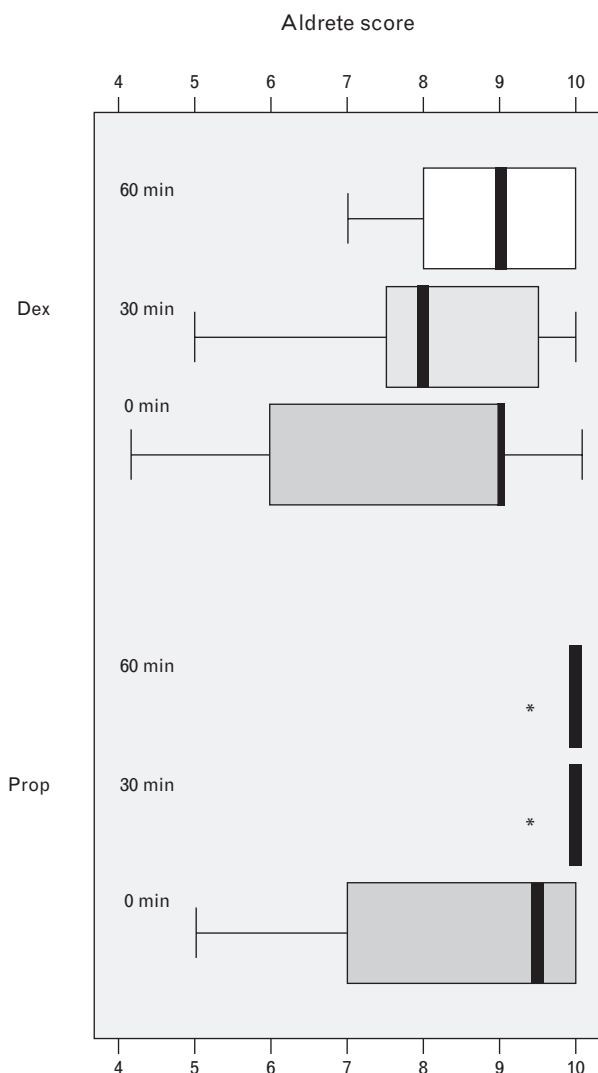
Compared with propofol, Arain and Ebert¹⁴ found a prolonged sedative effect after intraoperative use of dexmedetomidine among elective surgical patients. However, this hangover of sedation was not identified as a satisfaction problem because patients were not mobilised on the first postoperative day.

Table 4 Heart rate and blood pressure after procedure

	Dexmedetomidine	Propofol	P
Baseline HR, bpm	76 \pm 14	73 \pm 12	NS
Baseline BP, mmHg (SBP/DBP)	146 \pm 19/82 \pm 12	136 \pm 22/81 \pm 17	NS
HR 0 min	63 \pm 10	71 \pm 13	0.01
HR 30 min	60 (52 to 69)	70 (60 to 81)	0.031
SBP 0 min	114 \pm 18	122 \pm 24	NS
SBP 30 min	112 (92 to 132)	120 (108 to 132)	0.013
DBP 0 min	66 \pm 16	72 \pm 18	NS
DBP 30 min	63 (51 to 76)	70 (61 to 79)	0.027

Data are presented as mean \pm SD or median (IQR) (if data not normally distributed). BP, blood pressure; HR, heart rate.

Fig. 2



Modified Aldrete scores at 0, 30 and 60 min after procedure. * $P < 0.05$ vs. propofol. Data are median, IQR and range. Aldrete scores are minimum 0 to maximum 10. Discharge allowed when ≥ 9 . Dex, dexmedetomidine; Prop, propofol.

In our study, HR was lower during and after the endoscopic procedure with dexmedetomidine compared with propofol, and three patients in group D suffered syncope with severe bradycardia and unrecordable BP in the post-procedure period. BP was significantly different only during the recovery period. Two reasons might be responsible for these differences. First, propofol has a short elimination half-time leading to very short-lasting side-effects. Second, we hydrated patients prophylactically with 500 ml of 0.9% saline before starting the procedure. Pre-hydration was intended to compensate for the pre-procedural fluid deficit and vasodilatation caused by sedation, but might be too short lasting considering the pharmacokinetic profile of dexmedetomidine with an infusion time-dependent context-sensitive

half-life. This haemodynamic pattern of a decreased HR, CO and SV even after termination of a prolonged (longer than 10 min) continuous infusion of dexmedetomidine has been described previously in the literature.^{15,16} Jalowiecki *et al.*¹⁷ even had to stop pre-maturely a previous study during colonoscopies because of severe bradycardia. Ebert *et al.*¹⁶ concluded that cumulative cardiovascular effects of dexmedetomidine might limit its usefulness in less healthy populations, suggesting that these effects can aggravate patients with cardiovascular comorbidity in an unpredictable manner.

Takimoto *et al.*⁶ compared dexmedetomidine with propofol and midazolam for sedation in 90 patients during endoscopic submucosal dissection of gastric cancer and found dexmedetomidine to be safe and effective. However, NIBP, ECG and SpO₂ only were monitored at intervals of 10 min during the procedure compared with our study that applied extensive haemodynamic and respiratory monitoring. Furthermore, haemodynamic data on post-procedural recovery were not assessed.

In our study, all episodes of syncope occurred in patients declared ready for discharge with the modified Aldrete score ≥ 9 . This scoring system does not include HR; therefore, the modified Aldrete score is probably not the ideal discharge tool for patients treated with dexmedetomidine.

There is no universal definition of patient satisfaction. Pascoe defined patient satisfaction as the patient's reaction consisting of a 'cognitive evaluation' and 'emotional response' to the care they receive.¹⁸ This subjective affective component makes measurement of satisfaction challenging because frequently not all relevant items are addressed, and 'minimal clinically important difference' – meaning the smallest meaningful change that a patient can detect with confidence – is difficult to define precisely.¹⁹ This means that statistically significant data are not always clinically relevant and that satisfaction is difficult to compare in different settings and at different time points.

Consequently, one limitation of our study is that the instrument of assessment of patients' and endoscopists' satisfaction may be criticised. However, only a few validated questionnaires on patient satisfaction during sedation are available and we chose the validated questionnaire developed by Vargo *et al.*¹⁰ for sedation during colonoscopy and upper gastrointestinal endoscopy in the United States. Patients' expectations of the sedation experience, and therefore their satisfaction, are surely subject to national peculiarities and it might be a limitation to transfer a translated version of this questionnaire to Dutch patients without previous validation. Our sample size calculation was based on patient's satisfaction estimated by one specific questionnaire. Probably, it would have been more appropriate – considering that the safety profile of dexmedetomidine is more relevant

within a clinical setting – to power the study for acute respiratory or haemodynamic adverse events. However, much larger scaled studies would have been necessary to address this outcome. We considered all these events as possible problems and drawbacks, but their clinical impact cannot be determined definitively from the present results. Our dosage of dexmedetomidine was in line with other studies,^{20,21} and is in line with the recommended maximum dosage approved by the Food and Drug Administration for procedural sedation, but there was no preliminary study on a potential dose-response for dexmedetomidine. With the exception of one patient, it was not possible with this dosage to reach a sedation level (observer's assessment of alertness/sedation scale 2 to 4) sufficient to facilitate the tolerability of the procedure for patients and endoscopists. The OAA/S scale may not be the ideal tool to judge sedation depth using dexmedetomidine, as this score was not validated for sedation with dexmedetomidine.²²

Our study was designed as a single centre trial using our standard sedation regimen with propofol and alfentanil as a comparator for dexmedetomidine and alfentanil. Although propofol has gained the role as the 'gold standard' for sedation, the use of the AMC standardised TCI sedation protocol could limit generalisation of our data.

Conclusion

Dexmedetomidine sedation – even combined with analgesics – was less satisfactory than sedation with propofol and caused haemodynamic depression after endoscopic oesophageal procedures.

Acknowledgements relating to this article

Assistance with the study: none.

Financial support and sponsorship: none.

Conflicts of interest: none.

Presentation: none.

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