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A pilot study comparing Dexmedetomidine and Midazolam in sedation for upper endoscopy

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Abstract

Background Upper gastrointestinal endoscopy often causes discomfort and anxiety, requiring effective sedation to ensure patient comfort and procedural safety. This study compared the efficacy and safety of Midazolam and Fentanyl versus Dexmedetomidine and Fentanyl sedation during upper endoscopy, it was conducted as a preliminary investigation to guide the design of a future definitive trial.

Methods A prospective pilot study was conducted at An-Najah National University Hospital, Palestine, from October 2021 to January 2022. Sixty-eight ASA I and II outpatients aged 18–60 years were assigned to receive either Dexmedetomidine (0.3 mcg/kg) or Midazolam (0.05 mg/kg), both with Fentanyl (1 mcg/kg). Sedation depth was assessed using the Ramsay Sedation Scale (RSS) and recovery by the Post-Anesthesia Recovery Score (PARS). All procedures were performed by the same endoscopist; sedation was administered by an independent anesthesiologist.

Results Dexmedetomidine led to significantly higher patient and endoscopist satisfaction, shorter recovery time (9.5 ± 1.1 vs. 22.4 ± 7.7 min, $p < 0.05$), and reduced anxiety and discomfort. Adverse effects were fewer but not significantly different. Vital signs remained stable in both groups.

Conclusion Dexmedetomidine and Fentanyl offers a more effective and better-tolerated sedation option than Midazolam and Fentanyl for upper endoscopy, with higher satisfaction and faster recovery.

Keywords Conscious sedation, Dexmedetomidine, Endoscopy, Gastrointestinal, Midazolam, Patient satisfaction, Recovery time

1 Background

Effective sedation is vital in upper gastrointestinal endoscopy for patient comfort, reduced anxiety and pain, and procedural success [1–4]. It enhances cooperation and completion rates [5, 6]. However, patients may experience discomfort if sedation is not used, and there are risks such as respiratory depression, especially in high-risk patients [7, 8]. Sedation must be tailored to individual needs [2, 3]. While benzodiazepines with



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opioids are standard, they carry respiratory risks [1]; propofol offers faster recovery but requires close monitoring [4, 7]. Hypnosis is rarely used [9]. Midazolam is widely favored due to its rapid onset, short duration, and good safety profile, with better pharmacokinetics than diazepam [10, 11]. It offers effective anxiolysis, amnesia, and flexible administration routes [10, 12]. Downsides include slower recovery than propofol, less satisfaction, and possible respiratory depression [10, 12]. Dexmedetomidine yields deeper sedation, greater satisfaction, and fewer respiratory issues than midazolam, with less pain and lower analgesic needs [13–17]. Though it may cause bradycardia and hypotension, interventions are rarely needed [14, 16]. Recovery times are similar or slightly better, especially in elderly or high-risk patients [17].

Although both Midazolam and Dexmedetomidine are commonly used, data comparing their safety and effectiveness in upper GI endoscopy especially in Middle Eastern settings like Palestine are limited. This study addresses that gap by comparing both drugs (with Fentanyl) in terms of sedation depth, recovery, adverse effects, and satisfaction, aiming to guide best practices in endoscopy sedation. This study was designed as a pilot feasibility study to assess recruitment feasibility, protocol implementation, safety trends, and preliminary effect estimates, with the primary aim of informing the design of a future adequately powered randomized controlled trial, potentially using a non-inferiority framework.

Therefore, this study aims to provide new evidence on the comparison between Dexmedetomidine and Midazolam, specifically in the context of a Palestinian population, assessing not only efficacy and safety but also patient and endoscopist satisfaction in a real-world clinical setting.

2 Methods

2.1 Study design

This prospective pilot study used a convenience sampling approach to explore the feasibility, safety trends, and preliminary effectiveness of Dexmedetomidine compared to Midazolam for sedation during upper gastrointestinal endoscopy. As a pilot study, the primary purpose was to evaluate workflow feasibility, assess patient and provider acceptability to guide the design of a future trial. In this study, efficacy was defined as achieving adequate sedation depth, patient and endoscopist satisfaction, and shorter recovery time, while safety was defined as stable vital signs and absence of significant adverse events, (Stable vital signs were defined as fluctuations not exceeding 20% from baseline and not requiring clinical intervention). Patients were divided into two groups Dexmedetomidine or Midazolam. Baseline data were collected pre-sedation; post-sedation outcomes (comfort, sedation depth, complications) were assessed afterward. One endoscopist performed all procedures; sedation was managed by an anesthesiologist uninvolved in data analysis.

2.2 Study setting and site

The study was conducted in the Endoscopic Department at An-Najah National University Hospital, Nablus, Palestine. This department provides diagnostic and therapeutic endoscopic services under standardized protocols established by the hospital's endoscopy team. All procedures occurred in a clinical setting equipped with emergency resuscitation facilities, ensuring patient safety throughout the study period.

2.3 Study population and sampling

Participants were assigned using a sequence with 1:1 allocation. Group assignment was implemented by sealed opaque envelopes opened immediately before sedation. Due to the nature of the intervention, blinding was not feasible, resulting in an open-label design. As this was an exploratory pilot study, the sample size was based on feasibility considerations rather than formal hypothesis testing. This Institutional Review Board -approved study included 68 outpatients (aged 18–60) undergoing elective upper endoscopy at An-Najah Hospital. Patients were ASA I–II; key exclusions included ASA \geq III, drug allergies, pregnancy, and psychiatric issues. Data were collected from Oct 2021–Jan 2022. As a pilot study, a convenience sample of 68 participants (34 per group) was selected. Consent and confidentiality were ensured.

2.4 Data collection tools and procedure

Three tools were used:

1. Sociodemographic Sheet – recorded patient ID, age, gender, BMI, education, and indication for endoscopy.
2. Sedation/Recovery Record - used to document the depth of sedation. The target depth of sedation during the procedure was a Ramsay Sedation Scale (RSS) score of 4 ('asleep, brisk response to light glabellar tap or loud auditory stimulus'). This record also tracked the time to achieve adequate sedation (RSS \geq 4), recovery (RSS = 2), and the total procedure duration. The targeted depth was RSS level 4, assessed by the anesthesiologist at 5-minute intervals throughout the procedure to ensure it was maintained.
3. Follow-up Sheet – documented vitals and sedation depth at baseline, pre-endoscopy, 5 min into the procedure or at change points, and 1 h post-procedure. Adverse events (e.g., bradycardia, hypotension, hypoxia, discomfort) were noted.

Tools were validated by a panel (2 anesthesiologists, 1 anesthesia academic, 1 anesthesia nurse, 1 statistician).

2.5 Data collection process

2.5.1 Pre-procedure

Consent obtained; ASA class and baseline vitals recorded; patients advised to have post-procedure supervision.

2.5.2 During procedure

Patients were laterally positioned; vitals monitored.

- *Dexmedetomidine group* A loading dose of 0.3 mcg/kg Dexmedetomidine was administered as a slow intravenous infusion over 10 min, concurrently with 1 mcg/kg Fentanyl IV, 10 min before the procedure. This was followed by a continuous maintenance infusion (dose rate, 0.2–0.7 mcg/kg/h) throughout the procedure.
- *Midazolam group* 0.05 mg/kg Midazolam + 1 mcg/kg Fentanyl IV, with repeated doses every 2–5 min as needed.
- Sedation depth assessed using RSS, targeting \geq 4.

For the Dexmedetomidine group, the maintenance infusion (0.2–0.7 mcg/kg/h) was titrated to achieve a target RSS score of 4, with adjustments made based on sedation depth assessments. For the Midazolam group, additional boluses were administered only when $RSS < 4$, according to a predefined protocol. This ensured standardized criteria rather than discretionary clinician judgment.

2.5.3 Post-procedure

Monitored until $RSS = 2$. Discharge readiness evaluated using PARS. Patients received post-endoscopy care instructions.

Satisfaction of patients and endoscopists was assessed (1–10 scale) covering anxiety, discomfort, gagging, technical difficulty, and sedation adequacy.

2.6 Vital signs and adverse events

Vital signs including mean arterial pressure, heart rate, respiratory rate, and oxygen saturation were recorded at standardized intervals: at baseline before sedation, immediately before endoscope insertion, and at 5, 10, and 15 min after insertion, as well as immediately after the procedure and again at 30 min post-procedure. All measurements were analyzed as individual time points without any averaging or smoothing. To standardize reporting in accordance with hospital guidelines, adverse events were defined using established clinical thresholds: bradycardia was identified as a heart rate below 50 beats per minute, hypotension as a mean arterial pressure below 65 mmHg or a decrease of at least 20% from baseline, and hypoxemia as an oxygen saturation (SpO_2) below 92% lasting for 10 s or longer. These definitions were applied uniformly across both groups.

2.7 Ethical considerations

The study received ethical approval from the IRB at An-Najah National University and the Ethics Committee of An-Najah National University Hospital (Approval No.: Ng.Feb.2021/5). This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Informed consent to participate was obtained from all participants prior to their inclusion in the study, and participants were assured of the confidentiality and anonymity of their responses. All patients received a clear explanation of the study objectives, protocol, and potential risks and benefits.

2.8 Data analysis

Data were analyzed using SPSS v20. Means \pm SD were used for continuous variables (e.g., recovery time, satisfaction), compared with independent *t*-tests. Categorical data (e.g., adverse effects, vitals) were analyzed via chi-square tests. Significance was set at $p < 0.05$. Because this was an exploratory pilot study, no formal corrections for multiple comparisons (e.g., Bonferroni correction) were applied. We acknowledge that this approach increases the risk of Type I error, and the findings should therefore be interpreted as preliminary. There were no missing data for primary or secondary outcomes. All enrolled participants were included in the final analysis. Effect sizes (Cohen's *d*) were calculated for key continuous outcomes to inform future sample size estimation.

3 Result

This pilot study compared Midazolam and Dexmedetomidine during sedated upper endoscopy by evaluating vital signs, Ramsay Sedation Scale scores, time to full sedation and recovery, use of additional sedatives or side-effect treatments, as well as patient anxiety, discomfort, gagging, and satisfaction, and endoscopist-rated technical difficulty, sedation adequacy, and patient tolerance (Fig. 1).

3.1 Demographic data and indications for endoscopy

The study included 68 patients ($n=34$ each). No significant differences were found in sex, age, BMI, smoking, or education. Endoscopy duration was longer with Dexmedetomidine (11.0 ± 1.9 min) than Midazolam (9.9 ± 1.5 min), $p=0.008$. Significant group differences were found in indications: dysphagia (50% vs. 35.3%, $p=0.032$), reflux (20.5% vs. 50%, $p=0.035$), and dyspepsia (29.4% vs. 14.7%, $p=0.031$) (Table 1).

3.2 Pre and post procedural patient satisfaction

Before sedation, groups showed similar expected satisfaction and discomfort ($p>0.05$); Midazolam had less gagging ($p=0.020$), Dexmedetomidine less anxiety ($p=0.018$). After sedation, Dexmedetomidine had higher satisfaction (9.1 vs. 8.06), and lower discomfort (0.7 vs. 1.7) and anxiety (0.5 vs. 1.8), all $p=0.001$; gagging was similar (Table 2).

3.3 Endoscopy specialist satisfaction

Dexmedetomidine patients had higher endoscopist satisfaction (8.7 vs. 8.2, $p=0.001$) and less discomfort, gagging, retching, and technical difficulty (all $p<0.05$) than Midazolam, outperforming it in all endoscopist-assessed measures (Fig. 2).

3.4 Recovery data in Midazolam and Dexmedetomidine groups

Midazolam patients need 48.8 ± 6.0 min to recover while the Dexmedetomidine patients need 18.0 ± 5.2 min and this difference significant since the $p < 0.05$ (Fig. 3), Midazolam need 22.4 ± 7.7 min to sedate while the Dexmedetomidine need 9.5 ± 1.1 min and this difference significant since the $p < 0.05$. Although the Dexmedetomidine group had a longer mean procedure duration, this difference should be interpreted cautiously. Because this pilot study used convenience sampling, the groups were not fully comparable regarding clinical indications for endoscopy, and these differences may partly explain the variability in examination length. Therefore, attributing this finding solely to the sedation regimen would be inappropriate.

3.5 Vital signs and adverse effect of the patients in both Midazolam and Dexmedetomidine groups

There were no major differences in vital signs between the two groups, except for breathing rate. The Dexmedetomidine group had a lower respiratory rate (16.7 ± 1.9) compared to the Midazolam group (18.6 ± 4.7), $p=0.028$. Blood pressure, heart rate, and oxygen levels were generally the same in both groups. However, heart rate was lower in the Dexmedetomidine group at one time point ($p=0.049$), and respiratory rate was also lower at two time points ($p=0.004$ and $p=0.001$) Specifically, heart rate differences were noted at 10 min into the procedure, while respiratory rate differences were observed at 5 min and again at 15 min (Table 3). Hypertension was the most common side effect

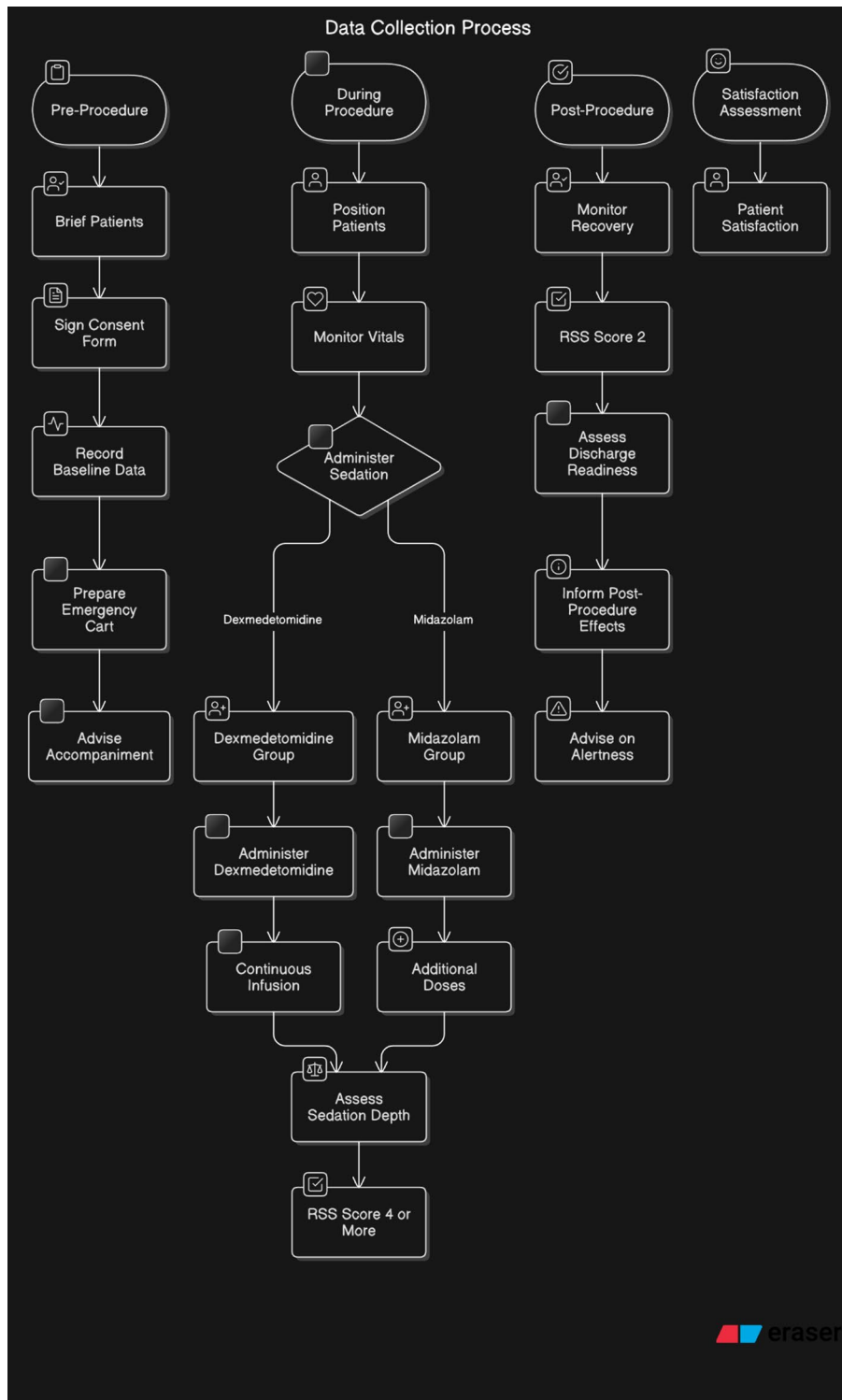


Fig. 1 Data collection flow diagram

in both groups. Although side effects were less frequent with Dexmedetomidine than Midazolam, the difference was not statistically significant. A total of 18 adverse events were recorded in the Midazolam group, compared to 5 in the Dexmedetomidine group. The most common side effect was hypertension in both groups, followed by bradycardia

Table 1 Demographic data of patients in Midazolam group and Dexmedetomidine group

Variable	Midazolam group (n=34)	Dexmedetomidine group (n=34)	p
Age, year*	39.8±13.0	40.8±11.4	0.744
Sex, Male%/Female%	47.05%/52.95%	52.95%/47.05%	0.809
Body mass index, kg/m2*	28.1±6.0	28.4±4.8	0.429
Duration of endoscopy, min*	9.9±1.5	11.0±1.9	0.008
Smoking%	35.29%	20.58%	0.280
Education level, n			
grammar school%	2.94%	0%	0.543
high school%	29.4%	20.59%	0.475
College%	38.23%	35.29%	0.841
graduate school%	29.4%	41.17%	0.542
Indications for endoscopy			
Dysphagia%	35.29%	50%	0.032
Esophageal reflux symptoms%	50%	20.59%	0.035
Dyspepsia%	14.70%	29.41%	0.031

Data is reported as mean standard deviation (SD) unless otherwise stated

Table 2 Pre and post procedural patient satisfaction

Variable	Midazolam group (n=34)	Dexmedetomidine group (n=34)	p
Pre procedure			
Expected satisfaction	7.7±1.2	7.1±1.9	0.228
Expected discomfort	1.7±1.6	2.1±1.8	0.515
Expected gagging	1.0±1.1	1.6±1.1	0.020
Anxiety score	2.6±0.9	2.1±1.4	0.018
Post procedure			
Satisfaction	8.06±0.9	9.1±1.0	0.001
Discomfort	1.7±1.1	0.7±0.9	0.001
Gagging	0.7±0.9	0.6±1.5	0.077
Anxiety	1.8±1.4	0.5±0.8	0.001

Data presents as mean ± SD

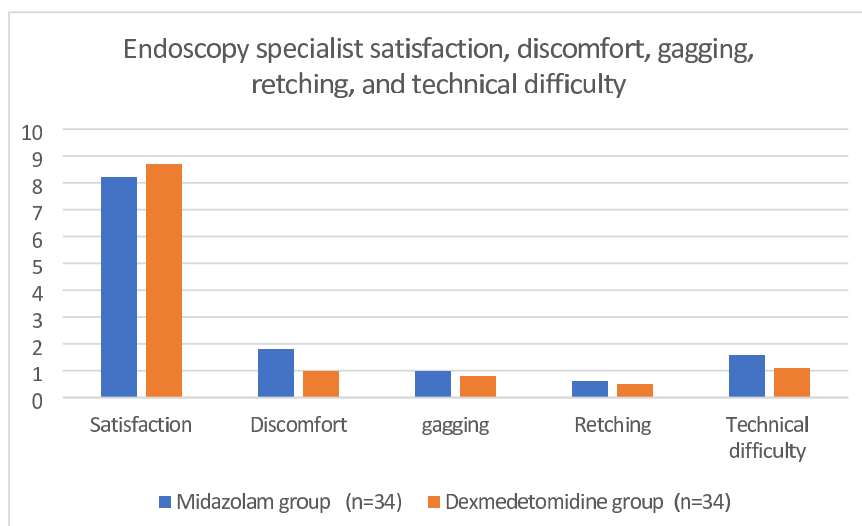


Fig. 2 Endoscopy specialist perception

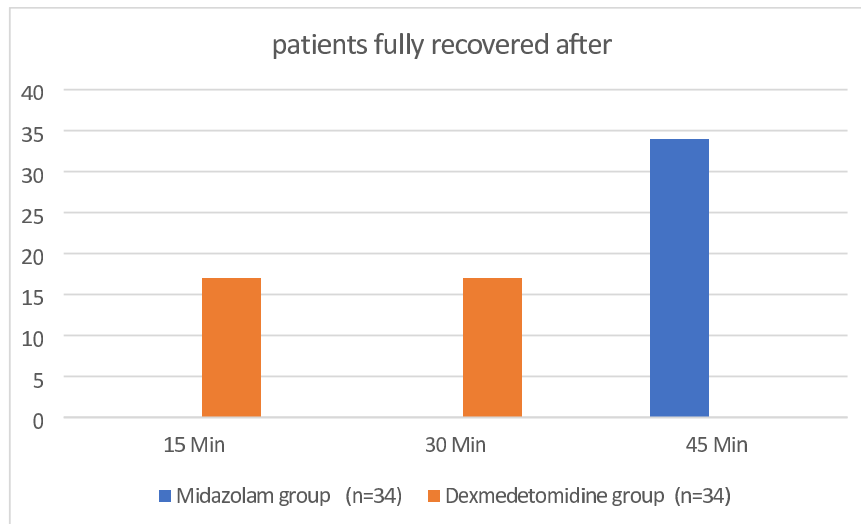


Fig. 3 Patients fully recovered time per min

Table 3 Vital signs of the patients in both Midazolam and Dexmedetomidine groups

Variable	Midazolam group (n = 34)	Dexmedetomidine group (n = 34)	p
Mean arterial pressure	90.7 ± 6.3	91.4 ± 8.5	0.713
Heart rate	80.7 ± 11.5	77.4 ± 11.6	0.238
oxygen saturation	97.7 ± 1.3	97.8 ± 2.5	0.861
Respiratory rate	18.6 ± 4.7	16.7 ± 1.9	0.028

Data displayed as Mean ± SD

and transient hypoxia. In total, 18 adverse events were recorded in the Midazolam group (hypertension = 9, bradycardia = 4, hypoxia = 5), compared to 5 in the Dexmedetomidine group (hypertension = 3, bradycardia = 2). Hypertension occurred more frequently in the Midazolam group, but the difference was not statistically significant ($p > 0.05$). All hypertensive episodes were transient and managed conservatively with observation and supplemental oxygen without requiring pharmacological intervention.

4 Discussion

This pilot study found Dexmedetomidine to be safer and more effective than Midazolam for upper GI endoscopy, with higher patient and endoscopist satisfaction, fewer side effects, more stable vital signs, and faster recovery. These benefits support its use over Midazolam, which is linked to more adverse effects and slower recovery [18–20]. Both drugs were combined with Fentanyl, aligning with prior studies [21, 22]. Dexmedetomidine patients had less discomfort, anxiety, and retching, consistent with findings from Barends et al. (2017), Zhang et al. (2016), and Kilic et al. (2011) [13, 23, 24]. Recovery was significantly faster with Dexmedetomidine (18.0 vs. 48.8 min), though onset was slower. Vital signs were largely similar, but Dexmedetomidine showed fewer respiratory issues [16, 19]. Fewer adverse events occurred with Dexmedetomidine (5 vs. 18), supporting its better safety profile [23, 24]. Being a pilot study, the sample size was not powered for detecting all possible clinical differences. Larger multi-center studies are recommended to confirm and expand upon these results. It is important to consider factors that may have influenced the outcomes. Notably, the procedural time was significantly longer in the Dexmedetomidine group. While this could potentially influence

recovery metrics, the markedly faster recovery observed with Dexmedetomidine despite a longer procedure time strengthens the conclusion of its superior recovery profile. Furthermore, there were significant differences in the indications for endoscopy between groups. Although the impact of this on satisfaction and recovery scores is uncertain, it represents a variable that should be acknowledged. This study was designed as a pilot feasibility study to assess recruitment feasibility, protocol implementation, safety trends, and preliminary effect estimates, with the primary aim of informing the design of a future adequately powered randomized controlled trial, potentially using a non-inferiority framework. Although statistically significant reductions in heart rate and respiratory rate were observed at selected time points in the Dexmedetomidine group, these changes remained within predefined clinically acceptable thresholds and did not require intervention. Similar findings have been reported in previous studies, supporting the known sympatholytic but clinically tolerable profile of Dexmedetomidine. Based on the observed difference in recovery time between groups, the estimated effect size was very large (Cohen's $d \approx 5.5$). Using this effect size, a future definitive trial would theoretically require a very small sample to achieve 80% power at $\alpha = 0.05$. However, given that pilot studies tend to overestimate effect sizes, a more conservative estimate should be used when planning a future randomized controlled trial, likely requiring a substantially larger sample per group. Multiple comparisons were conducted across satisfaction scores, vital signs at multiple time points, and recovery outcomes without adjustment, increasing the risk of Type I error. Results should therefore be interpreted cautiously.

4.1 Limitation

The findings of this pilot study suggest that Dexmedetomidine may show potential advantages in recovery time, patient satisfaction, and safety-related outcomes compared with Midazolam. These preliminary observations are consistent with previous studies reporting a favorable respiratory profile and anxiolytic properties of Dexmedetomidine. However, as a pilot study, the primary aim was to generate hypotheses and inform the design of a future larger-scale trial rather than to provide confirmatory evidence.

Several limitations should be acknowledged. First, the small sample size and convenience sampling limit the generalizability of the findings and increase the possibility that observed differences particularly subjective outcomes such as satisfaction scores may have been influenced by unmeasured confounding factors. These may include patient-related characteristics (personality traits, anxiety levels, prior procedural experiences) as well as potential inherent preferences or practice patterns of the single endoscopist involved in the procedures. Second, baseline imbalances between groups, particularly in procedural indications, may have affected outcome measures and further underscore the need for a more controlled and adequately powered randomized study. Third, this study was not prospectively registered in a public clinical trial registry. While trial registration was not mandated for this pilot study, the lack of prospective registration may limit transparency and should be considered when interpreting the results. Future definitive trials will be prospectively registered to enhance methodological rigor and transparency. Finally, the 10-minute loading period required for Dexmedetomidine induction may pose logistical challenges in high-throughput endoscopy units. Nevertheless, within our clinical workflow, this induction period coincided with routine preparation activities such as patient positioning, equipment checks, and consent verification, making

its integration feasible in practice. Future studies should formally evaluate workflow-adapted strategies to optimize induction time without compromising efficiency.

5 Conclusion

The preliminary data from this pilot study suggest a potential trend toward improved satisfaction, shorter recovery time, and fewer observed adverse events with Dexmedetomidine compared to Midazolam. While these signals are encouraging, they should be interpreted with caution given the exploratory design, small sample size, convenience sampling, and baseline group imbalances. Larger, well-powered, prospectively registered randomized controlled trials are required to confirm these findings and to support definitive clinical recommendations.

Abbreviations

ASA American society of anesthesiologists
RSS Ramsay sedation scale

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Author contributions

I.G. and A.A. conceptualized the study and prepared the main manuscript text. W.S. developed the anesthesia protocol. Data collection was conducted by Q.A., S.K., R.N., M.A., M.F.H, B.J.S and Amro Adas. All authors reviewed and approved the final manuscript.

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Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

The study received ethical approval from the IRB at An-Najah National University and the Ethics Committee of An-Najah National University Hospital (Approval No.: Ng.Feb.2021/5). This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Informed consent to participate was obtained from all participants prior to their inclusion in the study, and participants were assured of the confidentiality and anonymity of their responses. All patients received a clear explanation of the study objectives, protocol, and potential risks and benefits.

Consent for publication

Not applicable. No individual-level identifiable data are included in this manuscript.

Competing interests

The authors declare no competing interests.

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