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Development and validation of the PROcedural Sedation Assessment Survey (PROSAS) for assessment of procedural sedation quality

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Abstract

Background—Over 20 million invasive procedures are performed annually in the United States. The vast majority are performed with moderate sedation or deep sedation yet there is limited understanding of drivers of sedation quality and patient satisfaction. Currently, the major gap in quality assurance for invasive procedures is the lack of procedural sedation quality measures.

Objective—To develop and validate a robust, patient-centered measure of procedural sedation quality, the PROcedural Sedation Assessment Survey (PROSAS).

Design—Through a series of interviews with patients, proceduralists, nurses and anesthesiologists, and an interactive patient focus group, major domains influencing procedural sedation quality were used to create a multipart survey. The pilot survey was administered and revised in sequential cohorts of adults receiving moderate sedation for GI endoscopy. After revision, the PROSAS was administered to a validation cohort.

Setting—GI endoscopy unit.

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Patients—A expert panel of proceduralists, nurses and anesthesiologists, an initial survey development cohort of 40 patients, and a validation cohort of 858 patients undergoing sedation for outpatient GI endoscopy with additional surveys completed by the gastroenterologist, procedure nurse and recovery nurse.

Main Outcomes and Measures—Survey characteristics of the PROSAS.

Results—Patients were able to independently complete the PROSAS after procedural sedation before discharge. 91.6% of patients reported minimal discomfort; however, 8.4% of patients reported significant discomfort and 2.4% of patients experienced hemodynamic and/or respiratory instability. There was a high correlation between patient reported intraprocedure discomfort and both clinician assessments of procedural discomfort and patient recall of procedural pain 24 to 48 hours postprocedure ($p < 0.001$ for all), suggesting high external validity.

Limitations—Single-center study, variability of sedation technique between providers, inclusion of patients with chronic pain on analgesics

Conclusions—The PROSAS is a clinically relevant, patient-centered, easily administered instrument that allows for standardized evaluation of procedural sedation quality. The PROSAS may be useful in both research and clinical settings.

Keywords

Endoscopy; Sedation; Quality; Safety; Patient Satisfaction; Patient Reported Outcome

Background

Over 20 million non-operative invasive procedures are performed every year in the United States for diagnostic and therapeutic purposes.^{1, 2} The ability to perform diverse and frequently highly technical procedures is vital for a wide range of modern diagnostic and therapeutic modalities including gastrointestinal endoscopy, cardiac catheterization, bronchoscopy, orthopedic procedures, and interventional radiologic procedures. For example an US-guided biopsy of a suspicious mass or the insertion of a vascular stent into a stenosed artery can be performed as an outpatient with sedation even in patients with significant comorbid disease. In years past, these might have required surgery and lengthy hospitalizations in patients with complicated medical histories. However, despite advances in technology, many of these procedures are painful and anxiety provoking, requiring patients to lie still for significant amounts of time. The availability of cost effective and safe procedural sedation is a key factor contributing to the ability of physicians to perform complex, effective and innovative therapies.

In recent years there has been an increased focus on the quality of care surrounding invasive procedures. For example, in gastroenterology, the first practice statement on endoscopy quality by the American Society for Gastrointestinal Endoscopy, the major society covering these procedures, was published in 2006.³ At that time the authors noted that endoscopy performance measures were not well established, but that “In the near future, physicians will be required to track and report their performance.”⁴ Now in 2013, the current guidelines include standard monitoring for colonoscopy quality, including real-time monitoring of procedural adverse events,⁵ benchmarks for each of the most common adverse events,⁶⁻⁸

accepted colonoscopy withdrawal times,^{9, 10} cecal intubation rates,^{11, 12} polyp detection rates,^{13, 14} preparation quality,^{15, 16} and patient follow-up recommendations.^{17, 18} Similar advances in quality assessment have been seen in all specialties performing invasive procedures including cardiology, pulmonology, surgery and radiology.

Despite the robust array of measures and benchmarks for interventional procedures, there are currently no accepted quality measures for procedural sedation administration. Indeed, currently the single major recognized gap in quality assurance for invasive procedures across all areas is sedation monitoring.¹⁹ There is extensive medical literature on the choice of medications for sedation²⁰⁻²² and some limited information on factors that can contribute to difficulty with sedation, including patient characteristics.²³⁻²⁵ However, there is little agreement on how to measure the quality of sedation²⁶ or even which events should be considered sedation related adverse outcomes and how these should be tracked, reported and evaluated. Further, there is no method of gauging quality of sedation across healthcare settings, providers or patient subgroups, to compare the quality of often costly anesthesia administered deep versus nursing administered moderate sedation. More recently many sedation areas have been impacted by drug shortages including midazolam and fentanyl, leading to substitution with other medications; however, there are no data regarding how these supply problems affect patient satisfaction and safety. A method to evaluate quality is key in these situations when new regimens are being tried or developed.

The need for robust and validated measures of procedural sedation quality has also been noted by major societies including the Society for Pediatric Sedation,²⁷ the American Society of Anesthesiologists,²⁸ the American College of Radiology²⁹ and the American College of Gastroenterology³⁰ as well as by the FDA³¹ and CMS.³² It is currently accepted that modern metrics of medical quality are patient-centered and encompass safety as well as efficacy and patient satisfaction.³³ Our aim was to use modern patient reported outcome (PRO) development methodologies to derive and validate a robust, clinically practical procedural sedation quality instrument.

Methods

Tool development and validation

We conducted cross-sectional, qualitative one on one interviews with adult patients 18 years and older who had undergone invasive procedures with sedation to develop a robust understanding of the factors central to satisfaction with procedural sedation and to develop an initial conceptual framework. Domains and draft items assessing these domains were created and reviewed by a multidisciplinary team of stakeholders including eight patients, proceduralists (4 gastroenterologists, 1 cardiologist, 1 interventional radiologist), 2 anesthesiologists and 3 procedure area nurses. For the purposes of this study, face validity was defined as whether the items appear to participants to be asking questions relevant to sedation quality. External validity was defined as the degree to which findings can be applied broadly across populations and was assessed by comparing PROSAS performance across gender, age, ethnicity and procedure type. Agreed upon items were compiled into a draft pilot survey and administered to an initial cohort of adult patients undergoing invasive procedures with nurse administered moderate sedation for gastrointestinal endoscopic

procedures. This cohort clarified question intent and added items in areas felt to be deficient. Finally, patient facilitated discussions were convened to review the domains, the questions and the scoring of the preliminary survey tool. The finalized PROcedural Sedation Assessment Survey (PROSAS) was then validated in a secondary cohort of patients undergoing nurse administered moderate procedural sedation. (See Appendix)

Subjects

Patients older than 18 years of age, English speaking undergoing gastrointestinal endoscopy (upper endoscopy, colonoscopy, endoscopic ultrasound or flexible sigmoidoscopy) at our institution under moderate (nurse administered) sedation were considered eligible for participation in the study. During enrollment of the validation phase a subset of patients were prospectively identified by a research assistant on a daily basis.

Data collection

PROSAS was filled out by patients in the recovery area and collected by recovery area nursing. In addition to PROSAS, a subset of patients also completed preprocedure surveys and/or were contacted 24-48 hours post procedure to assess reliability of response. Sedation related adverse events (SRAE) were recorded by the procedure nurse using a standardized tool.²³ SRAE's were defined as any of the following occurrences: (1) hospitalization due to an adverse event of sedation including aspiration (2) use of narcotic or benzodiazepine reversal agents, (3) any episodes of O2 desaturation < 90% or leading to intervention, (4) any problematic changes in HR or BP during procedure (SBP <90, >160; HR <50, >120), (5) any hemodynamic or respiratory conditions that interrupted the procedure.

For participating patients, the proceduralist and procedural and recovery area nurses were also asked to complete a brief survey addressing the quality of sedation and an assessment of patient discomfort. Overall, 34 gastroenterologists and 52 nurses participated in the validation phase. All patients were placed on O2 by nasal cannula per unit protocol adjusted for a goal O2 saturation above 90%. Our policy for conscious sedation administration specifies for individual < 70 years of age and healthy, an initial dose of 0.5mg to 2mg of midazolam followed by 0.5mg to 1mg at 2 minute intervals as needed and an initial dose of 25mcg to 50mcg of fentanyl followed by 25mcg to 50mcg of fentanyl at 3-minute intervals as needed. For individuals >70 years of age, the fentanyl dosing remains unchanged; however, for midazolam the initial recommended dose is 0.5 mg to 1.5 mg. Oxygen desaturation was managed at the discretion of the clinicians involved in the procedure, common interventions included increase of oxygen flow rate by nasal cannula, adjustment of head and jaw position, less commonly change to mask ventilation, use of reversal agents and procedure abortion. All surveys can be found in the Appendix.

Data analysis

Primary analysis was qualitative with proceduralist and RN report used as measures of external validity. For evaluation of predictors of sedation quality, the Student T test, and the Fisher exact test were used for continuous and categorical variables, respectively. Spearman's Rho was used for correlation of linear data. Additionally, binary logistic regression was used to evaluate clinical factors independently related to risk of poor sedation

quality. Statistical analysis was completed using SPSS for Windows, Rel. 19.0. 2011. Chicago. SPSS Inc. All authors had access to the study data and reviewed and approved the final manuscript. This study was approved by the Beth Israel Deaconess Medical Center Institution Review Board (IRB), and supported by a Clinical Innovation Award from the center for Disease and Healthcare at Beth Israel Deaconess Medical Center.

Results

Preliminary exploratory interviews were conducted in 40 patients, 25 patients participated in facilitated discussions. These data were used to construct the final PROSAS tool. During the study period 858 patients completed the PROSAS between 9/27/2012 and 4/29/2013. The majority (57%) of patients underwent colonoscopy, 26.3% EGD, a smaller proportion underwent combined EGD/colonoscopy, 10.7%, and the remaining 5.9% underwent endoscopic ultrasound or flexible sigmoidoscopy. The mean age of participants was 54.7 years. 51.7% were female and 77.4% identified themselves as non-Hispanic white. The majority of patients were American Society of Anesthesiologists Class³⁴ I or II. (Table 1) During interviews, patients commonly reported that they were particularly concerned regarding the safety of sedation and anesthesia. This was consistently the primary concern with secondary commonly noted domains of comfort and control over level of sedation. Although there were many factors which were associated with overall procedural satisfaction, (Figure 1) the domains directly linking procedural sedation and patient satisfaction were fewer. (Figure 2) Based on these data, we subsequently defined high-quality procedural sedation quality from the patient perspective as 'adverse event free administration of sedation at a level appropriate to maintain comfort and at a level consistent with the patient's expressed wishes.' Conversely, a 'procedural sedation quality event' was considered to have occurred if there was a SRAE and/or patient satisfaction crossed a predetermined threshold, as described below. The PROSAS and definition for SRAEs was assessed by initial multidisciplinary team and in follow-up interviews with patients and clinicians, all of which confirmed that items were relevant, consistent with the construct framework, suggesting good face validity.

This definition provided the constructural foundation of the PROSAS with single items addressing procedural discomfort (How much discomfort did you experience during the procedure?), postprocedural discomfort (On a scale of 0-10, how much pain are you feeling now?) and relative procedural sedation preferences (If having this procedure again in the future, how much sedation would you prefer to have?). Of the 858 patients completing the PROSAS, 372 (43.4%) completed the preprocedure survey and of 200 participants solicited, 96 (48.0%) were able to be contacted 24-48 hours post procedure. Patients were observed in the recovery area for a mean of 48.8 minutes (range 20-197 minutes) and all included patients completed the PROSAS before discharge from the recovery area. Proceduralist, procedure nurse and recovery nurse evaluations were available on 642 (74.8%), 770 (89.7%) and 663 (77.3%) patients respectively. There were no significant differences in patient demographics between these groups.

Over the entire cohort, the mean score for patient reported procedural discomfort was 0.9 (range 0 - 10) with 87.9% in within the patient-derived satisfactory range of 0-2. (Figure 3)

For the item assessing preferences for relative level of future procedural sedation, 5.1% reported wanting significantly more sedation in future procedures (scores = 3) and a further 2.2% reported wanting significantly less sedation in future procedures (scores = -3). (Figure 4) The mean fentanyl dose was 142.2 mcg (range 0 – 300 mcg), 119.3 mcg for EGD and 148.9 mcg for colonoscopy. The mean midazolam dose was 4.4 mg (range 0 – 8.0), 4.15 mg for EGD and 4.27 mg for colonoscopy. (Table 3) Increasing age was highly associated with lower doses of fentanyl and midazolam ($p < 0.001$ for both), whereas BMI was not correlated with either agent ($p = 0.682$ for midazolam and $p = 0.875$ for fentanyl). In the 858 patients assessed, there were no sedation-related hospitalizations and no use of narcotic or benzodiazepine reversal agents; however, respiratory compromise with oxygen saturation $< 90\%$ requiring intervention occurred in 2.0% of cases, transient hemodynamic instability was seen in 0.6% of cases, and in 0.9% the procedure was interrupted due to issues with sedation. No differences in adverse event rates were seen between the different procedures.

Patient reported procedural discomfort was highly correlated with proceduralist and nurse rated procedural discomfort and 24-48 hour recall ($p < 0.001$ for all comparisons), suggesting both that patients are able to reliably report intraprocedure discomfort, whereas in recovery postprocedure and that the PROSAS has excellent inter-rater reliability. Additionally, this correlation remained similar evaluating men versus women, patients older than 60 years of age compared with younger patients, in white versus non-white patients and across all procedure types, suggesting external validity. As responses to items were not normally distributed, sedation outcomes were dichotomized into a single metric of sedation quality. In accordance with patients' priorities, procedural sedation was judged as successful when there was no adverse event, no issues with sedation leading to an incomplete procedure and when patient-reported procedural discomfort was = 2 and the patient was comfortable with the level of sedation obtained with a sedation preference score of between -2 and 2.

Using these criteria, successful procedural sedation was achieved in 737 (85.9%) patients. The most common reason for problematic sedation was patient discomfort, which occurred in 8.4% of patients followed by patient perceived under-sedation, in 3.5% of patients, 26.7% of whom reported procedural pain scores < 3 . Factors protective of problematic sedation included cancer (OR 0.42; 95% CI, 0.21-0.81) and diabetes (OR 0.47; 95% CI, 0.23-0.99). Although the most frequent reason for problematic procedural sedation was patient discomfort, mean total fentanyl and midazolam dosages were higher in cases with problematic sedation than in those with high-quality sedation. For midazolam the mean dose cases with a sedation quality event was 4.8 mg versus 4.3 mg in cases without an event, $p = 0.003$. For fentanyl the mean dose with a sedation quality event was 155.5 mcg versus 141.1 mcg in cases without an event, $p = 0.006$. Fentanyl and midazolam dosage were highly correlated by Spearman's Rho, (Rho 0.495, $p < 0.001$). Demographics and patient factors including gender, age, ethnicity, BMI as a continuous variable, ASA class, smoking status and recent alcohol or recreational drug use did not have any impact on risk for problematic sedation. (Table 2) See Table 2 for univariate analysis of factors associated with procedural sedation outcome and Table 3 for further data on ASA class and procedure type. In binary logistic regression, only 2 factors were independently associated with risk of a procedural sedation quality event: History of cancer (β 0.42; 95% CI, 0.21-0.81) and higher midazolam

dose (β 1.256 per mg; 95% CI, 1.081-1.459). Lower BMI also approached significance (β 0.97 per BMI point; 95% CI, 0.935-1.006).

Looking further at these 3 variables, 142 (16.6%) individuals had a history of cancer, excluding non-melanoma skin cancers, and in this cohort the risk of a procedural sedation quality event was reduced, 7.0% versus 15.5% in individuals without a history of cancer. To further explore the relationship between sedative dose and risk of sedation event, the cohort was divided into the following quartiles by midazolam dose: 3.5 mg (30.1%), 3.51-4.0 mg (24.7%), 4.1-5.5 mg (21.9%) and >5.5 mg (23.3%) and by fentanyl dose: 100.0 mcg (31.2%), 100.1-150.0 (39.1%), 150.1-175.0 (8.0%) and > 175.0 (21.7%). For midazolam, the risk of procedural sedation quality event was stable over the lower 3 quartiles, 10.9%, 13.2% and 9.0% respectively, but rose significantly in the highest quartile to 23.0% ($p<0.001$). For fentanyl, the risk of procedural sedation quality event was stable over the lower 2 quartiles, 12.0% and 10.3% respectively, but rose significantly in the higher quartiles from 18.3% in the third quartile to 21.6% in the fourth ($p=0.017$). For BMI, we classified patients according to classes based on WHO criteria³⁵ of <18.5 for underweight (2.8%), 18.5 to 24.99 for normal (33.1%), 25.0-29.9 for overweight (34.8%) and 30.0 for obese (29.3%). In these classes, BMI was inversely associated with risk of procedural sedation quality event, occurring in 26.1% of underweight patients, 15.3% of normal weight patients, 13.9% for overweight patients and 10.7% for obese patients although this did not reach statistical significance due to the small number of patients in the lowest BMI class (2.7% of total, $p=0.14$).

Discussion

Sedation is a central component of nearly all invasive procedures and, as we have demonstrated, is a primary driver of patient experience and satisfaction. For this reason, although attention to quality of the procedure itself is appropriate, the value of invasive procedures to patients cannot be optimized without robust, patient-centered measures of procedural sedation quality. The need for such measures has been commented upon by a number of governmental bodies and professional societies;^{27, 32, 36} however, recent reviews note that no single instrument currently available is suitable for this task,^{26, 37} and even high-quality safety data are limited.³⁸ In this work, we sought to address this issue through the development and validation of a patient-centered procedural sedation quality measure. Currently, the 2 leading gastroenterology procedure quality reporting systems GIQuIC³⁹ and the Digestive Health Outcomes Registry⁴⁰ each contain only a single checkbox on procedural sedation for “Sedation Related Adverse Event (Unplanned Intervention)” and “Complications Due to Anesthesia,” respectively. Although collection of these data is clearly important, these systems collect data on adverse incidents as opposed to the quality of the overall experience. They do not include data on satisfaction and do not represent a robust or patient-centered measure of sedation quality.

The PROSAS is primarily based on patient input and was developed with the input of multiple stakeholders representing clinicians involved with many facets of procedural sedation in line with recent guidance on patient reported outcome development. This instrument has excellent face validity judged by a multidisciplinary group of stakeholders

and more importantly the high degree of correlation between clinician and patient reports of discomfort and sedation adequacy suggest excellent external validity. Using the PROSAS, we confirmed the relatively low rate of traditional sedation related adverse events including respiratory and hemodynamic instability, but found more frequent issues with patient satisfaction regarding sedation administration. It was not surprising that a higher risk of procedural sedation quality event occurred in patients in the highest quartiles for fentanyl and midazolam dosing. In contrast to most medical literature we found an inverse correlation with BMI and sedation events, this will require further follow-up but may suggest that procedures in underweight patients may be more painful and that nurse administered medications are often weight based, thus limiting doses in smaller patients. The association between cancer and lower pain scores was unexpected and likely due to confounding by an unknown bias, possibly pre procedure medication use, or that this cohort of patients has undergone more prior procedures reducing anxiety surrounding endoscopy. Other factors including patient demographics and involvement of a trainee did not appear to be associated with procedural sedation quality events or with patient satisfaction. (Table 2)

There are limited instruments to measure moderate sedation, and as stated most measures of quality with moderate sedation are directed at an assessment of adverse incidents and the performance of the procedure. The Iowa Satisfaction with Anesthesia Scale (ISAS)⁴¹ is an instrument that was developed to assess patient satisfaction with monitored anesthesia care (MAC) and has similarities with the PROSAS. ISAS consists of 11 statements addressing a range of emotions and physical sensation: the presence of nausea and/or throwing up, itching, the degree of relaxation, pain or hurt, safety, heat, overall satisfaction and feeling 'good.' The ISAS is generally completed after the second phase of recovery or at 24 hours post procedure through a telephone interview. Similar to the PROSAS, questions are rated on a positive to negative scale – from agree very much with the statement to disagree very much. The tool has been validated in patients undergoing MAC anesthesia in multiple settings,⁴² however, it may not be readily applicable to patient undergoing sedation for simple procedures such as a colonoscopy. Although both ISAS and the PROSAS evaluate patient experience with respect to pain and overall satisfaction, the ISAS does not include any assessment of adverse events during surgery. During MAC an anesthesia provider is readily available to respond to changing hemodynamics and respiratory events, including advancing to a deeper anesthesia or administering cardiovascular medications. In contrast during nurse administered moderate sedation any adverse hemodynamic or respiratory events will result in interruption and possibly a discontinuation of a procedure, or alternately a patient may be more awake or experience more pain due to limitations of medication available for moderate sedation. Specific to gastroenterology, the Nurse-Assessed Patient Comfort Score (NAPCOMS)⁴³ and Patient Satisfaction with Sedation Instrument (PSSI)⁴⁴ have been described. The PROSAS differs from these tools as it directly assess patient report unlike NAPCOMS and is brief and can be reliably administered in the procedural recovery area, unlike the PSSI. During development, it was unclear if the amnesic properties of sedatives would render postprocedure patient reported outcomes inaccurate. It was for this reason we had procedure nurses and endoscopists rate patient comfort immediately postprocedure and also re-surveyed patients 24-48 hours post procedure. That all 4 surveys (endoscopist, nurse, patient immediately post procedure and patient 24-48

hours post procedure) were highly correlated ($p < 0.001$), this suggests that patients can reliably report procedural comfort even given the after-effects of sedation. This is also relevant to prior studies that have evaluated the ability of patients to self-administer sedation for endoscopy and a tool such as the PROSAS may help to further assess the potential benefits of this strategy.⁴⁵

By using a tool such as the PROSAS that includes succinct nursing and proceduralist components, we believe that clinicians will be able to assess quality of sedation and make decisions based on this information regarding appropriate choice of procedure and sedation modality, including potentially the choice of conscious sedation versus propofol, if this use is validated in future studies.

The development of a robust questionnaire is complex and requires extensive testing and re-testing to prove reliability and broad acceptability.^{37, 46} We believe that the PROSAS is a valid tool which can be used to assess sedation outcomes in research and clinical practice; however, we acknowledge some limitations and the need for further validation. First this study was conducted in a single center and limited to outpatients undergoing sedation for endoscopic procedures in gastroenterology. We also were not able to assess the effect of outpatient medication use including narcotics, benzodiazepines and analgesics, which may influence sedation efficacy. The preprocedure and 48-hour follow-up survey were completed by 43% and 48% of participants, which may suggest response bias; however, as the primary endpoint was the immediate postprocedure survey results, the effect of this on the results presented should be limited. Additionally, different sedation techniques practiced by the 34 gastroenterologists included in the validation phase and the inclusion of patients with chronic pain on analgesics may have introduced unadjusted confounding effects. Overall, the population evaluated is large and diverse and the fact that the rate of sedation related adverse events described above is similar to that seen in other studies,^{47, 48} suggests that our results are generalizable; however, further study in other populations and other procedure types is clearly warranted.

In conclusion, the PROSAS is a novel survey tool specifically developed to assess the quality of procedural sedation which meets essential criteria for face and external validity. The PROSAS requires little time to complete and is simple to administer, score and interpret. This patient-centered tool can be used alone or in conjunction with other metrics of procedural quality to assess safety and patient satisfaction with procedural sedation. Standardized instruments such as the PROSAS will be essential for future quality improvement, research and shared decision making regarding procedural sedation.

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Glossary

PROSAS	PROcedural Sedation Assessment Survey
EGD	Esophagogastroduodenoscopy
PRO	Patient Reported Outcome
FDA	Food and Drug Administration
CMS	Center for Medicare Services
SRAE	Sedation Related Adverse Event
HR	Heart Rate
SBP	Systolic blood pressure
BMI	body mass index
ASA	American Society of Anesthesiologists
ISAS	Iowa Satisfaction with Anesthesia Scale
NAPCOMS	Nurse-Assessed Patient Comfort Score
PSSI	Patient Satisfaction with Sedation Instrument

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Take Home Message

- Sedation is one of the major factors influencing patient satisfaction with endoscopic procedures, and options are currently limited for efficient assessment of procedural sedation safety and quality.
- The PROcedural Sedation Assessment Survey (PROSAS) is a brief instrument that reliably measures patient satisfaction and safety of procedural sedation and can be completed accurately by patients in the postprocedure recovery area.

Figure 1.
Domains directly influencing procedural patient satisfaction

Figure 2.
Domains directly influencing procedural sedation patient satisfaction

Figure 3.

Patient reported intraprocedure discomfort*

*0 represents no discomfort, 10 represents very severe pain

Figure 4.

Patient reported preference for administration of sedation in future procedures*

*Lower numbers represent desire for less sedation in future similar procedures, higher numbers represent desire for more sedation in future similar procedures

Table 1

Characteristics of Study Population

Participant characteristics	Mean (range) or % total n=858	Colonoscopy n=489 (57.0%)	EGD n=226 (26.3%)	EGD/ colon n=92 (10.7%)	Other* n=51 (5.9%)
Age	54.7 (18-92)	56.6 (18-87)	51.5 (19-92)	53.1 (20-82)	52.0 (24-74)
BMI	27.7 (15.2-63.5)	27.7 (16.3-50.2)	27.7 (15.2-63.5)	27.4 (17.7-46.3)	28.0 (18.8-53.9)
Female	51.7%	47.4%	59.7%	57.6%	55.9%
Primary English speaking	88.7%	94.5%	96.0%	92.4%	100%
Ethnicity:					
• Asian	3.0%	2.5%	3.1%	5.4%	2.9%
• AA	10.4%	10.8%	10.6%	6.5%	8.8%
• Hispanic	3.3%	3.1%	4.4%	3.3%	2.9%
• White	77.4%	77.3%	76.1%	77.2%	85.3%
• Other/unspecified	5.9%	6.3%	5.8%	7.6%	0%
Smoking status:					
• Current	9.4%	9.8%	9.4%	5.4%	11.8%
• Non	67.9%	66.7%	20.8%	75.0%	17.6%
• Past	22.3%	23.5%	69.0%	19.6%	67.6%
Recent alcohol use	56.6%	60.7%	50.9%	59.8%	47.1%
Recreational drug use	4.0%	3.1%	3.5%	8.7%	5.9%
Past medical history					
• Cardiovascular disease	38.0%	42.5%	33.2%	31.5%	23.5%
• Pulmonary disease	19.3%	16.8%	23.5%	23.9%	8.8%
• Neurologic illness	5.8%	6.3%	5.8%	4.3%	5.9%
• Kidney/liver disease	17.8%	14.1%	27.4%	14.1%	2.9%
• Diabetes	12.1%	11.9%	11.9%	16.3%	11.8%
• Cancer	16.6%	15.1%	17.3%	16.3%	26.5%
ASA class					
• 1	14.8%	15.7%	13.3%	12.0%	17.6%
• 2	78.4%	78.7%	77.9%	81.5%	79.4%
• 3	6.8%	5.5%	8.8%	6.5%	2.9%
Adverse Events:					
• O2 saturation <90% requiring intervention	2.0%	2.2%	1.9%	2.2%	0%
• Procedure interruption due to hemodynamic instability	0.6%	0.6%	0.9%	0%	0%
• Procedure interruption related to patient discomfort	0.9%	0.4%	1.3%	2.2%	2.9%
• Use of reversal agents	0%	0%	0%	0%	0%

Table 2

Univariate analysis of factors associated with increased risk of sedation quality event

Factor	P value
Reported recall of procedural discomfort at 48 hours	<0.001
Reported sedation preference for future procedures	<0.001
Preprocedure pain	<0.001
Postprocedure pain	<0.001
Physician rated discomfort during procedure	<0.001
Nurse rated discomfort during procedure	<0.001
Ever previously sedated for procedure	0.924
Expected discomfort during procedure	0.159
Fentanyl dose	0.012
Midazolam dose	0.031
Age	0.166
BMI	0.040
Alcohol use	0.773
Recreational drug use	0.690
Cardiovascular disease	0.107
Pulmonary disease	0.693
Neurologic disease	0.202
Renal/hepatic disease	0.716
Diabetes	0.045
History of cancer [*]	0.008
ASA class	0.358
Trainee involvement	0.111
Gender	0.291
Ethnicity	0.308
Preferred language	0.198
Smoking status	0.568

* Active or in remission, excluding non-melanoma skin cancers

Table 3

Rate of sedation safety and quality events by procedure type and ASA classification

Procedure type	EGD n=226	Colonoscopy n=489	EGD/Colonoscopy n=92	Other n=51
• Sedation quality event	11.1%	14.1%	14.3%	15.7%
• Discomfort score 3	5.0%	13.1%	18.2%	26.1%
• Sedation preference score 3 or -3	6.4%	6.6%	10.9%	13.0%
• Sedation related adverse events	2.7%	2.8%	2.2%	0%
• Mean fentanyl dose (mcg)	119.3	148.9	169.8	142.7
• Mean midazolam dose (mg)	4.15	4.27	5.30	4.91

ASA Class	1 n=127	2 n=673	3 n=58	4 n=0
• Sedation quality event	16.5%	13.8%	12.1%	N/A
• Discomfort score 3	15.2%	11.6%	10.8%	
• Sedation preference score 3 or -3	9.8%	6.8%	5.4%	
• Sedation related adverse events	2.4%	2.1%	3.4%	
• Mean fentanyl dose (mcg)	155.0	142.7	117.3	
• Mean midazolam dose (mg)	4.67	4.36	3.76	