

# Is sore throat an underreported and under-estimated quality indicator for endoscopic procedures? Results from a large prospective cohort



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## ABSTRACT

**Background and study aims** Patients often develop sore throat after upper endoscopy procedures but there data are very limited on the magnitude of the problem. The aim of

this study was to evaluate and identify independent risk factors of sore throat in patients undergoing endoscopy.

**Patients and methods** Data were collected prospectively on consecutive outpatient endoscopy procedures performed at Cedars-Sinai Medical Center from October 2018 to February 2019. Procedure nurses collected pre-procedure, intra-procedure, and immediate post-procedure surveys including evaluation of sore throat (pain scale from 1–10). Significant univariate variables ( $P < 0.05$ ) were entered into a multivariate logistic regression model.

**Results** Data were collected on 715 patients. Four hundred seventy-two patients (mean age = 61 years, females = 53%) were included in the analysis and 85 patients (18%) experienced post-procedure sore throat. On univariate analysis, female gender, oral endoscopic ultrasound (EUS), oral double balloon enteroscopy (DBE), fellow involvement, throat suctioning, general anesthesia, oral airway, and prolonged procedure (>30 minutes) were risk factors for sore throat (all  $P < 0.05$ ). On the multivariate analysis, independent risk-factors for post-procedure sore throat were oral DBE (odds ratio [OR] 5.2), oral airway (OR 4.8), general anesthesia (OR 2.7), fellow involvement (OR 2.5), oral EUS (OR 2.4), and female gender (OR 2.0).

**Conclusions** Contrary to popular belief, our study found that post-procedural sore throat is more common (18%) than previously reported. Two types of endoscopic procedures, two anesthesia maneuvers, female gender, and fellow involvement were all independent risk factors. This is of particular concern for interventionalists who perform EUS and oral DBE as these patients are at higher risk for sore throat.

## Introduction

Patients often develop sore throat after upper endoscopy procedures but data are limited on the magnitude of the problem, risk factors, and best practices to prevent this procedure-associated symptom. Post-procedure sore throat is not trivial for patients, often is a significant source of discomfort and significantly impacts patient satisfaction and quality of life. This has clinical implications because patients who experience neg-

ative outcomes post-procedure were found to be significantly less likely to agree to undergo an endoscopic procedure in the future if deemed necessary [1].

This also impacts providers because Medicare reimbursements are now, in part, based on patient satisfaction so there is increasing attention towards optimizing patient satisfaction [2]. Studies have consistently shown that well-managed pain is associated with more favorable ranking of patient interactions

with clinical staff and higher overall satisfaction scores [3]. Conversely, poor survey results could result in hospitals forfeiting reimbursement.

Regarding previously published data, 30-day post-procedure surveys reported that 9% to 12.8% of patients experienced sore throat after common endoscopic procedures [1, 4, 5]. However, these studies are potentially inaccurate due to recall bias, and they lack details such as the type of procedures, anesthetic methods and degrees of discomfort experienced by patients. Few studies have looked at immediate post-procedure sore throat; one study reported 0.6% sore throat after endoscopic ultrasound (EUS) which is an unexpectedly low incidence and further studies are warranted [6].

Another understudied area of interest is whether post-procedure sore throat is secondary to an endoscopy procedure itself or concomitant anesthesia maneuvers. While there are data showing that intubation increases risk of sore throat [7, 8], a comprehensive evaluation of endoscopic and anesthesia risk factors is lacking in the literature.

To our knowledge, this is the first large prospective study to comprehensively evaluate immediate post-procedure sore throat. The aims of this study were to evaluate the incidence and independent risk factors for sore throat in a high-volume academic endoscopic unit.

## Patients and methods

### Institutional review board

The study was approved as a quality improvement study by the hospital's Institutional Review Board. Additional written consent for participation in this study was waived because the survey was performed as part of a non-interventional quality improvement study.

### Data collection

Data were collected prospectively on consecutive outpatient endoscopy procedures performed at the Cedars Sinai Medical Center Gastrointestinal Unit from October 2018 to February 2019. Cedars Sinai is a high-volume quaternary referral endoscopy center with eight concurrent endoscopy rooms. This facility caters to a wide range of patients including those requiring regular screening endoscopic procedures to those with complex altered anatomy endoscopic retrograde cholangiopancreatographies (ERCPs). In addition, it is affiliated with more than 50 academic and community-based endoscopists as well as a high-volume advanced endoscopy group. Cedars Sinai is also affiliated with a large private practice anesthesia group of more than 140 anesthesiologists. Each room is staffed by an anesthesiologist and decisions are based on standard American Society of Anesthesiologists (ASA) guidelines. Cedars Sinai is a training institution with six general gastroenterology fellows and one or two advanced endoscopy fellows a year.

Any patient over age 18 presenting for an outpatient endoscopy who had capacity to answer basic survey questions was included in the study. These patients underwent upper gastrointestinal procedures such as endoscopic ultrasound (EUS), ERCP, double balloon enteroscopy (DBE) and gastroscopy (EGD). Any

patient with sore throat prior to endoscopy, patients who only underwent lower gastrointestinal procedures (colonoscopy, flexible sigmoidoscopy, or rectal DBE exclusively), and anyone who declined to participate in the study was excluded from the study.

All surveys were administered by the nursing staff; endoscopists and anesthesiologists were not involved in data collection. This was done so that the data collection would be unbiased. Before the procedure, patients were given real-time preoperative surveys that included demographic information and presence of sore throat. Data were entered in a de-identified database spreadsheet with pertinent demographic information including age and gender. Standard-of-care consent for endoscopy was obtained from all patients before the procedure. Intra-procedurally, the following information was collected: type of procedure(s) including EGD, EUS, ERCP, push enteroscopy, oral DBE, flexible sigmoidoscopy, colonoscopy, rectal EUS, rectal DBE, and the type of endoscope used (pediatric gastroscope, regular gastroscope, therapeutic gastroscope, pediatric colonoscope, adult colonoscope, side-viewing ERCP duodenoscope, EUS radial scope, EUS linear scope, single balloon enteroscope, double balloon enteroscope, and pediatric double balloon enteroscope). Of note, the DBE included in the study is the double balloon-assisted endoscope (Fujinon Endoscopy, Wayne, New Jersey, United States). Spiral enteroscopy was not performed at Cedars Sinai and was therefore not included in the study. Additional data points included the duration of procedure (scope in to scope out divided into 1 to 30 minutes, 31 to 60 minutes, 61 to 90 minutes, 91 to 120 minutes, and 121+ minutes), degree of endoscope intubation difficulty ("no difficulty" defined as one attempt, "some difficulty" defined as two attempts, and "much difficulty" defined as three or more attempts), use of NG/OG tube during procedure, and whether there was fellow involvement.

Regarding anesthesia factors, the following data were collected: number of times the patient was suctioned by the anesthesiologist or staff (no suctioning, suctioned less than five times, or suctioned more than five times), type of anesthesia (moderate sedation, deep sedation, or general anesthesia), and type of airway used (oral or nasal). Moderate sedation is defined as conscious sedation administered by an endoscopist and procedure nurse (generally without an anesthesiologist in the room). Patients undergoing moderate sedation have purposeful response to verbal or tactile stimulation, can protect their airway, and have adequate spontaneous ventilation [9]. Deep sedation, also known as monitored anesthesia care (MAC), is managed by an anesthesiologist. The patient has purposeful response after repeat or painful stimuli and needs monitoring of their airway. In this paper, this type of sedation will be called "deep sedation". Lastly, general anesthesia is also administered by an anesthesiologist and patients are all intubated and are unarousable even with painful stimuli. Oral airway, also known as oropharyngeal airway, refers to the rigid plastic oropharyngeal appliance that is sometimes placed by the anesthesiologist to prevent the tongue from covering the epiglottis [7]. This prevents oropharyngeal airway obstruction in deeply sedated patients. A nasal airway is occasionally used by anes-

thesiologists for a similar indication. Of note, topical anesthesia sprays are not routinely used prior to intubation at Cedars Sinai, and therefore, were not evaluated in this study. The names of the endoscopist and anesthesiologist were recorded.

After the procedure, a standard-of-care handoff was performed by the procedure nurse. Caution was taken not to disclose any of the aforementioned intra-procedural factors that might increase observer bias. Of note, per Cedars Sinai policy, patients are not transported out of the endoscopy rooms until they are awake per the anesthesiologist's discretion. Once a patient was awake and alert in the post-anesthesia care unit, routine post-procedure care was completed, and the postoperative nurse administered an immediate post-procedure survey evaluating for sore throat with a Likert pain scale from 1–10. Additional follow-up was not a part of this study. However, patients received routine clinical care, including follow-up phone calls if deemed necessary and charts were reviewed to identify any delayed complications related to sore throat.

## Biostatistics

For the biostatistics analysis, incidence of post-procedure sore throat was calculated. This was stratified to the various Fisher's exact test and Mann-Whitney *U* test were used for univariate analysis to determine association between demographic, endoscopic, procedure and anesthesia factors and post-procedure sore throat. Subsequently, a multivariate logistic regression model was created involving all significant variables identified in the univariate analysis. Variables with high multicollinearity were excluded from multivariate analysis. Odds ratios (ORs) and 95% confidence intervals (CI) were calculated. Statistical analysis was performed using a statistical software program IBM SPSS Statistics version 24, (IBM Corporation, Armonk, New York, United States) and a two-tailed  $P < 0.05$  was considered statistically significant.

## Results

Data were collected on a total of 715 patients. Lower procedures alone were performed on 226 patients (31.6%). As anticipated, sore throat in patients who only underwent lower gastrointestinal procedures alone was lower than in patients who underwent upper gastrointestinal procedures (1.3% vs 19.2%,  $P < 0.01$ ). These patients were excluded from further evaluation. Patients were also excluded if they had pre-procedure sore throat ( $n = 17$ , 2.4%).

In total, 472 patients met inclusion criteria and were included in the analysis (► **Table 1**). Mean age was 60.6 years (SD 15.8) and 52.8% were females. Types of endoscopic procedure included the following: 63 ERCP (13.3%) and 127 oral EUS (26.9%) of which 53 (11.2%) were radial EUS endoscope and 82 (17.4%) were linear EUS endoscope. Other procedures included 316 EGD (66.9%), 28 oral DBE (5.9%), three push enteroscopies (0.6%), 111 colonoscopies (23.5%), two rectal DBE (0.4%), and three flexible sigmoidoscopies (0.6%). Procedure characteristics included fellow involvement in 123 cases (26.1%), length of procedure >30 minutes was 260 cases (55.1%), and use of nasogastric/orogastric tube during procedure was seven cases

► **Table 1** Demographics.

	N = 472
<b>Patient characteristics</b>	
▪ Mean age in years	60.6 (15.8)
▪ Female gender	249 (52.8%)
<b>Type of endoscopic procedure</b>	
▪ ERCP	63 (13.3%)
▪ Oral EUS	127 (6.9%)
▪ Radial EUS endoscope	53 (11.2%)
▪ Linear EUS endoscope	82 (17.4%)
▪ EGD	316 (6.9%)
▪ Oral DBE	28 (5.9%)
▪ Push enteroscopy	3 (0.6%)
▪ Colonoscopy	111 (3.5%)
▪ Rectal DBE	2 (0.4%)
▪ Flexible sigmoidoscopy	3 (0.6%)
<b>Procedure characteristics</b>	
▪ Fellow involvement	123 (6.1%)
▪ Length of procedure (> 30 min)	260 (55.1%)
	1 = 212 (44.9%)
	2 = 192 (40.7%)
	3 = 43 (9.1%)
	4 = 14 (3%)
	5 = 11 (2.3%)
▪ Use of NG/OG tube during procedure	7 (1.5%)
<b>Anesthesia maneuvers</b>	
▪ Mod sedation	8 (1.7%)
▪ Deep Sedation	429 (90.9%)
▪ General Anesthesia	35 (7.4%)
▪ Oral airway	13 (2.8%)
▪ Nasal airway	0
▪ Suctioning of oral cavity during procedure	181 (8.3%)
▪ Suctioning more than 5 times	21 (4.4%)
<b>Post-procedure throat soreness</b> <b>85 (18.0%)</b>	
▪ Trivial (score 1–2)	18/85 (21.2%)
▪ Mild (score 3–4)	34/85 (40.0%)
▪ Moderate (score 5–7)	25/85 (29.4%)
▪ Severe (score 8–10)	8/85 (9.4%)

EUS, endoscopic ultrasound; EGD, esophagogastroduodenoscopy; DBE, double balloon enteroscopy; NG, nasogastric; OR, orogastric.

(1.5%). Regarding difficulty of endoscope intubation, there were six cases (1.3%) with “much difficulty”, 22 cases (4.7%) with “some difficulty” and the rest had no difficulty with endoscopic intubation.

Anesthesia maneuvers included moderate sedation in eight cases (1.7%), deep sedation in 429 cases (90.9%), general anesthesia in 35 cases (7.4%), oral airway in 13 cases (2.8%), suctioning of oral cavity during procedure in 181 cases (38.3%), and suctioning of oral cavity more than five times was done in 21 cases (4.4%). No cases of nasal airways were performed in the study.

Overall, 85 patients (18%) experienced post-procedure sore throat (► Fig. 1). Of them, 9.4% and 29.4% reported throat soreness as severe (level  $\geq 8/10$ ) and moderate (level 5 to 7 of 10), respectively. Trivial sore throat (score 1 to 2 of 10) and mild sore throat (score 3 to 4 of 10) were reported in 21.2% of patients and 40.0% of patients, respectively. Of note, charts were reviewed for any complications after the day of endoscopy, but no significant complications related to sore throat were found. No patients required examination by an ear, nose and throat specialist.

On univariate analysis (► Table 2), female gender was a significant risk factor for sore throat [55 (64.7%) vs 194 (50.1%);  $P=0.016$ ]. In terms of type of endoscopic procedure, oral EUS and oral DBE were significant [32 (37.6%) vs 95 (24.5%),  $P=0.021$  and 14 (16.5%) vs 14 (3.6%),  $P<0.001$ , respectively]. Of note, subgroup analysis of oral EUS with linear and radial EUS was done and neither was significant. Regarding other endoscopy factors, fellow involvement as well as prolonged procedure were associated with post-procedural sore throat [35 (41.2%) vs 88 (22.7%),  $P=0.001$  and 64 (68.1%) vs 205 (51.9%),  $P=0.005$ ]. Regarding anesthesia maneuvers, throat suctioning [45 (52.9%) vs 136 (35.1%),  $P=0.003$ ], general anesthesia [15 (17.6%) vs 20 (5.2%),  $P<0.001$ ] and use of an oral airway [6 (7.1%) vs 7 (1.8%),  $P=0.017$ ] were risk factors for sore throat.

On the multivariate analysis (► Table 3 and ► Fig. 2), the independent risk factors for post-procedure sore throat were oral DBE (OR 5.2,  $P<0.001$ ), fellow involvement (OR 2.5,  $P=0.001$ ), oral EUS (OR 2.4,  $P=0.002$ ), and female gender (OR 2.0,  $P=0.010$ ). Independent anesthesia risk factors included

oral airway (OR 4.8,  $P=0.011$ ) and general anesthesia (OR 2.7,  $P=0.021$ ). There was a trend towards significance with suctioning of oral cavity during the procedure (OR 1.7,  $P=0.06$ ).

## Discussion

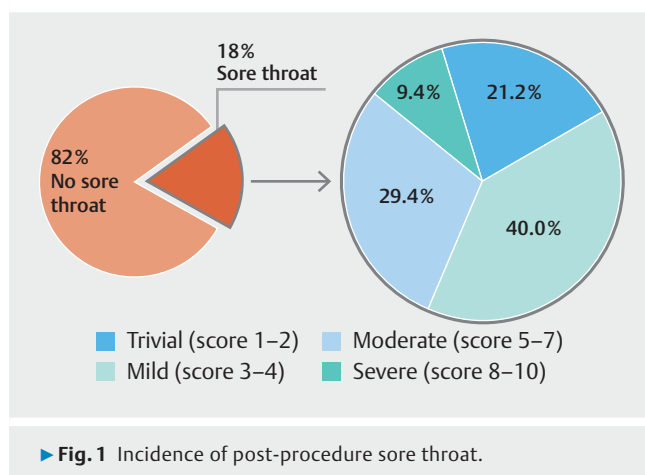
Post-procedure sore throat is common among patients who undergo upper endoscopy procedures but it is an understudied and underestimated condition. This prospective quality improvement study is the first to our knowledge to comprehensively investigate incidence and risk factors for sore throat immediately after upper endoscopy procedures. Our findings show that two endoscopy procedures, two anesthesia maneuvers, fellow involvement, and female gender are all independent risk factors.

In this study, throat soreness after endoscopic procedures was very common with 18% of patients reporting it. When stratified by severity of symptoms, 39% reported moderate or severe symptoms, which suggests these symptoms are not clinically insignificant to the patient. This has clinical implications because previous studies have shown that patients who experience negative outcomes post-procedure are more likely to have decreased patient satisfaction and are significantly less likely to agree to undergo endoscopic procedures in the future if deemed necessary [1]. Moreover, these quality indicators are increasingly affecting physician reimbursement.

This is a higher incidence than previously reported in the literature (9.5% to 12.8%) [1, 4–6]. This may be due to differences in study design and patient population. With previous studies that were 30-day questionnaires, incidence of sore throat may have been underestimated due to recall bias (patients are less likely to remember minor symptoms). However, there is also possible overestimation due to response bias (patients who are satisfied with their care are less likely to respond to postal surveys) so the reason for the discrepancy is unclear [10]. Another factor is that many of these studies only included EGD and did not include advanced procedures, which as our analysis showed, are more likely to cause sore throat.

Independent endoscopic risk factors were oral DBE (OR 5.2) and oral EUS (OR 2.4). Sore throat after oral DBE is likely due to the longer duration of the procedure, the large overtube, as well as the repetitive sliding motion of the overtube. Oral EUS may also be associated with sore throat due to the larger diameter of the endoscope and the bending mechanism at the distal end of the scope which, unlike EGD, is located a few centimeters proximally. It is also possibly due to the increased number of endoscopic intubations when both linear and radial EUS endoscopes were used. We had hypothesized that the linear EUS scope would cause more sore throat because of the larger ultrasound probe head, but rather, there was a trend towards significance with the radial EUS scope on univariate analysis (OR 1.9,  $P=0.056$ ) and not with the linear EUS probe. Overall, 25.2% of patients undergoing EUS reported sore throat, which is significantly higher than previously reported [6].

Regarding anesthesia-related characteristics, oral airway (OR 4.76,  $P=0.011$ ) and general anesthesia (OR 2.68,  $P=0.021$ ) were significant on multivariate analysis. No studies



► **Table 2** Univariate analysis evaluating risk of sore throat after an upper endoscopic procedure.

	Sore Throat (N=85)	No Sore Throat (N=387)	Unadjusted Odds Ratio (95% CI)	P Value
<b>Patient characteristics</b>				
▪ Mean age in years	60.5 (15.9)	60.6 (15.8)	–	0.856
▪ Female gender	55 (64.7%)	194 (50.1%)	1.8 (1.1–3.0)	0.016
<b>Type of endoscopic procedure</b>				
▪ ERCP	15 (17.6%)	48 (12.4%)	1.5 (0.8–2.8)	0.217
▪ Oral EUS	32 (37.6%)	95 (24.5%)	1.8 (1.1–3.0)	0.021
▪ Radial EUS endoscope	15 (17.6%)	38 (9.8%)	1.9 (1.0–3.8)	0.056
▪ Linear EUS endoscope	19 (22.4%)	63 (16.3%)	1.5 (0.8–2.6)	0.205
▪ EGD	45 (52.9%)	271 (70%)	0.5 (0.3–0.8)	0.003
▪ Oral DBE	14 (16.5%)	14 (3.6%)	5.3 (2.4–11.5)	<0.001
▪ Push Enteroscopy	0 (0%)	3 (0.8%)	–	1.000
▪ Rectal DBE	0 (0%)	2 (0.5%)	–	1.000
▪ Flexible sigmoidoscopy	0 (0%)	3 (0.8%)	–	1.000
<b>Procedure characteristics</b>				
▪ Fellow involvement	35 (41.2%)	88 (22.7%)	2.3 (1.5–3.9)	0.001
▪ Length of procedure (>30 min)	64 (68.1%)	205 (51.9%)	1.9 (1.2–3.2)	0.005
▪ Use of NG/OG tube	0 (0%)	7 (1.8%)	–	0.361
<b>Anesthesia maneuvers</b>				
▪ Moderate sedation	0 (0%)	8 (2.1%)	–	0.361
▪ Deep sedation	70 (82.4%)	359 (92.8%)	0.4 (0.2–0.7)	0.006
▪ General anesthesia	15 (17.6%)	20 (5.2%)	3.9 (1.9–8.0)	<0.001
▪ Oral airway	6 (7.1%)	7 (1.8%)	4.1 (1.3–12.6)	0.017
▪ Suctioning of oral cavity during procedure	45 (52.9%)	136 (35.1%)	2.1 (1.3–3.3)	0.003

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; DBE, double balloon enteroscopy; NG, nasogastric; OR, orogastric.

have previously evaluated anesthesia maneuvers as potential risk factors for post-procedure sore throat. Our data suggest that anesthesia-related factors are just as significant, if not more, in contributing to post-procedure sore throat, than endoscopic and patient factors. This has implications in the possible role of anesthesiologists exercising more caution when intubating and suctioning patients. An area of future research may be the use of a soft catheter tip versus Yankauer suction to prevent throat trauma and subsequent post-procedure sore throat.

Female gender was also an independent risk factor (OR 2.0,  $P=0.01$ ) and while the reason is unclear, it could potentially be due to anatomic gender differences versus possibly different physiologic response in regards to noxious stimuli. Previous studies have also showed that females are more likely to report complications [4]. Fellow involvement was also a significant risk factor, which is possibly due to more frequent unintentional

trauma during endoscopic intubation. Interestingly, duration of the procedure was not an independent risk factor for sore throat but oral DBE was a surrogate and significant risk factor. Also, older age was not a risk factor as previously reported [4].

There are several limitations to this study. The study was done at a single quaternary center so it may not be as generalizable to smaller centers or community practices. In addition, the post-procedure survey result may be affected by lingering sedation, possibly underestimating the level of pain in patients who were not fully awake. It is worth noting though that measures were taken to prevent this. Nurses were instructed to administer the survey when the patient was deemed to be awake and alert. In addition, patients are not transported out of the endoscopy rooms until they are awake per the anesthesiologist's discretion as part of Cedars Sinai policy. Despite this limitation, our data do not show a trend of deeply sedated patients reporting less pain. Rather, patients who received general anesthesia

► **Table 3** Multivariate analysis evaluating independent risk factors for throat soreness after an upper endoscopic procedure.

	Odds Ratio (95% CI)	P value
Patient characteristic		
Female gender	2.0 (1.2–3.4)	0.010
Type of endoscopic procedure		
Oral EUS	2.4 (1.4–4.3)	0.002
Oral DBE	5.2 (2.1–12.8)	<0.001
Procedure characteristics		
Fellow involvement	2.5 (1.5–4.3)	0.001
Prolonged procedure time (>30 minutes)	1.12(0.6–2.0)	0.705
Anesthesia maneuvers		
General anesthesia	2.7 (1.2–6.2)	0.021
Oral airway	4.8 (1.4–15.8)	0.011
Suctioning of oral cavity	1.7 (1.0–2.9)	0.057

EUS, endoscopic ultrasound; DBE, double balloon enteroscopy.

(and likely the deepest sedation) still reported the most sore throat (OR 2.7,  $P=0.021$  on multivariate analysis). And patients who received deep sedation actually reported less pain (OR 0.4,  $P=0.006$  on univariate analysis). Moderate sedation was only done in eight patients in this study, none of whom reported sore throat despite receiving the least amount of sedation.

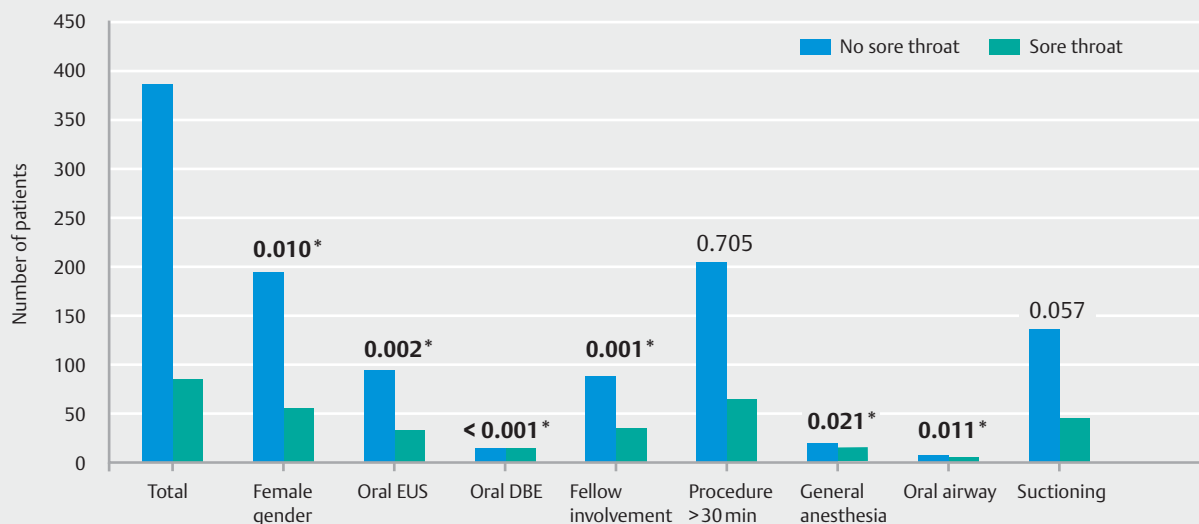
Other limitations included that a significant proportion of procedures were advanced endoscopic procedures and were more likely to cause sore throat, so this should be taken into account when interpreting the study. In addition, this was a non-

interventional study and the findings are purely observational and based on patient surveys. Longer follow-up was not done, however, no significant complications were reported related to sore throat in these patients. Lastly, the number of fellows was low and this may result in an operator-dependent variable that affects the rate of post-procedural symptoms.

There were several strengths to the study. This was a large prospective study with 472 patients included in the cohort. Second, our endoscopy center setting allowed for evaluation of a heterogeneous group of providers; over 50 endoscopists, of whom 35 performed more than five endoscopies, and 18 different anesthesiologists were included in the study. The immediate post-procedure survey was seen as a strength of the study because we were able to evaluate the real-time incidence of discomfort that patients are experiencing; in addition, with an immediate post-procedure survey, there is less recall bias so it is the most accurate measure of post-procedure symptoms.

## Conclusion

Contrary to popular belief, this study shows that post-procedural sore throat is more common than previously reported and is associated with certain endoscopic procedures, anesthesia maneuvers and patient factors. These findings are particularly relevant for interventionalists as their patients are at higher risk for sore throat. Understanding risk factors has important implications in patient satisfaction but more importantly, in patient adherence for future recommended procedures. It also has implications for physician and hospital reimbursements because of increasing emphasis on quality metrics. Future studies are warranted to further characterize this under-reported and underestimated quality indicator. There may be an important role in patient education, increased endoscopist/anesthesiologist awareness, and evaluation of interventions in the future.



► **Fig. 2** Independent risk factors for post-procedure sore throat (\*Red P values indicate statistical significance on multivariate analysis.)



## Competing interests

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The authors declare that they have no conflict of interest.

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