

Original Article

Effects of nasal cleansing and topical decongestants on patient tolerance during upper gastrointestinal endoscopy: a prospective randomized study

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Abstract: Adequate patient tolerance is essential for successful completion of safe endoscopic examination. Although there are many reported methods to increase patient tolerance, none of these fully resolve this problem. The aim of this study was to investigate whether relaxing the nasal airways increase patient tolerance to upper gastrointestinal endoscopy (UGE). A total of 300 patients scheduled for diagnostic UGE were randomized into three separate groups. Prior to the UGE procedure the first group was administered intranasal cortisone spray following nasal cleansing (INC). Patients in the second group were administered intranasal saline after nasal cleansing (INSP). The patients in the third group were treated with the standard endoscopic procedure alone (SEP). After the UGE procedure, both endoscopists and patients were asked to evaluate the ease of performing the procedure. Furthermore, patients who had undergone endoscopy before were asked to compare their current experience to their most recent endoscopy. Results shown that INC and INSP groups had significantly better tolerance than the SEP group. When comparing their current experience with the previous one, INC and INSP groups reported that the current experience was better. Conclusions: Taking measures to relax the nasal airways makes breathing more comfortable and increase patient tolerance during UGE.

Keywords: Endoscopy, esophagogastroduodenoscopy, intranasal corticosteroids, nasal airway, nasal decongestant, patient tolerance, upper gastrointestinal endoscopy

Introduction

Endoscopy plays an essential role in the diagnosis, treatment and monitoring of disease clinical course for upper gastrointestinal conditions. However, a number of patients cannot tolerate endoscopic procedures and subsequently experience severe discomfort. In addition to low procedural tolerance, cardiopulmonary complications may occur as well, which prevent the completion of an optimal endoscopic study [1]. To date many studies have reported on techniques that increase patient tolerance and contribute to an overall better endoscopy experience; however, a standard set of criteria that defines endoscopy tolerance has not yet been created. Many publications

describe endoscopy tolerance based on subjective observations, which makes it difficult to compare findings between them. The most commonly utilized methods to increase patient comfort are the use of a fine-caliber endoscope, inserting the endoscope via the transnasal route, using capsule endoscopy, and placing the patient under sedoanalgesia. Even though each technique has its own advantages and respective risks and limitations, they all have similar problems in patient tolerance [2].

The most common complication during upper gastrointestinal endoscopy (UGE) is hypoxemia. Hypoxia may result in an abnormal breathing pattern, apnea, coma, hypotension, and even myocardial ischemia [3]. It is important to

ensure airway patency in order to avoid hypoxemia. The extent of the openness of the nasopharyngeal space, which comprises the entry point into the respiratory system, plays a critical role in determining patient tolerance to UGE. In our clinical experience we observed that patients that were not able to breathe easily during peroral endoscopy demonstrated a lower tolerance for the procedure. Based these observations, we designed this randomized prospective study to investigate whether nasal cleansing and intranasal corticosteroids facilitated tolerance to UGE performed without sedation.

Material and methods

Patients presenting to the endoscopy unit of the gastroenterology clinic for diagnostic UGE procedures from January 1, 2013 to March 1, 2013 were enrolled in the study. Exclusion criteria included emergent procedures, the use of sedation during the UGE, pregnancy, undergoing UGE for therapeutic reasons, patients that had serious comorbidities with an American Society of Anesthesiologists' (ASA) score ≥ 4 , patients with active otorhinolaryngological disease, and obese patients with a body mass index of 30 and above. In addition, patients with deficits in vision and hearing and psychiatric and/or cognitive disorders that rendered them incapable of answering questions were also excluded from the study. Three experienced gastroenterologists carried out all endoscopic procedures and were blinded throughout the duration of the study. The CLV-180 Evis Exera II video endoscope (Olympus, Japan) was used to perform the endoscopic examinations.

Prior to the endoscopy procedure the patients were asked to fill out a survey regarding their general health, education, occupation, habits, and the reason why they were receiving UGE. Chronic use of analgesics including narcotics was defined as regular if used for 3 weeks or longer [4]. Greater than moderate levels of alcohol consumption was defined according to the "diet guide for Americans" that was published in 2010 and stated that moderate alcohol consumption is up to one drink daily for women and up to two drinks per day for men [5]. Patients were randomized into one of three groups depending on the chronological order of presentation to the endoscopy unit. Specifically,

randomization was accomplished via the sealed envelope technique. Sealed envelopes were prepared at the beginning of the study and double-sealed to prevent bias, and they were only opened until immediately prior to the endoscopy procedure for each patient. The study sample was capped when the number of enrolled patients in each group reached 100 subjects. Patients in the first group, the intranasal cortisone (INC) group, received nasal cleansing and were given a treatment of intranasal cortisone nasal spray comprised of 0.05% mometasone furoate monohydrate mixed with 0.9% saline (Schering-Plough, Singapore). INC group patients received two sprays per nostril 15 to 20 minutes preceding the procedure. Specifically, one spray delivers 50 mcg of the active ingredient. Patients in the second group called the intranasal saline (INSP) group received nasal cleansing and were administered two saline nasal drops per nostril 15 to 20 minutes prior to the procedure. Health assistants performed both intranasal cortisone sprays and saline drop administrations in accordance with the technical instructions published by Benninger et al [6]. The patients in the third group underwent the standard endoscopic procedure (SEP) alone.

Prior to the endoscopy, 10% lidocaine and topical pharyngeal anesthesia was administered to every patient. Upon directly visualizing the esophagus the scope was carefully fed down the upper gastrointestinal tract via the peroral route. The endoscope was advanced up to the second part of the duodenum and retroflexion was performed to examine the gastric cardia. Blood pressure, heart rate, and oxygen saturation determined via pulse oximetry were measured throughout the procedure. Complications were documented if they occurred during the procedure. The endoscopists evaluated the degree of ease to perform the procedure, and patients rated how well they tolerated the UGE. The Visual Analogue Scale (VAS) was used to for both endoscopist and patient ratings; a rating of 1 indicates the best possible outcome whereas a rating of 10 indicates the worst possible outcome [4, 7]. Furthermore, subjects that received previous endoscopies were also asked to compare how well they tolerated their current procedure relative to the last one that they received as either the same, better or worse.

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Table 1. Patient Demographics

Patient Characteristics	INC (n = 100)	INSF (n = 100)	SEP (n = 100)	p-value
Gender (Male/Female)	50/50	53/47	52/48	<i>p</i> = 0.274
Age (Mean ± SD)	48.16 ± 15.00	48.80 ± 14.39	49.71 ± 14.17	<i>p</i> = 0.754
Education				
• Uneducated	17 (17%)	15 (15%)	18 (18%)	<i>p</i> = 0.997
• Elementary School	50 (50%)	48 (48%)	47 (47%)	
• High School	14 (14%)	20 (20%)	16 (16%)	
• University	19 (19%)	18 (18%)	19 (19%)	
Profession				
• House wife	41 (41%)	39 (39%)	42 (42%)	<i>p</i> = 0.999
• Retirement	16 (16%)	21 (21%)	20 (20%)	
• Worker	9 (9%)	8 (8%)	7 (7%)	
• Self-employed	8 (8%)	8 (8%)	7 (7%)	
• Student	5 (5%)	5 (5%)	4 (4%)	
• Technician	3 (3%)	4 (4%)	2 (2%)	
• Officer	4 (4%)	2 (2%)	3 (3%)	
• Engineer	4 (4%)	2 (2%)	3 (3%)	
• Farmer	1 (1%)	3 (3%)	1 (1%)	
• Other profession	9 (9%)	8 (8%)	11 (11%)	
Habits				
• Smoking	22 (22%)	22 (22%)	18 (18%)	<i>p</i> = 0.722
• Alcohol	0 (0%)	3 (3%)	1 (1%)	<i>p</i> = 0.329
• Chronic analgesic	3 (3%)	4 (4%)	2 (2%)	<i>p</i> = 0.912
• Neuropsychiatric drug	5 (5%)	4 (4%)	6 (6%)	<i>p</i> = 0.810
Comorbid Conditions				
• Cardiac Dis.	13 (13%)	10 (10%)	11 (11%)	<i>p</i> = 0.793
• Hypertension	22 (22%)	20 (20%)	23 (23%)	<i>p</i> = 0.872
• Diabetes Mellitus	6 (6%)	8 (8%)	7 (7%)	<i>p</i> = 0.858
• COPD	7 (7%)	5 (5%)	5 (5%)	<i>p</i> = 0.779
• Thyroid Dis.	5 (5%)	3 (3%)	4 (4%)	<i>p</i> = 0.932
• Chronic Liver Dis.	3 (3%)	1 (1%)	3 (3%)	<i>p</i> = 0.706
• Chronic Kidney Dis.	2 (2%)	1 (1%)	0 (0%)	<i>p</i> = 0.776
• Rheumatologic Dis.	3 (3%)	2 (2%)	1 (1%)	<i>p</i> = 0.874
• Neuropsychiatric Dis.				<i>p</i> = *
1. Panic disorder	1 (1%)	4 (4%)	0 (0%)	
2. Anxiety disorder	1 (1%)	1 (1%)	2 (2%)	
3. Depression	5 (5%)	2 (2%)	3 (3%)	
4. Epilepsy	0 (0%)	1 (1%)	1 (1%)	
5. Migraine	0 (0%)	1 (1%)	1 (1%)	
6. Multiple Sclerosis	0 (0%)	1 (1%)	1 (1%)	
7. CVA-Hemiplegia	1 (1%)	0 (0%)	0 (0%)	
• Other Disease	2 (2%)	2 (2%)	2 (2%)	<i>p</i> = *
ASA score				
• 1	66 (66%)	68 (68%)	64 (64%)	<i>p</i> = 0.939
• 2	29 (29%)	29 (29%)	31 (31%)	
• 3	5 (5%)	3 (3%)	5 (5%)	
Number of patients that had prior UGE	47 (47%)	41 (41%)	46 (46%)	<i>p</i> = 0.713

INC: Intranasal Corticosteroid, INSP: Intranasal Serum Physiologic, SEP: Standard Endoscopic Procedure, COPD: Chronic Obstructive Pulmonary Disease, Dis: Disease, CVA: Cerebrovascular Accident, UGE: Upper Gastrointestinal Endoscopy, *p* = * the comparison was not performed due to inadequate sample size.

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Table 2. Endoscopist ratings of procedure ease and patient ratings of procedure tolerance

Evaluation		INC (n = 100)	INSP (n = 100)	SEP (n = 100)	p-value
Patient rating	Mean ± SD	4.37 ± 1.23	4.82 ± 1.47	7.15 ± 1.51	p < 0.001
	Median (Min-Max)	4.0 (2-8)	4.5 (2-10)	7 (4-10)	
Endoscopist rating	Mean ± SD	4.34 ± 1.56	5.03 ± 1.47	6.61 ± 1.57	p < 0.001
	Median (Min-Max)	4.5 (1-10)	5.0 (2-10)	7 (2-10)	

INC: Intranasal Corticosteroid, INSP: Intranasal Serum Physiologic, SEP: Standard Endoscopic Procedure.

Table 3. Patient comparison of current with prior UGE experience

Rating of current UGE	INC (n = 47)	INSP (n = 41)	SEP (n = 46)	p-value
Better than previous UGE	41 (87.2%)	36 (87.8%)	5 (10.9%)	p < 0.001
Same as previous UGE	6 (12.8%)	4 (9.8%)	30 (65.2%)	
Worse than previous UGE	0 (0.0%)	1 (2.4%)	11 (23.9%)	

INC: Intranasal Corticosteroid, INSP: Intranasal Serum Physiologic, SEP: Standard Endoscopic Procedure.

Prior to starting the clinical trial we obtained approval from the ethical committee of Yildirim Beyazit University School of Medicine. Informed consent was obtained from all patients after they were given a detailed description of the entire procedure. The study was carried out in adherence to the recommendations made by the ethics committee and by the Helsinki Declaration.

Statistical analysis

Descriptive statistics were expressed as the mean plus or minus one standard deviation, and quantitative data were expressed as the median and minimum and maximum values in parenthesis. Qualitative data was expressed as frequency percentages. Pearson's chi-square test, Yates' chi-square test or Fisher's exact test were used to determine the relationship between categorical variables. The Mann-Whitney U-test was utilized to compare differences between two independent groups for quantitative variables. Comparisons between groups for non-normally distributed quantitative variables were evaluated by the Kruskal-Wallis test. Conover's multiple comparison test was used as a post hoc test. A p-value less than 0.05 was considered statistically significant. Data analyses were performed by SPSS version 15.0 software (SPSS Inc., Chicago, Illinois, USA).

Results

There were 50 males and 50 females in the INC group, 53 males and 47 females in the INSP

group, and 52 males and 48 females in the SEP group. Patient ages ranged from 17 to 85 years and the mean age was 48.16 ± 15.00 years for the INC group, 48.80 ± 14.39 years for the INSP group, and 49.72 ± 14.17 years for the SEP group. Sex (p = 0.274) and age (p = 0.754) distributions were similar between all three groups. No significant difference was appreciated between each group in terms of educational status; occupation; smoking, alcohol use, drug use, use of chronic analgesics, and neuropsychiatric drug use; comorbid diseases; presence of neuropsychiatric disorders, and ASA scores (p < 0.05), (Table 1).

No complications occurred during any of the endoscopic procedures. There were no significant differences between groups in terms of blood pressure, heart rate and oxygenation throughout the procedure (p > 0.05). Following the procedure, VAS evaluations from the endoscopists and patients were recorded (Table 2). Upon comparing patient-rated procedure tolerance it was found that both INC and INSP groups had similar results (p > 0.05), but both groups had significantly higher ratings of tolerance in comparison to the SEP group (p < 0.001). Endoscopists rated that the ease of performing the procedure was improved in the INC group relative to the INSP and SEP groups; however, the ease of procedure performance in the INSP group was significantly better than that of the SEP group (p < 0.001). When endoscopy tolerance was analyzed for the entire study sample, it was determined that there were no significant differences in terms of gender and age (under 49 years and above 50 years) in tolerating the procedure (p > 0.05). Similarly, no differences were observed in procedure tolerance in terms of occupation type,

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education level, drug and alcohol habits, and neuropsychiatric comorbidities ($p > 0.05$).

Forty-seven patients from the INC group, 41 patients from the INSP group, and 46 patients from the SEP group had UGE procedures before. None of the subjects were sedated during their previous UGE procedures. Patient demographics and medical characteristics between all three groups were similar ($p = 0.713$). Patients with previous UGEs compared most recent experience with the current one. Among the 47 patients in the INC group, 87.2% reported that their current UGE experience was better than the previous one, while 12.8% reported that it was the same. Of the 41 patients in the INSP group, 87.8% reported that their experience was better than the previous one, 9.8% reported that it was the same, and 2.4% stated that it was worse. Only 10.9% out of 46 patients from the SEP group reported that they had a better experience than the previous procedure, 65.2% of patients reported that it was the same, and 23.9% reported that it was worse (**Table 3**). The difference in patient ratings of procedure tolerance between groups was statistically significant ($p < 0.001$).

Discussion

Currently UGE is the standard method for diagnosing and treating many upper gastrointestinal diseases. With the increasing elderly population and rising number of patients with multiple chronic diseases in Western countries, endoscopy is being used for more complex procedures, which heightens the chances for complications. Beyond medico-legal incentives to improve care, the impetus to improve health services stems from bettering the quality of care delivered to patients. Even though UGE is a relatively safe procedure with a low complication rate of 0.1% and a mortality rate 0.5 to 3 in 10,000, the potential risks of performing the procedure imposes stress on both patients and endoscopists [7-9]. This anxiety may contribute to difficulties encountered and discomfort experienced during the procedure that might ultimately lead to early termination and potential complications.

Defining tolerance to endoscopy is difficult as such a definition must encompass a wide variety of symptoms and complications. Since procedural tolerance is largely a subjective con-

cept no consensus has been reached regarding its definition [1]. In fact there have been no studies to date that attempt to introduce a standard, objective measuring system to assess tolerance to endoscopy. However, the Visual Analog Scales (VAS) may be used for this purpose [4, 7, 10]. Tolerance to endoscopy can be loosely defined as a patient's reaction while sustaining normal vital signs during a routine, optimally performed procedure. It has been reported that the following traits have been commonly found in patients that have poorer endoscopy experiences and decreased procedure tolerance: young age, high income, higher education, female gender, strong gag reflex, nasal obstruction, psychological problems, and poor previous endoscopy experiences [1, 4, 7, 10]. Chronic alcoholism and the use of other CNS depressants such as benzodiazepines also reduce procedure tolerance [4]. In addition to patient traits, the skill and experience of the endoscopist may also affect patient procedural tolerance. However, in our study we did not find any significant correlation between endoscopy tolerance and patient demographic and medical characteristics ($p > 0.05$).

In current practice the majority of clinics that provide UGE prefer providing sedoanalgesia to patients as it helps to reduce discomfort and anxiety while increasing procedure tolerance and satisfaction [2, 4, 7, 10]. Sedoanalgesia facilitates the endoscopist's ease of performing UGE and minimizes the risk of incurring physical injury to the patient during the procedure [2]. Many sedoanalgesic techniques have been described in the literature and different pharmacological agents have been used [2, 11-13]. However, no consensus has yet been reached as to what is the optimal sedoanalgesic technique [11]. Several agents utilized to promote sedoanalgesia are associated with cardiopulmonary side effects that must be carefully considered when deciding which patients are to receive such agents so to avoid poor tolerance and procedural outcomes [2]. Complications such as apnea, hypoxia, respiratory depression, vomiting, aspiration, hypotension, hypoglycemia, agitation, and allergic reactions have been observed with sedoanalgesia [11]. Patients under sedoanalgesia must be monitored throughout the procedure and during recovery, which prolongs time to discharge [14]. Due to the increased cost of performing

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sedoanalgesia and the lengthened time to discharge, the total number of procedures that may be performed decreases and so the cost of performing each UGE rises to compensate.

The transnasal-esophagogastroduodenoscopy (T-EGD) was introduced in 1994 to improve patient tolerance to the procedure [15]. Overall, patients tolerated T-EGD better than conventional EGD (C-EGD), and unlike the conventional method T-EGD does not require sedation [14, 15]. However, the ultraslim endoscope used in T-EGD has a reduced field of view as the air and water channels are smaller [16]. Also, T-EGD takes smaller tissue biopsies due to its slim configuration [16]. These limitations make the use of slim endoscopes more challenging, especially for therapeutic purposes. Moreover, as the T-EGD is introduced through the nasal canal, complications such as severe epistaxis, vasovagal syncope, and laryngospasm have been reported [14]. In recent years capsule endoscopy (CE) was developed and is an easily performed, noninvasive and well-tolerated procedure to evaluate the gastrointestinal tract [17]. Yet, CE has low diagnostic value and so is primarily used to screen for gastric disease [18]. As sedation and air insufflation is not required during CE, it may be particularly useful in screening numerous patients simultaneously. However, CE is not recommended for use in patients with digestive tract obstructions, suspected strictures, or swallowing problems.

It is of utmost importance to determine how to best increase patient tolerance to UGE procedures. A number of techniques have been employed to facilitate patient tolerance including psychological support, hypnosis, acupuncture, educational visual aids, relaxing music, and allowing patient relations and friends to be present during the procedure [19-21]. Although it is difficult to compare the efficacy of each method, the benefits that they incur via anxiety reduction cannot be overlooked. Health providers may also build rapport with patients by describing the procedure in detail beforehand and conveying a compassionate and understanding attitude when addressing patient concerns.

One of the most common side effects while performing UGE is hypoxemia, which has an incidence of about 1.5-70% [3]. Severe hypoxemia during endoscopy may lead to apnea,

coma, hypotension, abnormal respiratory patterns, and even myocardial ischemia [3]. Certain risk factors that trigger hypoxemia are a high ASA score, conscious sedation, obesity, advanced age, and compromised lung function [3]. Such complications occur partially because the endoscope is fed through the airway and so partially obstructs air flow, especially for patients with decreased respiratory reserve. In order to avoid hypoxemia during the procedure, the airways must be sufficiently patent. The nasal airway accounts for nearly half of the resistance to air flow encountered in the entire respiratory system [22, 23]. Both intrinsic and environmental factors contribute to nasal resistance such as obstructing nasal diseases, hyperventilation, lying supine, alcohol and aspirin use, and cold weather. According to the Poiseuille's law of laminar flow, resistance is inversely proportional to the fourth power of the lumen radius. As such, even a small narrowing of the nasal passage causes a considerably large increase in the resistance to air flow [24].

In attempt to increase nasal passage patency, nasal decongestants may be administered to promote vasoconstriction, which decreases edema and mucosal congestion allowing for decreased resistance to air flow. Such pharmaceutical agents are often prescribed to relieve congestion experienced from upper respiratory illnesses, environmental allergies, deviated septum, nasal polyps, nasal turbinate hypertrophy, and cancer [25]. Nasal sympathomimetics, corticosteroids, mast cell stabilizers, antihistamines, and saline can all be utilized as nasal decongestants [26]. The local and systemic side effects of corticosteroids are well known, but over the last thirty years many studies have reported that intranasal corticosteroids (INC) have an excellent safety profile and cause less systemic side effects as compared to inhalers and oral steroids [27].

The most commonly observed local side effects of INC use are nosebleeds, throat irritation, nasal dryness, and a burning or stinging sensation [25, 27]. Often times the incidence of these side effects are similar to that of placebo, except for epistaxis, and often these side effects are mild and self-limited without needing to terminate treatment. INC causes epistaxis by thinning and drying the nasal mucosa, and more severe side effects such as mucosal atro-

phy and ulceration arise only when the drug is administered over a prolonged period. Corticosteroids should be avoided in the presence of an active local infection. Many clinical studies have reported that newer INC agents are safer than the older generation corticosteroids. Newer INC agents include mometasone furoate nasal spray, fluticasone propionate, fluticasone furoate, and ciclesonide [27]. For this study we utilized mometasone furoate monohydrate (MFM), which is a third generation intranasal corticosteroid. MFM is easily available, effective, fast-acting, and has a low systemic bioavailability of less than 0.1%.

We found that patient and endoscopist self-ratings of procedure tolerance and ease of procedure performance were improved after performing nasal cleansing followed by the administration of INC or INSP ($p < 0.001$). Though many techniques have been suggested to facilitate patient tolerance to endoscopy, this is the first study that suggests that relaxing the nasal air passages increases patient tolerance to endoscopy. Taking measures to relax the nasal airways prior to endoscopy increases patient comfort and satisfaction and reduces the need for sedoanalgesia and the complications associated with sedation. Prior to endoscopy, assessing the extent of nasal congestion may be useful while questioning the patients beforehand to determine their risk factors for the procedure. It must be noted that nasal passages are especially congested during seasons when environmental allergens are prevalent and in the presence of comorbid conditions such as nasal trauma and anatomical malformations. Furthermore, ICU patients and patients with reduced lung reserves are more apt to experience complications during endoscopy. Compared to other methods that increase tolerance to endoscopy, measures to relax the nasal airways may be preferred as they are easily performed, low-cost, and do not require specialized care or equipment.

Since pulse oximetry is noninvasive, it is frequently utilized to monitor tissue oxygenation continuously throughout endoscopy. As such, we used pulse oximetry in this study as a means to determine how well patients tolerated the procedure. For patients that had compromises in oxygenation, we presumed that tolerance would also decrease. Even though we did not

observe a statistically significant difference in pulse oximetry monitoring between patients that reported decreased tolerance, the VAS scores for these patients were significantly lower. Several studies have reported that disturbances in ventilation are most frequently observed during the first minutes of the endoscopic procedure and during endoscope entry into the esophagus [28]. However, signs of suboptimal ventilation may have a delayed presentation, and pulse oximetry may not show alveolar hypoventilation right away [29]. It has been suggested that capnography may be more sensitive than pulse oximetry as it may detect alveolar hypoventilation earlier [2, 29]. Therefore, the use of capnography during endoscopy in patients with cardiopulmonary problems may provide better monitoring and information regarding tolerance of endoscopy. We suggest that further studies investigate modalities of monitoring oxygenation and ventilation during endoscopy so to better determine how these affect tolerance to this procedure.

Disclosure of conflict of interest

None.

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