

ประสิทธิภาพของสเปรย์ลิโดเคนเพียงอย่างเดียวหรือร่วมกับสเปรย์พ่นคอชนิดด้านการอักเสบ ในการบรรเทาอาการไม่สบายระหว่างการส่องกล้องตรวจหลอดอาหาร กระเพาะอาหาร และลำไส้เล็กส่วนต้นโดยไม่ใช้ยาระงับความรู้สึก: การทดลองแบบสุ่มที่มีกลุ่มควบคุม และปกปิดสองฝ่าย

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บทคัดย่อ

การควบคุมความเจ็บปวดของผู้ป่วยระหว่างการส่องกล้องตรวจหลอดอาหาร กระเพาะอาหาร และลำไส้เล็กส่วนต้น (EGD) เป็นปัจจัยสำคัญที่ช่วยเพิ่มความพึงพอใจ ลดความไม่สบายตัว และเพิ่มความร่วมมือของผู้ป่วย แม้ว่าสเปรย์ลิโดเคนจะเป็นยาชาที่ใช้กันทั่วไป และปลอดภัยสำหรับการส่องกล้องแบบไม่ใช้ยาระงับความรู้สึก แต่แพทย์ผู้ทำการส่องกล้องยังคงมุ่งหวังที่จะพัฒนาการเตรียมตัวก่อนการทำ EGD ให้ดียิ่งขึ้น การศึกษานี้มีวัตถุประสงค์เพื่อเปรียบเทียบความพึงพอใจ ความเจ็บปวด และความไม่สบายตัวของผู้ป่วยระหว่างการใช้สเปรย์ลิโดเคนเพียงอย่างเดียวกับการใช้ร่วมกับสเปรย์แก้ไอในลำคอ โดยมีวิธีการศึกษาเชิงทดลองแบบสุ่ม ดำเนินการที่โรงพยาบาลยะลา จังหวัดยะลา ระหว่างเดือนมกราคม ถึงพฤษภาคม 2567 โดยคัดเลือกผู้ป่วยที่เข้ารับการทำการ EGD และทำการสุ่มแบ่งออกเป็นสองกลุ่มในอัตราส่วน 1:1 ได้แก่ กลุ่มที่ได้รับสเปรย์ลิโดเคนเพียงอย่างเดียว (กลุ่ม A) และกลุ่มที่ได้รับสเปรย์แก้ไอในลำคอก่อนใช้สเปรย์ลิโดเคน (กลุ่ม B) จากนั้นประเมินความพึงพอใจ ความเจ็บปวด และความไม่สบายตัว โดยใช้มาตรวัดระดับตัวเลข ตั้งแต่ 0 ถึง 10 หลังทำการ EGD พบว่าผู้ป่วยร่วมทั้งหมดจำนวน 100 คนถูกสุ่มให้อยู่กลุ่ม A จำนวน 50 คน หรือกลุ่ม B จำนวน 50 คน คะแนนความพึงพอใจ (ค่ามัธยฐาน (ค่าพิสัยระหว่างควอไทล์) กลุ่ม A 10 (9,10); กลุ่ม B 9 (9,10); $p=0.248$) ความเจ็บปวด (ค่ามัธยฐาน (ค่าพิสัยระหว่างควอไทล์) กลุ่ม A 3 (1,5); กลุ่ม B 2.5 (0,5); $p=0.624$) และความไม่สบายตัว (ค่ามัธยฐาน (ค่าพิสัยระหว่างควอไทล์) กลุ่ม A 3 (1,5); กลุ่ม B 3 (2,5); $p=0.203$) ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติระหว่างทั้งสองกลุ่ม แนวโน้มของผลข้างเคียง เช่น อาการเจ็บคอ รสขม คลื่นไส้ และอาเจียน พบน้อยกว่าในกลุ่ม B แต่ความแตกต่างไม่มีนัยสำคัญทางสถิติ สรุปได้ว่าทั้งสองวิธีมีประสิทธิภาพเทียบเท่ากันในการควบคุมความพึงพอใจของผู้ป่วย ระดับความเจ็บปวด และความไม่สบายตัว ดังนั้น การเตรียมตัวสำหรับการทำการ EGD โดยใช้สเปรย์ลิโดเคนเพียงอย่างเดียวจึงยังคงเป็นวิธีที่ปลอดภัย และมีประสิทธิภาพในการให้ยาชาเฉพาะที่ แต่การเพิ่มสเปรย์แก้ไอในลำคออาจเป็นทางเลือกหนึ่งในการช่วยลดผลข้างเคียงบางอย่างของผู้ป่วย

คำสำคัญ: การส่องกล้องตรวจทางเดินอาหารส่วนต้น; สเปรย์ลิโดเคน; สเปรย์แก้ไอในลำคอ; การไม่ใช้ยาระงับความรู้สึก

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Efficacy of lidocaine spray, either alone or in combination with anti-inflammatory throat spray, in alleviating discomfort during unsedated esophagogastroduodenoscopy: A double-blind randomized controlled trial

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Abstract

Controlling patients' pain during Esophagogastroduodenoscopy (EGD) is a fundamental factor in increasing patient satisfaction, reducing discomfort, and improving patient cooperation. Although lidocaine spray is a common and safe anesthetic option for unsedated EGD, endoscopists continue to seek ways to improve the preparation process before the EGD procedure. This study aimed to compare patient satisfaction, pain, and discomfort between the use of lidocaine spray alone and in combination with anti-inflammatory throat spray. This prospective, randomized clinical trial was conducted at Yala Hospital, Yala, Thailand between January 2024 and May 2024. Patients were randomly assigned to one of two groups: one received only a lidocaine spray (Group A), while the other received a combination of lidocaine spray and an anti-inflammatory throat spray (Group B, using Benzydamine Hydrochloride). After the procedure, patients rated their satisfaction, pain, and discomfort on a numerical scale from 0 to 10. A total of 100 subjects were randomized to receive either Lidocaine Spray alone (n=50) or a combination of Lidocaine Spray and an Anti-inflammatory Throat spray (n=50). The patient satisfaction score (Group A: median (IQR) 10 (9,10); Group B: median (IQR) 9 (9,10); $p=0.248$), pain score (Group A: median (IQR) 3 (1,5); Group B: median (IQR) 2.5 (0,5); $p=0.624$) and discomfort score (Group A: median (IQR) 3 (1,5); Group B: median (IQR) 3 (2,5); $p=0.203$) were not significantly different between the groups. Adverse events, including sore throat, bitter taste, nausea, and vomiting, were lower in group B, though the differences were not statistically significant. This study concludes that both methods have similar effects on patient satisfaction, pain and discomfort. Therefore, preparation for EGD using lidocaine spray alone remains a safe and effective approach to local anesthesia. Adding an anti-inflammatory throat spray may be an option to help reduce certain adverse events.

Keywords: esophagogastroduodenoscopy; lidocaine spray; anti-inflammatory throat spray; unsedation

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Introduction

Esophagogastroduodenoscopy (EGD) is an important and widely used diagnostic and therapeutic procedure for evaluating disorders of the upper gastrointestinal tract¹⁻⁴. However, inserting the endoscope through the pharynx into the digestive tract can cause significant discomfort and pain for patients due to the activation of the gag reflex, especially when they are conscious⁵⁻⁶. Therefore, there are preparation steps before performing an EGD, which can be done using local anesthesia for the pharynx, intravenous sedation, or a combination of both. The advantage of using local anesthesia is that it helps avoid adverse cardiovascular and respiratory events associated with intravenous sedation, such as aspiration, respiratory depression and cardiac event, particularly in patients with coronary artery disease, the elderly, and those with obesity⁷⁻⁹.

Currently, in Thailand, lidocaine spray is commonly used as a safe and convenient option for preparing patients for EGD without sedation. However, its bitter taste can cause throat irritation when swallowed. Several studies have compared different local anesthetic techniques, such as viscous lidocaine, lozenges, lollipops, and lidocaine spray, but it remains unclear which method is the most optimal¹⁰⁻¹⁵. A meta-analysis study found that the use of lidocaine spray had higher satisfaction scores compared to viscous lidocaine, but there was no significant difference in pain and discomfort levels¹⁶. Notably, topical lidocaine itself can also cause

significant discomfort and throat irritation in many patients. Moreover, it provides only short-term anesthetic effects and lacks anti-inflammatory properties, which may lead to irritation and inflammation caused by mechanical stimulation during endoscope insertion. Consequently, patients may develop sore throat and experience discomfort associated with EGD.

An anti-inflammatory throat spray is a topical non-steroidal anti-inflammatory drug (NSAID) that inhibits the production of prostaglandins, helping to reduce pain and inflammation in the oral cavity and throat. A previous randomized study found that the use of benzydamine hydrochloride sprayed in patients undergoing elective surgery with a laryngeal mask airway significantly reduced postoperative sore throat and increased patient satisfaction compared to the placebo group¹⁷. The combined use of an anti-inflammatory throat spray with lidocaine spray may provide a synergistic effect in alleviating discomfort in both the short and long term. This combination may help reduce post-EGD sore throat and enhance patient satisfaction, particularly among those undergoing the procedure without sedation.

To date, no randomized trial has compared the use of lidocaine spray alone with its combination with a throat inflammation-reducing spray in patients undergoing EGD without sedation. Therefore, we designed this randomized trial to improve patient satisfaction, reduce pain, and alleviate discomfort during the procedure.

This study aimed to compare the patient satisfaction, pain, and discomfort between lidocaine spray alone and combination with Anti-inflammatory throat spray.

Materials and Methods

Study design and participants

This prospective, double-blind, randomized controlled study was conducted at Yala Hospital, a tertiary care hospital in Yala, Thailand from January 2024 to May 2024. The study protocol was approved by the office of the Yala Hospital Ethics Committee for Human Research (EC approval No. 07/2567) and registered with the Thai Clinical Trial Registry (TCTR) under the identifier TCTR20250329002. Adult patients (aged ≥ 15 years old) who came for EGD for diagnostic purposes without intravenous sedation at Yala Hospital were eligible for enrollment. Subjects with any one of the following criteria were excluded from the study: (1) head and neck cancer patients; (2) previous surgery of the upper aerodigestive tract; (3) corrosive ingestion; (4) pregnant; (5) contraindications for EGD; (6) allergy to medications, lidocaine, or NSAID; (7) psychiatric problem; (8) neuromuscular disorder; or (9) emergency conditions or with unstable vital signs.

Randomization and Interventions

All patients were fully informed of the objectives of this study. Written informed consent was obtained from each patient before randomization.

Eligible patients were randomized into either a lidocaine spray alone (Group A) or a lidocaine spray combination with anti-inflammatory throat spray (Benzydamine hydrochloride; Difflam Forte®) (Group B). Randomization was performed in blocks 1:1 of 20 persons per each group and patients were enlisted to one of the two groups. The medication was administered by one of three endoscopy nurses, who took turns and were blinded to patient group allocation. The medication bottles were masked and labeled only as A1 and A2 for Group A, and B1 and B2 for Group B, without revealing their contents. The spraying technique was standardized across all patients. Bottle 1 (either A1 or B1) was sprayed with two puffs each to the left, right, and center of the oropharynx using a tongue depressor, followed by Bottle 2 (either A2 or B2), using the same technique. The procedure was followed by a waiting period of approximately 5 minutes before starting the endoscopy.

Group A consisted of Bottle A1, containing 0.9% normal saline, and Bottle A2, containing lidocaine spray (Xylocaine Spray 10%, AstraZeneca; 1 puff = 10 mg lidocaine). Group B consisted of Bottle B1, containing benzydamine hydrochloride spray, and Bottle B2, containing lidocaine spray (Xylocaine Spray 10%, AstraZeneca; 1 puff = 10 mg lidocaine).

EGD was performed by a single gastroenterologist, having experience with > 1,000 EGDs, accompanied by a second endoscopy nurse (a registered nurse skilled in assisting endoscopists performing endoscopies).

The endoscopist and second endoscopy nurse were blinded to the allocation group. A Fujifilm video gastroscope (EG-760R, Fujifilm Holdings Corporation, Tokyo, Japan) was used for all patients. Each procedure was monitored according to standard protocols, including blood pressure measurement, heart rate monitoring, single-lead electrocardiography (ECG), and oxygen saturation assessment. No premedication was administered before the endoscopy.

After completing the endoscopic examination, the research assistant administered a questionnaire. Patient satisfaction, pain, and discomfort were assessed using a Numerical Rating Scale (NRS) ranging from 0 to 10. Satisfaction was rated from 0 (no satisfaction) to 10 (extreme satisfaction). Pain was rated from 0 (no pain) to 10 (pain as bad as it could be). The discomfort was rated from 0 (no discomfort) to 10 (the worst discomfort imaginable).

The endoscopist's satisfaction was categorized as follows: 1 = very satisfied, 2 = satisfied, 3 = neutral, and 4 = not satisfied. Patient tolerance to the procedure was rated by the endoscopist as follows: 1 = excellent, 2 = good, 3 = neutral, and 4 = poor. The ease of endoscope insertion was assessed as follows: 1 = very easy, 2 = easy, 3 = neutral, and 4 = difficult.

The duration of the endoscopy procedure was recorded in minutes, starting from the insertion of the endoscope through the mouth until its withdrawal. Successful endoscopy was defined as completing the procedure without the need for additional intravenous sedation.

Adverse events included changes in vital signs, such as hypertension or hypotension (an increase or decrease in blood pressure by 20% from baseline), tachycardia or bradycardia (an increase or decrease in heart rate by 20% from baseline), and oxygen desaturation ($SpO_2 < 90\%$). Other symptoms, such as sore throat, nausea, or vomiting, were also recorded.

Outcomes

The primary endpoint of the study was to compare the patient satisfaction, pain, and discomfort between lidocaine spray alone and in combination with anti-inflammatory throat spray throat. Which was assessed by intention-to-treat (ITT) and per-protocol (PP) analyses. All randomized patients were included in the ITT analysis. Patients who were switched to the intravenous sedation group were excluded from the PP. The secondary endpoint was the endoscopist's satisfaction, the endoscopist's perception of the patient's tolerance, ease of endoscope insertion, procedure duration, successful endoscopy, and adverse events.

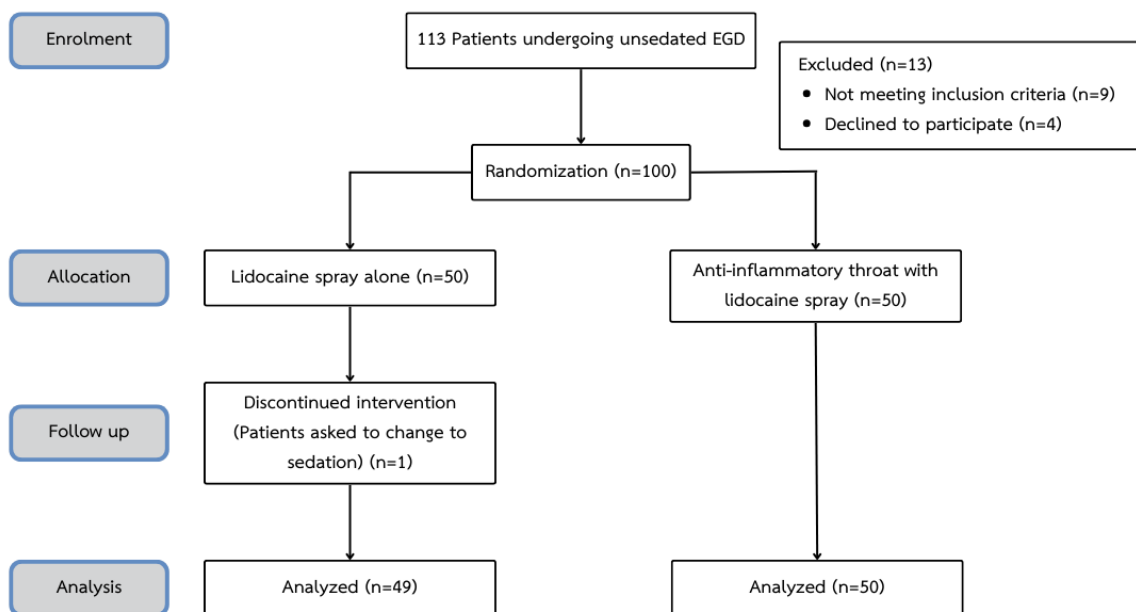


Figure 1 Flow chart of patient enrollment

Statistical analysis

The sample size calculation was based on a previous study. The patient satisfaction after using lidocaine spray before undergoing EGD without anesthesia was 89.6%¹⁰ and the incidence of preventing sore throat in postoperative patients who used Anti-inflammatory Throat spray as a preventive measure before intubation was 47.5%¹⁷. Our sample size estimation was 18 for each group, given a power of 80% and a confidence level of 95%, assuming a 20% loss to follow-up. From the calculation, the total sample size needed to be more than 44 patients.

The data are expressed as mean $\pm$ standard error of the mean for normally distributed variables and as median (interquartile range, IQR) for non-normally distributed variables. Statistical analysis was

performed using the chi-square test and Fisher's test for categorical data, and the Mann-Whitney U-test was used for continuous data. The data were analyzed using both the intention-to-treat and per-protocol analyses. A p -value < 0.05 was considered to be statistically significant. All statistical analyses were performed using STATA MP 18.

Results

Baseline characteristics of patients

From January 2024 and May 2024, 113 patients with underwent diagnostic EGD were assessed for eligibility. Of these, 100 were enrolled and randomized to receive one of two groups. Fifty patients were assigned to groups A and 50 patients to group B. A total of 99 patients successfully completed the protocol, 49 in the group A and 50 in the group

B. The flow chart for patients enrolled in the study is shown in Figure 1. The baseline characteristics of the two groups were not

significantly different (Table 1). One patient in group A was switched to intravenous sedation.

Table 1 Baseline characteristics of subjects in the two groups

Baseline characteristics	Lidocaine spray alone (Group A) (n=50)	Combination with anti-inflammatory (Group B) (n=50)	p-value
Age (years), mean $\pm$ SD	49.64 $\pm$ 17.45	55.34 $\pm$ 17.58	0.107
Male gender, n (%)	21 (42%)	18 (36%)	0.539
BMI (kg/m ²), median (IQR)	23.25 (20.6, 26.6)	24.65 (21.3,27.3)	0.393
SBP (mmHg), median (IQR)	135.5 (127,154)	141.5 (129,163)	0.191
DBP (mmHg), mean $\pm$ SD	83 $\pm$ 10.433	82.5 $\pm$ 11.355	0.819
HR (bpm), median (IQR)	74 (67,82)	77 (70,86)	0.408
RR (bpm), median (IQR)	20 (20,20)	20 (20,20)	0.552
Sat (%), median (IQR)	100 (99,100)	99 (99,100)	0.417
Smoking > 1 pack/week, n (%)	8 (16%)	4 (8%)	0.218
Alcohol > 1 day/week, n (%)	5 (10%)	1 (2%)	0.092
ASA class			
Class I, n (%)	27 (54%)	26 (52%)	0.601
Class II, n (%)	23 (46%)	23 (46%)	
Class III, n (%)	0 (0%)	1 (2%)	
Prior EGD, n (%)	15 (30%)	16 (32%)	0.829
Indication			0.639
Dyspepsia, n (%)	26 (52%)	26 (52%)	
Upper gastrointestinal hemorrhage, n (%)	2 (4%)	1 (2%)	
Variceal screening, n (%)	7 (14%)	3 (6%)	
Gastroesophageal reflux disease, n (%)	6 (12%)	7 (14%)	
Anemia, n (%)	7 (14%)	8 (16%)	
Peptic ulcer, n (%)	2 (4%)	3 (6%)	
Other, n (%)	0 (0%)	2 (4%)	

Abbreviations: BMI, body mass index. SBP, systolic blood pressure. DBP, diastolic blood pressure. HR, heart rate. RR, respiratory rate. Sat, oxygen saturation. ASA class, American Society of Anesthesiologists (class I: normal healthy patient, class II: patient with mild systemic disease, class III: patient with severe systemic disease)

Evaluation of unsedated upper gastrointestinal endoscopy

The patient satisfaction, pain score, and discomfort by ITT and PP analysis were not significantly different between groups

(Table 2). However, one participant who had received group A could not tolerate the procedure and had to proceed with the intervention under sedation.

There is no statistically significant difference in endoscopist satisfaction, patient tolerance to the procedure, and the ease of endoscopy insertion for the endoscopist part (Table 3). The median procedure times of EGD were similar in both groups. Intra- endoscopic oxygen desaturation was identified in one patient in Group B but this difference was not statistically significant. The common adverse

events included bitter taste, sore throat which were found in both groups the common adverse events included bitter taste and sore throat, which were found in both groups. The trends of sore throat, bitter taste, nausea, and vomiting were lower in group B; however, they were not statistically significant. Documented side effects are shown in Table 4.

Table 2 Differences in pain and situation during endoscopy, across different analytical methods

Participants (Intention-to-treat (ITT) analyses)	Group A (n=50)	Group B (n=50)	p-value
Patient's satisfaction median (IQR)	10 (9,10)	9 (8,10)	0.248
Pain score median (IQR)	3 (1,5)	2.5 (0,5)	0.624
Procedural discomfort median (IQR)	3 (1,5)	3 (2,5)	0.203
Participants (Per-protocol (PP) analyses)	Group A (n=49)	Group B (n=50)	p-value
Patient's satisfaction median (IQR)	10 (9,10)	9 (8,10)	0.171
Pain score median (IQR)	3 (1,5)	2.5 (0,5)	0.522
Procedural discomfort median (IQR)	3 (1,4)	3 (2,5)	0.148

Table 3 Evaluation of unsedated upper gastrointestinal endoscopy

Evaluation	Group A	Group B	p-value
Complete endoscopy, n (%)	50 (100%)	50 (100%)	0
Switched to sedation, n (%)	1 (2%)	0 (0%)	0.310
Procedure duration, median (IQR), minutes	4 (3,4,5)	3.7 (3,2,4,5)	0.590
Endoscopist' satisfaction			0.171
- Very satisfied	36 (72%)	35 (70%)	
- Satisfied	12 (24%)	9 (18%)	
- Neutral	1 (2%)	6 (12%)	
- Not satisfied	1 (2%)	0 (0%)	
Patient tolerance to the procedure			0.536
- Excellent	33 (66%)	30 (60%)	
- Good	13 (26%)	14 (28%)	
- Neutral	3 (6%)	6 (12%)	
- Poor	1 (2%)	0 (0%)	
Ease of endoscope insertion			0.618
- Very easy	40 (80%)	38 (76%)	
- Easy	7 (14%)	8 (16%)	
- Neutral	2 (4%)	4 (8%)	
- Difficult	1 (2%)	0 (0%)	

Table 4 Endoscopy outcome

Endoscopy	Group A	Group B	<i>p</i> -value
Change BP > 20% of BL	9 (18%)	5 (10%)	0.249
Change HR > 20% of BL	21 (42%)	16 (32%)	0.3
Sat drop < 90%	0 (0%)	1 (2%)	0.315
Adverse events			
Sore throat	15 (30%)	13 (26%)	0.656
Bitter taste	33 (66%)	27 (54%)	0.221
Nausea	10 (20%)	4 (8%)	0.084
Vomiting	1 (2%)	0 (0%)	0.315

Abbreviations: BP, blood pressure. HR, heart rate. Sat, oxygen saturation.

Discussion

In general, topical anesthesia is typically used before performing unsedated EGD¹⁸. Currently, lidocaine spray is commonly used as a safe and convenient option for preparing patients for EGD without sedation. Many publications report the use of different local anesthetic preparations for EGD such as viscous lidocaine solution, lozenges, lollipops, and nebulized lidocaine¹⁰⁻¹⁶ but the efficacy and tolerability of these techniques are still under debate. A previous randomized study found that the use of benzydamine hydrochloride sprayed in patients undergoing elective surgery with a laryngeal mask airway significantly reduced postoperative sore throat and increased patient satisfaction compared to the placebo group¹⁷. This study is using an anti-inflammatory spray in combination with lidocaine spray, which is a commonly used method today, with the aim of increasing patient satisfaction, reducing pain, and alleviating discomfort during the procedure.

This study founds that the patient satisfaction, pain score, and discomfort were

similar and no statistically significant differences were found in the endoscopist's satisfaction, patient tolerance to the procedure, and the ease of endoscopy insertion for the endoscopist. The trend of adverse events, including sore throat, bitter taste, nausea, and vomiting, appeared to be lower in Group B. Particularly for nausea, where the *p*-value was 0.084, increasing the sample size could improve the ability to detect a true difference and potentially result in statistical significance. However, these differences did not reach statistical significance in this study. Therefore, adding an anti-inflammatory throat spray to lidocaine spray before EGD to reduce patient discomfort and improve patient satisfaction remains unclear and further research with larger sample size may be required. Discomfort during unsedated EGD is likely multifactorial. Topical anesthetic and anti-inflammatory agents can alleviate just a portion of the pain and discomfort, but issues such as gag reflex, pharyngeal pressure, stomach gas distension, fear, and anxiety remain unaddressed. There were several limitations in this study. First,

there was no previous study to guide the appropriate dose and timing of anti-inflammatory throat spray. In this study, six puffs of anti-inflammatory Throat spray were sprayed on the oropharynx based on the manufacturer's recommended dose of 2-4 sprays directly onto the sore/inflamed area. Increasing the amount of anti-inflammatory throat spray sprayed on the oropharynx may improve patient outcomes. However, any increase in the amount of benzydamine hydrochloride used should be weighed against any potential risk of side effects. Moreover, EGD is a brief procedure, whereas the anti-inflammatory throat spray, despite its rapid onset, may require several minutes to achieve its maximal analgesic and anti-inflammatory benefits. Second, this investigation is a randomized double-blind trial; however, the cohort of patients administered normal saline spray may have discerned the treatment due to the distinct taste of NSS, which differs from the mint-flavored benzydamine hydrochloride spray. Third, this study was conducted at a single center, where the environment, resources, and patient characteristics may differ from those of other locations. Additionally, the procedure was performed by a single endoscopist, whose experience and technique may vary from other physicians, potentially affecting the outcomes. Finally, adding Diffiam incurs additional costs. A cost-effective analysis is valuable information for practicing physicians to justify treatment decisions.

Conclusions

Both methods were safe and effective in producing local anesthesia and were liked by patients. The trends of adverse events were lower in Lidocaine spray combination with Anti-inflammatory Throat spray group. Therefore, preparation for EGD using lidocaine spray alone should remain safe and effective in producing local anesthesia, but adding anti-inflammatory throat spray might be an option to help reduce some patient side effects however, they were not statistically significant.

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