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Study of ideal topical pharyngeal anesthesia in upper gastrointestinal system endoscopy: A double-blind, randomized, controlled trial

UPPER GI

Hakan Çam[1], Seda Pehlivan[2], Muhammed Sait Dağ[1], Nimet Yılmaz[1], Umut Demir[1], Murat Taner Gülşen[1]

[1]Department of Gastroenterology, Gaziantep University School of Medicine, Gaziantep, Turkey
[2]Department of Nursing, Uludağ University School of Health, Bursa, Turkey

Original Article

ABSTRACT

Background/Aims: This study is designed to determine which drug forms provide ideal pharyngeal anesthesia when used during upper gastrointestinal system endoscopy.

Materials and Methods: A total of 180 patients were included in the study. Using the random number table, these patients were divided into three groups. Group 1, lidocaine gel+isotonic spray; Group 2, base lubricant gel+lidocaine spray; and Group 3: lidocaine gel+lidocaine spray. Data were collected from the patient identification form, compliance to operation form, and State Anxiety Inventory.

Results: Anesthetization and compliance to procedure scores were higher and anxiety scores were lower in Group 3 than in other groups ($p<0.05$). It was observed that as the compliance score increased, the anesthetization and satisfaction scores also increased; however, coughing during the procedure, duration of the procedure, and anxiety scores decreased ($p<0.05$). It was determined that as anesthetization scores increased, discomfort in the throat caused by the device, coughing during the procedure, and anxiety scores decreased ($p<0.05$).

Conclusion: Lidocaine gel and spray combination is the most ideal pharyngeal anesthesia to ensure the adaptation of the patient to the procedure and to decrease anxiety and discomfort during the procedure.

Keywords: Gastrointestinal endoscopy, lidocaine, pharyngeal anesthesia

INTRODUCTION

Upper gastrointestinal system (GIS) endoscopy is a procedure that is commonly used for diagnosis and treatment purposes. Topical pharyngeal anesthesia (TPA) and/or conscious sedation are used in patients before the procedure (1,2). Conscious sedation increases the patient's tolerance and acceptance of the procedure (3); however, it has several disadvantages, such as prolonged duration of the procedure, increased cost, and increased complication risk (4). TPA is preferred in many centers, particularly for diagnostic endoscopy (5,6). TPA enhances patient tolerance and eases endoscopy in the absence of conscious sedation (5,7,8). Besides enhancing patient comfort, TPA creates a convenient work environment for the endoscopist. This condition may prevent omitting some significant lesions (9). Lidocaine is widely used for topical anesthesia. The gel, spray, and inhaler forms of lidocaine are commercially available, and the spray form is more preferred (8-10). There is no satisfactory study regarding the form having a better efficacy. Therefore, this study was designed to compare the gel, spray, and combined uses of lidocaine and to determine the most effective topical anesthesia form.

Patient comfort is very important during endoscopy. An effective topical anesthesia significantly reduces patient discomfort, thereby making it easier for the patient to tolerate the operation and providing a comfortable working environment for physicians and nurses.

MATERIALS AND METHODS

Design and setting

The study was a prospective, double-blind, randomized, controlled trial. Randomization of 180 individuals was conducted using the random number table. The patients were divided into three groups each comprising 60 patients.

Group 1: Lidocaine gel+isotonic spray
Group 2: Base lubricant gel+lidocaine spray
Group 3: Lidocaine gel+lidocaine spray

Address for Correspondence: Seda Pehlivan E-mail: pehlivan_seda@hotmail.com
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The list indicating the group in accordance with the procedure order was provided to the endoscopy nurse. The patients were determined to be suited for the research. The patient groups were determined according to the procedure order. After that, appropriate pharyngeal anesthesia was applied by endoscopy nurse Only the endoscopy nurse knew in which group the patient belonged. The gastroenterologist was blinded.

Between October 2010 and January 2011, 180 consecutive patients who visited our endoscopy unit were included. Patients with no known lidocaine intolerance, between the age of 18 and 65 years, and who were literate enough to fill out a form were included. Patients with a comorbid severe disease, with neurological sequelae, who had an endoscopy before, with communication problems, with a stomach operation, who came from the emergency room, who were psychiatric cases, or who were pregnant were excluded.

Procedure

Endoscopy was performed right after the gel was applied as a thin layer on the first 5 cm part of the endoscope. Two percent xylocaine jelly was used as lidocaine gel (5 mL=100 mg lidocaine, AstraZeneca, Mississauga, Canada). Endoscopy was performed 2 min after the spray was applied to the pharynx as three consecutive puffs. Ten percent xylocaine pump spray was used as lidocaine spray (1 puff=10 mg lidocaine, AstraZeneca; Luton, UK). When used with different drug forms, the lidocaine dose should not exceed 400 mg. The total dose of lidocaine (130 mg) administered in our study was within the safe range. The same gastroscope model (Olympus GIF240, Olympus Europa SE and CO; Southend-on-Sea, UK) was used in endoscopy. The procedures were performed by experienced gastroenterologists who had performed at least 1000 endoscopic procedures. Before the procedure started, an assistant medical attendant completed the preparations for pharyngeal anesthesia; thus, the procedure was conducted without both the patient and physician knowing in which group the patient belonged. The duration of the procedure was recorded, and the patients filled out the patient evaluation form and State Anxiety Inventory. Data were collected from the patient evaluation form, physician evaluation form, and State Anxiety Inventory. Study data were acquired by a researcher outside the endoscopy team. To prevent observer bias, study data (patient and physician evaluations) were combined with the group information from the endoscopy nurse during data entry.

Measurements

The patient evaluation form included sociodemographic characteristics of the patients (age, gender, and education) and questions regarding the procedure (pain, difficulty, satisfaction, evaluation of the procedure, anesthetization, discomfort in the throat caused by the device, taste of the medicine, level of coughing, and gag reflex). The 5-point Likert scale answers and 100-mm visual analog scale (VAS) were used to evaluate the questions regarding the procedure.

The State Anxiety Inventory was developed by Spielberger and was adapted in Turkish by Öner et al. (11). The scale comprises 20 questions and determines how an individual felt in specific conditions at a specific time; one of the options, which are "none," "some," "a lot of," and "entirely," is marked for every question. The score obtained from the scale changes between 20 and 80. A high score indicates that the anxiety is increasing, and a score of ≥60 indicates pathological anxiety.

Physician evaluation form: Right after the procedure, the patient's level of eligibility to the procedure was determined by the endoscopist using the 5-point Likert scale answers and 100-mm VAS. Status of taking biopsy and the duration of the procedure were recorded.

Statistical analysis

Analysis was conducted to determine the effect of the study, which was determined as a power calculation of 83.1% and a significance level of 5%. Data were analyzed using Statistical Package for the Social Sciences (SPSS) for the Windows version 13.0 software (SPSS Inc; Chicago, Illinois, USA). The statistical analyses were performed using chi-square, one-way ANOVA, Pearson correlation analysis, and Tukey' HSD test when required. A p value of <0.05 was considered significant.

Ethical approval

This study was approved by the ethics committee of the Gaziantep University. Informed consent was obtained from all the patients who were included in the study.

RESULTS

There was no difference among the three groups with regard to sociodemographic characteristics (p>0.05) (Table 1). The scores of anesthetization and compliance to procedure were higher in Group 3 than in other groups, whereas anxiety

Table 1. Sociodemographic characteristics and the biopsy receipt status of the patients according to groups

	Group I (n=60)	Group II (n=60)	Group III (n=60)	Statistics p
Age (mean/yrs)	33.03±12.30	35.14±12.28	34.15±10.46	F=0.490, p=0.613
Gender (n, %)				
Female	33 (55.0)	28 (46.7)	33 (55.0)	X^2=1.113, p=0.573
Male	27 (45.0)	32 (53.3)	27 (45.0)	
Educational status (n, %)				
Primary school	28 (46.7)	24 (40.0)	22 (36.7)	
Middle school	17 (28.3)	14 (23.3)	22 (36.7)	X^2=6.678, p=0.352
Collage	15 (25.0)	22 (36.7)	16 (26.6)	
Biopsy (n, %)				
Taken	7 (11.7)	8 (13.3)	3 (5.0)	X^2=2.593, p=0.274
Not taken	53 (88.3)	52 (86.7)	57 (95.0)	

Table 2. The distribution of the patient data on the procedure by groups

	Group I mean±SD	Group II mean±SD	Group III mean±SD	Statistics F, p
Duration of procedure (minute)	03:21±01:32	03:09±01:40	03:04±01:52	0.448, 0.640
Pain	32.50±23.09	33.08±25.57	29.68±25.40	0.325, 0.723
Difficulty	42.16±27.94	43.58±29.76	38.61±25.50	0.509, 0.602
Satisfaction	65.50±23.38	61.36±26.88	71.33±23.64	2.468, 0.088
Evaluation of the procedure (patient)	42.03±26.36	38.75±27.47	45.38±27.29	0.902, 0.408
Discomfort of the device created in the throat	52.38±28.26	54.41±25.44	43.21±27.26	2.926, 0.056
Coughing and gagging	59.38±30.19	58.16±28.49	51.00±29.46	1.425, 0.243
Taste of the medicine	50.58±25.95	51.00±25.24	54.50±27.44	0.404, 0.669
Anesthetization status of the drug	64.10±22.00	66.58±19.81	74.41±16.67	4.519, 0.012
Compliance to procedure (physician)	56.38±20.44	64.35±18.33	72.83±14.86	12.493, 0.000
Anxiety	39.65±9.33	40.55±9.84	35.35±8.77	5.323, 0.006

scores were significantly lower in Group 3 than in other groups (p<0.05) (Table 2).

Negative correlation was detected among the anesthetization score and difficulty of procedure, discomfort in the throat caused by the device, coughing during the procedure, and anxiety scores (p<0.05). It was determined that as anesthetization scores increased, the evaluation of the procedure (patient) and compliance to procedure (physician) scores increased (p<0.05). Moreover, as compliance scores increased, satisfaction and evaluation of the procedure scores also increased, and the difficulty of the procedure, coughing during the procedure, duration of the procedure, and anxiety scores decreased (p<0.05) (Table 3).

No correlation was found among the three groups with regard to age, gender, education status, pain during the procedure, overall procedure evaluation, satisfaction, taste of the medicine, discomfort in the throat, coughing during the procedure, duration of the procedure, and whether or not biopsy was taken (p>0.05). Positive correlation was detected among the satisfaction score and age, taste of the medicine, anesthetization, and compliance scores; negative correlation was detected among pain, discomfort in the throat caused by the device, coughing during the procedure, and anxiety scores (p<0.05). Furthermore, it was detected that as the duration of the procedure extended, compliance to procedure scores decreased and anxiety scores increased (p<0.05). It was detected that as the pain score increased, the anxiety score also increased (p<0.05) (Table 3).

Table 3. Correlation coefficient

	Anesthetization		Compliance		Anxiety	
	r	p	r	p	r	p
Age	-0.037	0.622	0.009	0.907	-0.002	0.983
Duration of procedure	-0.076	0.310	-0.373	0.000	0.193	0.010
Pain	-0.118	0.115	-0.133	0.075	0.275	0.000
Difficulty of procedure	-0.248	0.001	-0.176	0.018	0.321	0.000
Satisfaction	0.211	0.005	0.149	0.047	-0.345	0.000
Evaluation of the procedure (patient)	0.270	0.000	0.200	0.007	-0.418	0.000
Discomfort of the device created in the throat	0.260	0.000	0.140	0 061	-0.264	0.000
Coughing and gagging	-0.220	0.003	-0.167	0.025	0.299	0.000
Anesthetization of the drug	-		0.255	0.001	-0.265	0.000
Compliance to procedure (physician)	0.255	0.001	-		-0.240	0.001

DISCUSSION

Conscious sedation during upper GIS endoscopy enhances patient comfort, thereby also enabling a comfortable working environment for the physicians during the interventional procedures. However, there are also undesirable side effects of intravenous sedatives and analgesics. These side effects may result in mortality, although the rate is very low (12,13). Furthermore, there are other disadvantages, such as the necessity of experienced nurses and perioperative monitorization, prolonged duration of procedures, and increased cost. Conscious sedation is troublesome because of limited time and space in busy endoscopy units (14).

Various studies revealed that diagnostic upper GIS endoscopy without sedation is safe, doable, and repeatable (13,15-18). Unsedated procedures have advantages, such as reduction of hypoxemia and cardiopulmonary side effects, short duration of the procedure, ability to drive immdiately after the procedure, and ability to resume work (15,19). However, gagging, coughing, and pain during the procedure are the disadvantages of this sedation type, and they are considered to be very irritating conditions. At the same time, this situation negatively affects the endoscopists and makes them anxious to complete the procedure in a shorter duration (20).

TPA is administered to enhance patient comfort, particularly for diagnostic endoscopy (21). Lidocaine is mostly preferred as the active ingredient (18). In the literature, there are conflicting results regarding which form of lidocaine is the most effective (3,10). Therefore, our study was designed to determine the most effective topical form that enhances patient comfort.

In our study, the application of the spray or gel form alone did not provide a significant difference. However, it was observed that when used together, these drug forms increased compliance and anesthetization and decreased anxiety scores in patients. Total anesthesia dosage increases with the combined use of the gel and spray forms. At the same time, the gel has a lubricating effect in a mechanical manner. In a study, high (100 mg) and low doses (30 mg) of the lidocaine spray were compared. A decrease was detected in the discomfort of patients who were administered high doses (22). In addition, we believe that the gel's lubricating effect is also important for this satisfaction.

In a recent study, lidocaine spray and its viscous form were compared. It was stated that the spray form increased patient and physician satisfaction, decreased pain, and made intubation easier; however, combined usage was not compared in this study (8). In another double-blind, randomized, controlled study, it was determined that patient tolerance increased above the age of 40 years. The study also showed that anxiety scores measured before endoscopy had a significant effect over tolerance (23). In another study, it was determined that TPA decreased the discomfort of patients who were under 40 years during endoscopy and in whom endoscopy was performed for the first time, while the high anxiety level increased discomfort during the procedure (6). Consistent with the literature, in our study, we found a positive correlation between age and the satisfaction score and a negative correlation between compliance to procedure and anxiety scores.

We observed that as the duration of procedure increased, the compliance score to the procedure decreased and anxiety score increased. For this reason, it is crucial that the procedure should be completed as soon as possible. By specifying clinical history and the causes for performing endoscopy, time loss can be prevented. Before the procedure, the endoscopist needs to know clearly what he is looking for. Besides, conscious sedation can be administered to patients for whom the procedures are expected to take a long time.

This study, which was conducted as a double-blind, randomized, controlled trial, has some limitations. We compared the different drug forms in this study. Therefore, the lidocaine dose was not the same between the groups.

In conclusion, we believe that the most ideal pharyngeal anesthesia is the combination of lidocaine spray and gel for the purposes of ensuring compliance of the patient to the procedure, reducing anxiety, increasing satisfaction, and decreasing discomfort during the procedure.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Gaziantep University Local Ethical Committee

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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REFERENCES

1. Daneshmend TK, Bell GD, Logan RF. Sedation for upper gastrointestinal endoscopy: results of a nationwide survey. Gut 1991; 32: 12-5. [CrossRef]
2. Keeffe EB, O'Connor KW. 1989 A/S/G/E survey of endoscopic sedation and monitoring practices. Gastrointest Endosc 1990; 36: 13-8.
3. Ristikankare M, Hartikainen J, Heikkinen M, Julkunen R. Is routine sedation or topical pharyngeal anesthesia beneficial during upper endoscopy? Gastrointest Endosc 2004; 60: 686-94. [CrossRef]
4. Fleischer D. Monitoring for conscious sedation: perspective of the gastrointestinal endoscopist. Gastrointest Endosc 1990; 36: 19-22.
5. Hedenbro JL, Ekelund M, Jansson O, Lindblom A. A randomized, double-blind, placebo-controlled study to evaluate topical anesthesia of the pharynx in upper gastrointestinal endoscopy. Endoscopy 1992; 24: 585-7. [CrossRef]
6. Soma Y, Saito H, Kishibe T, Takahashi T, Tanaka H, Munakata A. Evaluation of topical pharyngeal anesthesia for upper endoscopy including factors associated with patient tolerance. Gastrointest Endosc 2001; 53: 14-8. [CrossRef]
7. Evans LT, Saberi S, Kim HM, Elta GH, Schoenfeld P. Pharyngeal anesthesia during sedated EGDs: is "the spray" beneficial? A meta-analysis and systematic review. Gastrointest Endosc 2006; 63: 761-6. [CrossRef]
8. Amornyotin S, Srikureja W, Chalayonnavin W, Kongphlay S, Chatchawankitkul S. Topical viscous lidocaine solution versus lidocaine spray for pharyngeal anesthesia in unsedated esophagogastroduodenoscopy. Endoscopy 2009; 41: 581-6. [CrossRef]
9. Waring JP, Baron TH, Hirota WK, et al. Guidelines for conscious sedation and monitoring during gastrointestinal endoscopy. Gastrointest Endosc 2003; 58: 317-22. [CrossRef]
10. Ayoub C, Skoury A, Abdul-Baki H, Nasr V, Soweid A. Lidocaine lollipop as single-agent anesthesia in upper GI endoscopy. Gastrointest Endosc 2007; 66: 786-93. [CrossRef]
11. Öner N, Le Compte A. State/Trait Anxiety Inventory Handbook (in Turkish, Süreksiz Durumluk/Sürekli Kaygı Envanteri El Kitabı). İstanbul: Boğaziçi Üniversitesi Yayınları; 1985.
12. de la Morena F, Santander C, Esteban C, et al. Usefulness of applying lidocaine in esophagogastroduodenoscopy performed under sedation with propofol. World J Gastrointest Endosc 2013; 5: 231-9. [CrossRef]
13. McQuaid KR, Laine L. A systematic review and meta-analysis of randomized, controlled trials of moderate sedation for routine endoscopic procedures. Gastrointest Endosc 2008; 67: 910-23. [CrossRef]

14. Amornyotin S. Sedation-related complications in gastrointestinal endoscopy. World J Gastrointest Endosc 2013; 5: 527-33. **[CrossRef]**
15. al-Altrakchi HA. Upper gastrointestinal endoscopy without sedation: a prospective study of 2000 examinations. Gastrointest Endosc 1989; 35: 79-81. **[CrossRef]**
16. Hedenbro JL, Lindblom A. Patient attitudes to sedation for diagnostic upper endoscopy. Scand J Gastroenterol 1991; 26: 1115-20. **[CrossRef]**
17. Abraham N, Barkun A, Larocque M, et al. Predicting which patients can undergo upper endoscopy comfortably without conscious sedation. Gastrointest Endosc 2002; 56: 180-9. **[CrossRef]**
18. Chan CK, Fok KL, Poon CM. Flavored anesthetic lozenge versus Xylocaine spray used as topical pharyngeal anesthesia for unsedated esophagogastroduodenoscopy: a randomized placebo-controlled trial. Surg Endosc 2010; 24: 897-901. **[CrossRef]**
19. Pereira S, Hussaini SH, Hanson PJ, Wilkinson ML, Sladen GE. Endoscopy: throat spray or sedation? J R Coll Physicians Lond 1994; 28: 411-4.
20. Tsai HI, Tsai YF, Liou SC, et al. The questionable efficacy of topical pharyngeal anesthesia in combination with propofol sedation in gastroscopy. Dig Dis Sci 2012; 57: 2519-26. **[CrossRef]**
21. Campo R, Brullet E, Montserrat A, Calvet X, Rivero E, Brotons C. Topical pharyngeal anesthesia improves tolerance of upper gastrointestinal endoscopy: a randomized double-blind study. Endoscopy 1995; 27: 659-64. **[CrossRef]**
22. Mulcahy HE, Greaves RR, Ballinger A, et al. A double-blind randomized trial of low-dose versus high-dose topical anaesthesia in unsedated upper gastrointestinal endoscopy. Aliment Pharmacol Ther 1996; 10: 975-9. **[CrossRef]**
23. Froehlich F, Schwizer W, Thorens J, Köhler M, Gonvers JJ, Fried M. Conscious sedation for gastroscopy: patient tolerance and cardiorespiratory parameters. Gastroenterology 1995; 108: 697-704. **[CrossRef]**