

Research article

Comparison of Spraying and Nebulized Lidocaine in Patients Undergoing Esophago-Gastro-Duodenoscopy: A Randomized Trial

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Abstract

Objective: Esophago-gastro-duodenoscopy (EGD) was performed under the topical anaesthesia of the pharynx. However, spraying lidocaine was found to be an annoying maneuver to patients, while nebulized lidocaine appeared to efficiently suppress gags and cough reflexes in the airway. Investigators compared the effectiveness of spraying and nebulized lidocaine for patients undergoing EGD. **Material and Method:** A total of 110 patients undergoing elective EGD, with a history of neither lidocaine intolerance nor irritable airways due to smoking, chronic obstructive pulmonary disease (COPD), upper respiratory infection, asthma, cardiac and pulmonary diseases and allergy to lidocaine were included. All patients were randomized into two groups: A – where 5 puffs (10mg/puff) of spraying lidocaine were administered four times at 5-minute intervals, up to a total dose of 200 mg; and B – where 250 mg of nebulized lidocaine was administered via a nebulization kit with an oxygen face mask of 7 LPM for 15 minutes prior to the commencement of EGD. The procedure was performed by the same board-certified endoscopist. The co-researcher who was blinded to the technique assessed the ease of esophageal instrumentation as either difficult, poor, fair or excellent. Both the endoscopist and the patients expressed their satisfaction by using the Numerical Rating Scale. **Results:** The endoscopist expressed her satisfaction with instrumentation, which showed significant difference between group A and group B as 84.8±8.3 and 79.2±11.2, respectively. The co-researcher also found that group A patients responded to the ease of esophageal instrumentation better than those in group B. However, nebulized lidocaine had significant advantages over spraying lidocaine, with better acceptance in patients undergoing EGD. **Conclusion:** The endoscopist expressed her approval of spraying lidocaine for taking less time to start the procedure, ease for instrumentation, less gag reflex during the procedure, less presence of hypersecretion, and smooth operation. However, participants favored nebulized lidocaine administration.

Keywords: anaesthetic technique-topical, esophago-gastro-duodenoscopy

Introduction

Endoscopy of the upper alimentary tract is an invasive technique resulting in gag reflex, bradyarrhythmias and unpleasant symptoms in patients. In practice, esophago-gastro-duodenoscopy (EGD) is performed under the topical anaesthesia of the pharynx or parenteral administration of sedative drugs [1-6], or both. Topical lidocaine plays a crucial role in accomplishing this assignment because it yields a rapid onset with a high safety margin. The successful criteria of the procedure under local anaesthesia are not only safety and simplicity but also provides adequate anaesthesia.

Spraying lidocaine was broadly accepted as a simple technique because of rapid onset. It might produce an unexpectedly stressful reflex with pain during swallowing [7, 8]. Moreover, the efficacy of lidocaine appeared to decrease in cases of patient's hypersecretion or anatomical variability as well as quick swallowing of the drug [4]. Thus, anaesthesia personnel should be aware of their practical skills and desire to gain more knowhow [10, 11].

Nebulized lidocaine has long been claimed for its medical usefulness in many modalities without any complications, or pa-

tient discomfort [12-14]. Though lidocaine has a very low blood level because of nebulization, it dramatically decreases systemic pain [14-16]. Interestingly, nebulized lidocaine appeared efficient in suppressing gags and cough reflexes as well as airway anaesthesia [12, 14, 17, 18].

This study aimed to comparison of the effectiveness; successful completion of the endoscopic procedure of spraying and nebulized lidocaine for patients undergoing EGD.

Materials and Methods

The prospective randomized study was approved by Siriraj Institutional Review Board (Si-IRB), COA: Si534/2013 (17/09/2013), and was written informed consent was obtained from all subjects. Study setting was registered at ClinicalTrials.gov, NCT02317770 (12/11/2014). The study was conducted at the Department of Siriraj Gastro-Intestinal Endoscopy Center.

Patients

A total of 110 patients were enrolled in the study between September 2013 and August 2015. Inclusion criteria were patients aged between 18 and 65, underwent elective EGD, American Society of Anaesthesiologist (ASA) physical status class I/II, without a history of lidocaine intolerance, and able to complete questionnaires.

Exclusion criteria were patients with irritable airways due to smoking, chronic obstructive pulmonary disease (COPD), upper respiratory tract infection, or asthma, cardiac or pulmonary diseases, and allergy to lidocaine.

Withdrawal or termination criteria were patients' refusal to continue under the study, bronchospasm, signs of lidocaine overdose or toxicity including tinnitus, light-headedness, circum-oral numbness, visual disturbances, involuntary muscle spasm, convulsions, cardiac depression, and cardiac arrest [19].

At the Endoscopy Center.

All patients were randomized into two groups by using a computer program and closed envelopes as A-spraying lidocaine and B-nebulized lidocaine.

Intervention

In group A, the co-researcher administered five puffs of spraying lidocaine (10mg/puff) four times at 5-minute intervals, up to the total dose of 200 mg. The drug was sprayed at the tonsils, anterior pillars, and base of tongue.

In group B, patients in the semi-sitting position received 250 mg of nebulized lidocaine via a nebulization kit (Hudsons, Aerosol nebulizer mask with tubing, supplied by Bever Medical Industry, Co., Ltd., Thailand) with 7 liter per minute (LPM) of oxygen via face mask for 15 minutes.

The administration of lidocaine in both groups was finished five minutes before the start of EGD. A supplemental oxygen (3 LPM) via nasal cannula was administered to all patients who had already been monitored with standard monitoring. The procedure was performed by **oneboard**-certified endoscopist who conducted more than 1,000 cases of EGD annually.

During procedure, the co-researcher who was blinded to the lidocaine administration technique assessed the ease of esophageal instrumentation as following [20]; difficult, poor, fair or

excellent.

Step 1 = Difficult for esophageal instrumentation was defined as patient refused esophageal instrumentation.

Step 2 = Poor was defined as patient had gag reflex and needed sedation.

Step 3 = Fair was defined as patient had mild gag reflex.

Step 4 = Excellent was defined as patient had no gag reflex.

After the procedure, the endoscopist assessed the ease of esophageal instrumentation by using the Numerical Rating Scale (NRS: 0-100), with 0 being difficult and 100 being easy. In addition, she expressed her satisfaction with the lidocaine administration technique by using the NRS 0-10 with 0 being dissatisfied and 10 being satisfied; the topics of time to start the procedure; instrumentation technique; gag reflexes during the procedure; presence of hypersecretion; and smooth operation.

The patients were delivered to the recovery room for **1-hour-observation** of vital signs and other complications under the guidelines of the Siriraj Gastro-Intestinal Endoscopy Center. Before discharge, the co-researcher interviewed the patients using the questionnaires for their satisfaction with the topical anaesthesia techniques by using NRS 0-10, with 0 being dissatisfied and 10 being very satisfied.

Statistical analysis

The study was designed to test the clinical hypothesis that topical anaesthesia with nebulized lidocaine was as effective as spraying lidocaine in patients undergoing EGD. The data were expressed as mean and standard deviation. The categorical variables were carried out using the Chi-square test. The interval variables between the two groups such as NRS were compared using the independent t-test. Finally, p-value less than 0.05 with 95% confidence interval was considered statistically significant difference.

Results

Demographic data including sex, age, weight, height, ASA physical status, allergy, history of EGD and/or EGD under anaesthetic technique were not significant differences between the two groups (Table 1). One hundred and ten patients were equally randomized into two groups. Three patients were excluded from the study: one in group A was dropped out due to the extended protocol, and other two in group B due to the incidence of bronchospasm and recall of upper respiratory tract infection.

The endoscopist expressed to the procedural effectiveness: satisfactions core with instrumentation, which showed significant difference between group A and group B as 84.8 ± 8.3 and 79.2 ± 11.2 respectively and so does the co-researcher as the NRS (Table 2).

The endoscopist commended group A patients for taking less time to start the procedure, ease for instrumentation, less gag reflexes during the procedure, less presence of hypersecretion, and smooth operation (Table 3).

In group A, participants showed the sensation during instrumentation better than group B and performed equal physical feeling during drug administration. However, for other categories, sensation after drug administration, willingness for drug

Table 1. Patients' demographic data between the spraying and nebulized lidocaine groups.

	Group A (n=54)	Group B (n=53)	P-value
Age (yr)	51.80 (10.84)		
Sex (M:F)	19:35		
Weight (kg)	57.69 (10.49)	58.89 (12.25)	
Height (cm)	160.64 (8.22)	161.64 (8.86)	0.5
ASA physical status, n (%)			0.4
1	19 (35.2)	23 (43.4)	
2	35 (64.8)	30 (56.6)	
Allergy, n (%)			0.6
none	45 (83.3)	48 (90.6)	
drugs	6 (11.1)	4 (7.5)	
food	2 (3.7)	1 (1.9)	
drugs and food	1 (1.9)	0 (0)	
History of EGD, n (%)			0.7
none	28 (51.9)	32 (60.4)	
once	19 (35.2)	15 (28.3)	
more than one	7 (13)	6 (11.3)	
History of EGD under anesthetic technique, n (%)			0.8
none	28 (51.9)	32 (60.4)	
spraying lidocaine	19 (35.2)	15 (28.3)	
IV sedation	4 (7.4)	4 (7.5)	
spraying lidocaine and IV sedation	3 (5.6)	2 (3.8)	

Table 2. The endoscopist and the co-researcher assessed the procedural effectiveness under the numerical rating scale (mean±SD) and number of patients' response n (%) in consequence.

	Patients' response	Group A (n=54)	Group B (n=53)	p-value
Endoscopist		84.8 ± 8.3	79.2 ± 11.2	0.004
Co-researcher	difficult	0(0)	0(0)	
	poor	1(1.9)	4(7.5)	
	fair	27(50)	40(75.5)	
	excellent	26(48.1)	9(17.0)	

Table 3. The endoscopist's satisfaction score with the operation and participants' satisfaction score with the drug administration.

Evaluator	Topic	Group A (n=54)	Group B (n=53)	p-value
Endoscopist	time to start the procedure	9.1 (0.6)	8.7 (1.2)	0.051
	instrumentation technique	8.5 (1.0)	7.4 (1.7)	0.000*
	gag reflex during the procedure	8.4 (1.2)	7.3 (1.8)	0.000*
	presence of hypersecretion	8.2 (0.8)	8.0 (0.9)	0.269
	smooth operation	8.2 (1.1)	7.7 (1.0)	0.024*
Participants	sensation during drug administration	8.2 (1.9)	8.2 (1.7)	0.863
	taste of medication	7.7 (2.0)	7.9 (1.9)	0.623
	sensation during the instrumentation	7.7 (2.1)	7.4 (1.8)	0.426
	sensation after drug administration	8.3 (1.6)	8.9 (1.0)	0.010*
	willingness for drug administration	8.4 (1.7)	8.8 (1.3)	0.127
	sore throat	8.6 (1.6)	9.1 (1.4)	0.056
	dysphagia	8.6 (1.8)	9.3 (1.3)	0.039*
Treatment of choice [n (%)]	yes	52 (96.3%)	51 (96.2%)	
	no	2 (3.7%)	2 (3.8%)	

administration, incidence of sore throat and dysphagia, Group B performed better than group A. Patients still chose either spraying or nebulized lidocaine for EGD (Table 3).

Discussion

In view of the endoscopist's satisfaction, spraying lidocaine was more effective for the instrumentation than nebulized lidocaine. We found that patients in the nebulized group responded as "fair" more often than that in the spraying group; however, the responses were not "poor" and "excellent". On the other hand, patients showed receptiveness to nebulized lidocaine administration.

In the current study, spraying lidocaine seemed to be a practical maneuver for the surgeon to deal with the patients during the procedure. This finding is well-accepted by many operators. Korttila K. et al (1981) administered spraying lidocaine and ultrasonic nebulization in patients underwent bronchoscopy and found that spraying lidocaine was more efficient than ultrasonic nebulization [14]. Hedenbro JL. et al (1992) claimed that after topical anaesthesia of the pharynx with spraying lidocaine, endoscopists expressed less discomfort from the intubation and satisfied with the technique [21]. Somchai A. et al (2009) studied patients undergoing EGD using viscous and spraying lidocaine and found that spraying lidocaine led to better tolerance and ease of intubation as well as high patients' satisfaction and pain scores [20]. However, spraying lidocaine carries some adverse effects. It can cause discomfort among patients needing to open their mouths widely while the drug is sprayed over the surrounding areas. Hsin-I Tsai et al. (2012) studied patients under moderate to deep sedation for diagnostic gastroscopy and found that topical pharyngeal anaesthesia with lidocaine yielded an irritating sensation and a bitter taste to patients [7]. Dhir V. et al. (1997) compared lidocaine with placebo in unsedated patients undergoing EGD and claimed that the spraying lidocaine did not ease the procedure [4]. Because of the difficulty of spraying lidocaine over the mucosa or the presence of saliva, or because patients swallowed the drug immediately, the pharynx was only partially

anaesthetized [4]. Also, Fresh AC. et al. (1998) stated that their patients experienced a bad taste after lidocaine spraying [8].

It is therefore not surprising that nebulized lidocaine was well-accepted, since the technique is familiar (oxygen administration via face mask). Williams KA. et al. (2005) used nebulized lidocaine in unsedated patients for awake fiber-optic intubation and claimed that lidocaine nebulization was acceptable among patients [19]. Keane D. et al. (1992) stated that nebulized lidocaine had significant advantages over spraying lidocaine, with better acceptance in patients undergoing fiber-optic bronchoscopy [22]. Therefore, it was a convenient, well-tolerated method of drug delivery for upper airway endoscopy [9].

However, Korttila K. et al. (1981) noted that it was difficult to determine the exact dosage of inhaled lidocaine [14]. This might agree with many researchers who claimed that up to 60% of lidocaine was lost to the atmosphere or in patients' mouth during the nebulization [16, 23, 24]. As a result, it was not easy to figure out the dosage of nebulized lidocaine to alleviate the discomfort during instrumentation. Thus, it became an advantage to decrease the incidence of systemic adverse effects due to its serum level was remarkably low [9, 12, 25, 26].

Conclusion

For the EGD, spraying lidocaine was dramatically more effective than nebulized lidocaine. However, patients expressed more satisfaction with nebulized lidocaine administration during the instrumentation.

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