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

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Objective: *Esophago-gastro-duodenoscopy (EGD) was performed under the topical anesthesia 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 airway anesthesia. This study aimed to compare 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 (10 mg/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 lidocaine administration 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$\pm$8.3 and 79.2$\pm$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: *Anesthetic technique-topical, Esophago-gastro-duodenoscopy*

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Endoscopy of the upper alimentary tract is an invasive technique resulting in gag reflex, bradyarrhymias and unpleasant symptoms in patients. In practice, esophago-gastro-duodenoscopy (EGD) is performed under the topical anesthesia of the pharynx or parenteral administration of sedative drugs[1-5], or both. Both 2% viscous and 10% liquid lidocaine play 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 anesthesia are not only safety and simplicity but also provides adequate anesthesia.

Spraying lidocaine was found to be an annoying maneuver to patients, since it might produce an unexpectedly stressful reflex with pain during swallowing. Some patients complained of pungent taste or smell of drug flowing in their throat[6,7]. Also, a gastroenterologist might experience dissatisfaction during the instrumentation[8]. Moreover, the efficacy of lidocaine appeared to decrease in cases of patient's hyper secretion or anatomical variability as well as quick

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swallowing of the drug[4]. Thus, anesthesia personnel should be aware of their practical skills and desire to gain more knowhow[9,10].

Nebulized lidocaine has long been claimed for its medical usefulness in many modalities such as bronchoscopy, endobronchial culture without any complications, or patient discomfort[11-13]. Though lidocaine has a very low blood level because of nebulization, it dramatically decreases systemic pain[13-15]. Interestingly, nebulized lidocaine appeared efficient in suppressing gags and cough reflexes as well as airway anesthesia[11,13,16,17].

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

Material and Method

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. The patients were recruited at the outpatient clinic (OPD) by the co-researcher on the day of appointment. The project was explained in detail to the participants who were interested in the project. All patients took home all documents to study the information.

Inclusion criteria were patients aged between 18 and 65, underwent elective EGD, American Society of Anesthesiologist (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[18].

At the Endoscopy Center

On the day of EGD, the volunteers signed the informed consent. All patients were randomized into two groups by using a computer program and closed envelopes as A-spraying lidocaine and B-nebulized lidocaine. At PACU, patients received intravenous fluid on either side of the forearm. No premedication was given.

Intervention

In group A, the co-researcher administered five puffs of spraying lidocaine (10 mg/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 electrocardiography (EKG), heart rate (HR), pulse oximetry (SpO_2), and non-invasive blood pressure (NIBP) every five minutes. The procedure was performed by one board-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[19]; 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 hyper secretion; 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 anesthesia techniques by using NRS 0-10, with 0 being dissatisfied and 10 being very satisfied; the topics of sensation during drug administration; taste of medication; sensation during the instrumentation; sensation after drug administration; willingness for drug administration; sore throat; and dysphagia.

Statistical analysis

The study was designed to test the clinical hypothesis that topical anesthesia 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 anesthetic 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: satisfaction score with instrumentation, which showed significant difference between group A and group B as 84.8$\pm$8.3 and 79.2$\pm$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).

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

	Group A (n = 54)	Group B (n = 53)	*p*-value
Age (year)	51.80 (10.84)	49.60 (11.37)	0.3
Sex (Male: Female)	19:35	23:30	0.4
Weight (kg)	57.69 (10.49)	58.89 (12.25)	0.6
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)	

EGD = esophago-gastro-duodenoscopy
Data are expressed as n (%)

In group A, participants only showed equal physical feeling during the instrumentation. However, for other categories, namely sensation during drug administration, taste of medication, sensation after drug administration, willingness for drug administration, incidence of sore throat and dysphagia, they performed better than group B. 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". Logically, this confirmed the procedural effectiveness of spraying lidocaine, which was notified by the endoscopist. 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 et al (1981) administered spraying lidocaine and ultrasonic nebulization in patients underwent bronchoscopy and found that spraying lidocaine was more efficient than ultrasonic nebulization[13]. Hedenbro et al (1992) claimed that after topical anesthesia of the pharynx with spraying lidocaine, endoscopists expressed less discomfort from the intubation and satisfied with the technique[20]. Amornyotin S. 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[19]. However, spraying lidocaine carries some adverse effects. It can cause discomfort among patients needing to open their

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 hyper secretion	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)	

Data are expressed as mean (SD)

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 anesthesia with lidocaine yielded an irritating sensation and a bitter taste to patients[6]. Dhir 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 anesthetized[4]. Also, Fresh el al (1998) stated that their patients experienced a bad taste after lidocaine spraying[7].

It is therefore not surprising that nebulized lidocaine was well-accepted, since the technique is familiar (oxygen administration via face mask). Williams et al (2005) used nebulized lidocaine in unsedated patients for awake fiber-optic intubation and claimed that lidocaine nebulization was acceptable among patients[18]. Keane et al (1992) stated that nebulized lidocaine had significant advantages over spraying lidocaine, with better acceptance in patients undergoing fiber-optic bronchoscopy[21]. Therefore, it was a convenient, well-tolerated method of drug delivery for upper airway endoscopy[8].

However, Korttila et al (1981) noted that it was difficult to determine the exact dosage of inhaled lidocaine[13]. 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[15,22,23]. 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[8,11,24,25].

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.

What is already known on this topic?

Topical anesthesia-either spraying or viscous lidocaine-has long been used in EGD. Though it may produce unexpectedly stressful reflexes, sore swallowing sensation, or pungent taste, it is broadly accepted as a simple technique for its rapid onset and adequate anesthesia. On the other hand, though nebulized lidocaine yields less discomfort on upper airway management, it has been scarcely mentioned in upper gastro-endoscopy.

What this study adds?

We compared nebulized lidocaine with spraying lidocaine in patients undergoing EGD and found more "fair" responses by patients in the nebulized group than those in the spraying group, as opposed to "poor" and "excellent" conditions. Logically, this confirmed the procedural effectiveness of spraying lidocaine, which was notified by the endoscopist. On the other hand, patients apparently expressed comfort with nebulized lidocaine administration.

Limitation of the study

We were unable to measure the blood lidocaine levels in both groups. As mentioned, most nebulized drug was deposited along the upper airway passage. The concentration of nebulized lidocaine seemed lower than that of spraying lidocaine, and so they might not be comparable.

Suggestion of further study

Since most nebulized lidocaine is deposited along the upper airway passage, its concentration used in topical anesthesia becomes an interesting issue. If the dose is increased up to an optimal effect, EGD would be an advantageous process for both the endoscopist and patients.

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Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบการใช้ยาชาเฉพาะที่ด้วยวิธีการพ่นกับการสูดฝอยละอองในผู้ป่วยที่เข้ารับการตรวจทางเดินอาหารส่วนต้นด้วยวิธีการส่องกล้อง

พาพิรุฬ น้อยตาแสง, พงศ์ธารา วิจิตเวชไพศาล, อวยพร เค้าสมบัติวัฒนา, ทัศนีย์ ใจเย็น, สุวรรณี ศิริวงษา

ภูมิหลัง: การตรวจทางเดินอาหารส่วนต้นด้วยวิธีการส่องกล้อง เป็นหัตถการซึ่งนิยมปฏิบัติต่อผู้ป่วยภายใต้การให้ยาระงับความรู้สึกด้วยยาชาเฉพาะที่ที่นิยมใช้คือ viscous lidocaine 2% และ lidocaine spray 10% เพราะเป็นวิธีที่สะดวก รวดเร็ว และมีความปลอดภัยค่อนข้างสูง อย่างไรก็ตาม ผู้ป่วยบางรายอาจมีความรู้สึกอึดอัด ไม่สบาย เนื่องจากกลิ่นและรสชาติของยาชาที่สัมผัสบริเวณทางเดินหายใจส่วนต้น มีการศึกษาพบว่า การบริหารยาชาแบบฝอยละอองสามารถตัดปัญหาต่าง ๆ เหล่านี้ออกไปได้

วัตถุประสงค์: เพื่อเปรียบเทียบผลสัมฤทธิ์ของการตรวจทางเดินอาหารส่วนต้นด้วยวิธีการส่องกล้องในผู้ป่วยที่ได้รับการบริหารยาชาเฉพาะที่แบบพ่นกับแบบฝอยละออง

วัสดุและวิธีการ: การศึกษานี้ได้ผ่านการรับรองจากคณะกรรมการจริยธรรมการวิจัยในคน คณะแพทยศาสตร์ ศิริราชพยาบาล ผู้เข้าร่วมศึกษาเป็นผู้ป่วยทั่วไปในเวลาราชการจำนวน 110 คนที่เข้ารับการตรวจทางเดินอาหารส่วนต้นด้วยวิธีการส่องกล้อง ไม่มีประวัติแพ้ยาชา ไม่มีการระคายเคืองในระบบทางเดินหายใจอันเนื่องมาจากการสูบบุหรี่ การติดเชื้อ การอุดกั้นทางเดินหายใจหรือโรคหอบหืด และผู้ป่วยโรคหัวใจ ผู้ป่วยทั้งหมดถูกสุ่มแยกออกเป็น 2 กลุ่มโดยใช้โปรแกรมคอมพิวเตอร์ กลุ่ม A ได้รับยาชาแบบพ่นบริเวณโคนลิ้นและทอนซิลทั้งสองข้างในขนาด 200 มิลลิกรัม แบ่งให้ 4 ครั้ง ๆ ละเท่า ๆ กัน ห่างกันทุก 5 นาที กลุ่ม B ได้รับยาชาแบบฝอยละอองในขนาด 250 มิลลิกรัมครั้งเดียว หลังจากนั้นผู้ป่วยทั้งสองกลุ่มจะได้รับการตรวจทางเดินอาหารส่วนต้นด้วยวิธีการส่องกล้องจากแพทย์คนเดียวกัน ผู้ร่วมศึกษาซึ่งไม่ทราบว่าผู้ป่วยแต่ละคนได้รับยาชาประเภทใด เป็นผู้สังเกตและประเมินความยากง่ายของการส่องกล้อง เช่นเดียวกับแพทย์ผู้ทำหัตถการ นอกจากนี้แพทย์ยังได้ประเมินความพึงพอใจในการใส่เครื่องมือพร้อม ๆ กับผู้ป่วยประเมินความพึงพอใจเกี่ยวกับการระงับความรู้สึกโดยใช้ Numerical rating scale โดยกำหนดนัยสำคัญเมื่อ p-value น้อยกว่า 0.05 ที่ระดับความเชื่อมั่นร้อยละ 95

ผลการศึกษา: การศึกษาไม่พบความแตกต่างระหว่างผู้ป่วยทั้งสองกลุ่มในเรื่องเพศ อายุ น้ำหนักและลักษณะทั่ว ๆ ไป ผู้ป่วยหนึ่งรายในกลุ่ม A ถูกคัดออกจากการศึกษาเนื่องจากหัตถการใช้ระยะเวลานานกว่าที่กำหนด ส่วนผู้ป่วยอีกสองรายในกลุ่ม B มีปัญหาหลอดลมหดเกร็งและมีประวัติการติดเชื้อในทางเดินหายใจส่วนบนมาก่อน แพทย์แสดงความพึงพอใจการทำหัตถการกับผู้ป่วยกลุ่ม A คิดด้วยคะแนน 84.8±8.3 ซึ่งแตกต่างจาก คะแนนของกลุ่ม B ที่คะแนน 79.2±11.2 อย่างมีนัยสำคัญ ในขณะเดียวกันผู้ร่วมศึกษายังสังเกตพบว่ากลุ่ม A ตอบสนองต่อการทำหัตถการได้ดีกว่ากลุ่ม B อย่างมีนัยสำคัญ การที่เป็นเช่นนั้นน่าจะเป็นเพราะว่า ยาชาชนิดฝอยละอองเกือบ 60% สูญเสียไปในสภาพแวดล้อมโดยรอบหรือในปากของผู้ป่วย ทำให้ยากต่อการคำนวณขนาดของยาที่เหมาะสมเพื่อให้ผู้ป่วยรู้สึกสบายในระหว่างการส่องกล้อง อย่างไรก็ตามผู้ป่วยส่วนใหญ่ให้การยอมรับการบริหารยาชาด้วยเทคนิคนี้มากกว่า

สรุป: แพทย์พึงพอใจการทำหัตถการภายใต้การใช้ยาชาเฉพาะที่ชนิดพ่นเนื่องจากใช้เวลาในการเริ่มทำหัตถการสั้นกว่าการสอดใส่เครื่องมือง่ายกว่า ผู้ป่วยมีอาการขย้อนและมีสารคัดหลั่งระหว่างการตรวจน้อยกว่า อย่างไรก็ตามเมื่อถามผู้ป่วยถึงความรู้สึกสัมผัส กลิ่น รสในระหว่างการบริหารยาชา อาการแสบคอและอาการกลืนลำบากแล้ว ผู้ป่วยส่วนใหญ่ให้การยอมรับการบริหารยาชาด้วยเทคนิคฝอยละอองมากกว่า