EFFECTIVENESS OF LIDOCAINE GEL LUBRICATION AS AN ADJUNCT TO LIDOCIAINE SPRAY FOR ADULT UNDERGOING UNSEDATED ESOPHAGOGASTRODUODENOSCOPY: A RANDOMIZE DOUBLE-BLIND PLACEBO COTROLLED TRIAL

[1]Alex Y. Pang Jr. MD, Mark Lester S. Sy MD, Rei Joseph P. Prieto MD, [2]Felix L. Domingo, MD, Marichona C. Naval, MD, Michael Angelo Chu MD, Lovell B. Gatchalian, MD
[1]Gastroenterology fellow in training, [2]Gastroenteorology Consultant,
Department of Internal Medicine- Section of Gastroenterology, East Avenue Medical Center

ABSTRACT

Significance: Lidocaine spray is the most commonly used topical pharyngeal anesthesia in unsedated Esophagogastroduodenoscopy (EGD). However, many patients still complain of severe discomfort due to gagging and pain cause by device. The addition of Lidocaine gel as a lubricant may improve patient's comfort while performing EGD.

Methods: This is a randomized parallel two-arm superiority double blind placebo-controlled trial conducted from March 2016 to June 2017. We randomly assigned 104 patients to receive either with Lidocaine gel 2% or placebo as a lubricant with Lidocaine spray 10% as pharyngeal anesthesia prior to unsedated EGD. The primary endpoints were patients' discomfort, and tolerance of the procedure. Secondary endpoints were throat pain, level of gagging, ease of procedure, willingness to repeat the same anesthetic for the next procedure and safety.

Results: Patients randomized to Lidocaine gel lubrication reported less throat pain (2.79 ± 1.04 vs. 3.94 ± 0.92, P<0.0001) and discomfort (4.17 ± 0.73vs. 5.06 ± 0.67, P<0.0001) than those who received placebo. In addition, overall level of gagging (2.6 + 0.77 vs. 3.7 + 0.73, P < .0001) and tolerability (4.04 + 0.71 vs. 3.65 + 0.59, P=0.0034) during the procedure were better compare to the placebo group.

Conclusion: The combination of Lidocaine spray and Lidocaine gel lubrication is safe and effective technique to improve patient comfort and tolerability of unsedated EGD procedure.
Keywords: Randomize, Double blind, Lidocaine gel, Esophagoduodenoscopy

INTRODUCTION

Background and significance of the study

Esophagoduodenoscopy (EGD) is a procedure that allows visualization of the oropharynx, esophagus, stomach, and proximal duodenum, with real-time assessment and interpretation of the findings encountered. It is the most common endoscopic procedure in clinical practice with an incidence of about 8.6 per 1000 population[4]. In the Philippines, patients undergoing diagnostic EGD are given the choice of being sedated or fully conscious during the procedure. The use of sedation in EGD improves patients' tolerance and has resulted in widespread acceptance of this procedure among both physician and patients, however, it has several disadvantages, such as prolonged duration of the procedure, increase cost and these sedative frequently cause significant oxygen desaturation, occasionally a cardiopulmonary complication and rarely death[5]. There are no well establish data which patient benefit most from sedation and a common practice is to allow patients themselves to choose whether or not to be sedated, after providing them with full information about the advantages and disadvantages of sedation[6-7].

Esophagoduodenoscopy can be performed without sedation[8-9]. Study have showed that performing unsedated EGD, although was less tolerated, did not lead to longer procedure times, higher risks or increase reluctance to undergo a repeat procedure[10]. However, patients usually experience discomfort while undergoing EGD due to a strong gag reflex[11]. To reduce the EGD-induce gag reflex and pain, EGD is generally performed using topical Lidocaine spray for anesthesia[12]. Lidocaine is to be applied specifically at different area of the pharynx, which will markedly attenuate or even ablate the gag reflex during the procedure. Currently, different formulations of Lidocaine are used as local pharyngeal anesthesia and are administrated as a gel, inhaler, or spray[13]. The use of Lidocaine in gel form in addition to the Lidocaine spray may be ideal since the Lidocaine gel is dense/sticky form and may provide additional anesthesia not reach by Lidocaine spray. One study showed that when Lidocaine spray and gel use are use together, there was improve compliance, anesthetization and decrease in anxiety of the patients[14]. Other studies show conflicting result regarding the ideal pharyngeal anesthesia [15,16].The purpose of this study is to compare the efficacy of Lidocaine spray plus Lidocaine gel and Lidocaine spray alone on patient tolerance to the procedure and ease of performance of the procedure.

RESEARCH QUESTION

Is Lidocaine gel as an adjunct to Lidocaine spray superior to using Lidocaine spray alone for increasing ease of performance, and patient's tolerance to Esophagoduodenoscopy?

OBJECTIVES

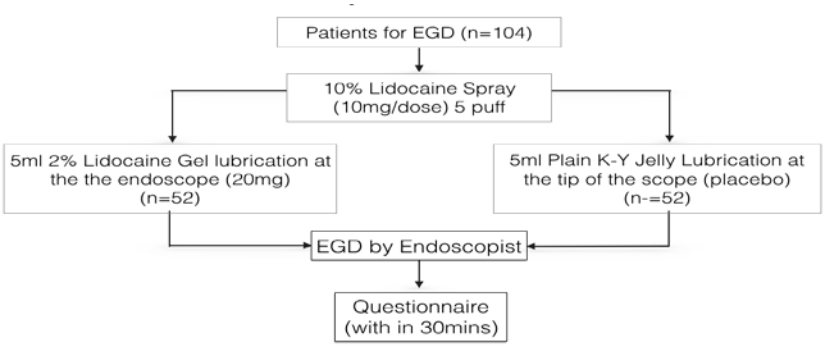
Primary Objective

To compare safety and effectiveness of Lidocaine gel as an adjunct to Lidocaine spray for patient tolerance and Discomfort during the procedure

Secondary Objectives

1. To compare the patients satisfaction of Lidocaine spray before procedure using a 5-point Likert Scale.
2. To compare the effectiveness of Lidocaine spray plus Lidocaine gel and Lidocaine spray plus placebo on patient's throat pain cause by the device as measured by a 100mm visual analog scale (VAS).
3. To compare the effectiveness of Lidocaine spray plus Lidocaine gel and Lidocaine spray plus placebo on patient's throat pain cause by the device as measured by a 100mm visual analog scale (VAS).
4. To compare the effectiveness of Lidocaine spray plus Lidocaine gel and Lidocaine spray plus placebo on ease of procedure reported by endoscopist using 5-point Likert Scales
5. To assess both physicians and patient willingness to repeat the same anesthetic that was use in the session for future procedure.
6. To assess the known side effects (nausea, vomiting, abdominal pain, cough and dyspnea) of local anesthesia between the application of topical anesthetic and the beginning of the procedure.

Diagram of the study process flow



Operational Definition/Definition of terms:

1. Unsedated EGD: Performing an upper gastrointestinal endoscopy without using any form of sedation (e.g. Midazolam, Fentanyl, Propofol).
2. Level of gagging: Frequency of severity of gagging during the procedure
3.

Limitation of the Study:

The cases were gathered from East Avenue Medical Center Gastro-intestinal unit from March 2016 to June 2017, reflecting conclusions only to this time and setting. Lidocaine dose was also different between the two group.

METHODOLOGY

Study design and setting

This is a randomized parallel two-arm superiority double blind placebo-controlled trial to be conducted at the EAMC Endoscopy Unit from March 2016 to June 2017.

Study Population

This study included adult patients who underwent esophagogastroduodenoscopy at East Avenue Medical Center-GI Clinic form March 2016 to June 2017

Inclusion Criteria

Adult patients aged 18 to 80 years old who will undergo diagnostic esophagogastroduodenoscopy

Exclusion Criteria

Adult patient who will undergo sedation during EGD, Patients who are pregnant or breastfeeding, with previously known allergy to Lidocaine, anatomic defect in the throat regions that might cause difficulty performing EGD, inability to answer questions (e.g. altered consciousness), patients with unstable hemodynamics (Systolic blood pressure <90 mmHg, pulse rate >100/min, Respiratory rate >20/min), intoxicated and patients with no written form of informed consent for research was excluded in this study.

Sample size determination

A minimum of 103 patients was required for this study, or 52 per arm, based on a level of significance of 5% and a power of 80% with an 0.558 effect size of patients anxiety score in the treatment Lidocaine spray + Lidocaine gel versus Lidocaine spray alone prior to upper gastrointestinal system (GIS) endoscopy. The computed sample size assumes that the proportion of patients to be assigned to the two groups is equal.

Randomization and Treatment

An independent research statistician generated block randomization codes, in permutation blocks of four, from a random generator program. The two arms are as follows: Group A: Total of 5 spray 10% Lidocaine spray (10mg/dose) with placebo (K-Y Jelly) Group B: Total of 5 spray 10% Lidocaine spray (10mg/dose) with 5ml 2% Lidocaine Gel (CATHAJELL) containing Lidocaine hydrochloride 2% and Chlorhexidine dihydrochloride 0.05%.

Criteria for Evaluation

Primary Efficacy Endpoints are discomfort cause by the device during the procedure and overall tolerance of the procedure. Secondary endpoints are satisfaction after being sprayed before the procedure, throat pain cause by the device to the~~,~~ level of gagging of the patient, willingness to use the same anesthetic procedure for the next EGD by the physician and the patient and complications/adverse events during and after the procedure. The primary and secondary endpoints were both measured using a Visual Analogue scale and a 5-point Likert scale.

Data Collection

All patient who underwent diagnostic endoscopy for various indications at East avenue medical center was recruited in this study if no exclusion criteria are met. The Medical resident or gastrointestinal fellow gathered the study population demographic data into structured forms. The primary investigator of this study carried out the randomization. The endoscopist as well as the patient was blinded to the randomization procedure to Lidocaine spray plus Lidocaine gel or Lidocaine spray alone. Questionnaire using VAS and 5-point Linker score was given to both endoscopist and patients after the EGD procedure.

Endoscopist assessments

Immediately after the procedure, the endoscopist answered in a questionnaire rating the quality of the procedure, the tolerability of the patient, and the level of the gag of the patient. Gag reflexes were manually assessed after the administration of the Lidocaine spray plus Lidocaine gel and Lidocaine spray alone at the onset of the procedure on a 5-point linker Scale (1 being absent gag reflex and 5 being strong gag reflex). Endoscopist also assessed if whether they were willing to choose the same anesthetic that was used in the session for the next EGD procedure.

Patient's assessments

The following data were gathered: Socio-demographic variables (age, sex, noxious habits (active daily smoker or alcohol intake >40g.day), body mass, symptoms of GERD), Prior experience of EGD, Pain and discomfort (VAS), Gag reflex (5 point Likert score), Endoscopist variable (Length of examination, Biopsy performed) and Endoscopist assessment (VAS)

After the procedure, patient was discharged to the recovery area were a blinded member of the research team interviewed the patient and filled up a questionnaire evaluating (1) patients satisfaction after administration of the anesthesia using a 5 point Linker scale (2) pain and discomfort of the procedure using 100mm VAS (3) tolerability of the procedure (4) whether they will choose the same anesthetic that was use in the session for the next EGD procedure. The subjects were asked to keep a patient diary noting the day and date they take their study drug and any adverse events. They were also asked to bring their patient diary to each study visit.

Data Analysis:

Descriptive statistics was used to summarize the clinical characteristics of the patients. Frequency and proportion was used for nominal variables, median and range for ordinal variables, and mean and SD for interval/ratio variables. Independent sample t-test, Mann-Whitney U test and Fisher's Exact/Chi-square test was used to determine the difference of mean, median and frequency between groups, respectively. All valid data was included in the analysis. Missing variables was neither replaced nor estimated. Confidence interval was set at 0.05α-level of significance. STATA 12.0 was used for data analysis.

Ethical consideration:

The protocol was approved by the Technical Review Board of the East Avenue Medical Center. All data was collected at the Gastroenterology and Pathology section of East Avenue medical Center. No potential conflicts of interest have been identified. The principal investigators and co-investigators report no disclosures.

RESULTS

Demographic and clinical profile

We enrolled 104 patients randomized equally to Lidocaine gel or placebo. They were in their early 50s, had a slight preponderance of males, and were mostly of normal BMI. Less than one-fifth in each group were smokers, while roughly one in ten were alcohol drinkers. Only a few have undergone EGD before, and the most common indications for the current one was dyspepsia (51%) and GI bleeding (22%). The time from beginning to end of the procedure took a median of 5 to 6 minutes (Table 1).

Table 1. Demographic and clinical profile by treatment arm (n = 104)

	Lidocaine Gel (n = 52)	Placebo Gel (n = 52)	P-value
	Frequency (%); Mean ± SD; Median (Range)		
Age (years)	53.6 ± 9.85	53.94 ± 10.4	0.877*
Height (cm)	157.52 ± 7.99	157.15 ± 8.1	0.811*
Weight (kg)	52.9 ± 8.96	53.71 ± 11.2	0.685*
BMI	21.48 ± 4.3	21.8 ± 4.7	0.686*
Sex			0.693§
Male	30 (57.7)	28 (53.85)	
Female	22 (42.3)	24 (46.15)	
Smoker	9 (17.3)	8 (15.4)	0.791§
Alcohol drinker	6 (11.5)	5 (9.6)	0.750§
Prior experience of EGD	5 (9.62)	4 (7.7)	0.727§
Indication for EGD			0.942‡
Dyspepsia	25 (48.08)	28 (53.85)	
Melena	12 (23.08)	11 (21.15)	
Dysphagia	2 (2.85)	2 (3.85)	
Hematemesis	4 (7.69)	5 (9.62)	
Caustic injury	9 (17.31)	6 (11.54)	
Duration of EGD procedure (mins)	6 (3 to 11)	5 (3 to 9)	0.417ƨ

EGD, esophagogastroduodenoscopy. Statistical tests used: * - Independent sample t test; ƨ - Mann-Whitney U test; § - chi square test; ‡ - Fisher's exact test.

Outcomes of EGD by treatment arm

Patients randomized to Lidocaine gel lubrication gave lower ratings of pain (2.79 ± 1.04 vs. 3.94 ± 0.92, P<0.0001) and discomfort (4.17 ± 0.73vs. 5.06 ± 0.67, P<0.0001) on VAS than did those who received placebo (Table 2). In addition, overall level of gagging (2.6 + 0.77 vs. 3.7 + 0.73, P < .0001) and tolerability (4.04 + 0.71 vs. 3.65 + 0.59, P=0.0034) during the procedure were better compare to the control. There were no difference in the duration of the procedure, satisfaction after being spray before the procedure, ease of procedure reported by the endoscopist, willingness to choose the same anesthetic for the next procedure and complication between the two groups. (Table 2)

Table 2. Outcomes of EGD by treatment arm (n = 104)

	Lidocaine Gel (n = 52)	Placebo Gel (n = 52)	P-value
	Frequency (%); Mean ± SD		
Throat Pain cause by the device VAS score	2.79 ± 1.04	3.94 ± 0.92	<0.0001*
Discomfort cause by the device VAS score	4.17 ± 0.73	5.06 ± 0.67	<0.0001*
Patients satisfaction after being sprayed	4.19 ± 0.53	4.10 ± 0.57	0.373*
Level of gag during procedure (patient)	2.6 ± 0.77	3.7 ± 0.73	<0.0001*
Tolerability of the procedure	4.04 ± 0.71	3.65 ± 0.59	0.0034*
Ease of the procedure (physician)	4.12 ± 0.47	3.98 ± 0.58	0.195*
Adverse events (cough)	3 (5.77)	4 (7.69)	1.000‡
Failure to complete the procedure	0	0	-
For patient: willing to use the same anaesthetic for the next EGD procedure	37 (71.15)	33 (63.46)	0.403§
For physician: willing to use the same anaesthetics for the next EGD procedure	46 (88.46)	44 (84.62)	0.566§

Except for pain and discomfort, which were measured by Visual Analog Scale (VAS), other outcomes were rated on a Likert scale of 1 to 5 (1-very unsatisfied; 2-unsatisfied; 3-neutral; 4-satisfied; 5-very satisfied).
*Statistical tests used: * - Independent sample t test; § - chi square test; ‡ - Fisher's exact test.*

DISCUSSION:

Conscious sedation during upper GI 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. [17, 18]

Conscious sedation is troublesome because of limited time and space in busy endoscopy units. [27] Various studies revealed that diagnostic upper GI endoscopy without sedation is safe, doable, and repeatable.[1,18,19,20,21]. Unsedated procedures have advantages, such as reduction of hypoxemia and cardiopulmonary side effects, short duration of the procedure, ability to drive immediately after the procedure, and ability to resume work. [7,20] 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.[22]

Risk factors for poor tolerance to upper GI endoscopy are high level of anxiety, young age and a strong gag reflex.[23, 24] Local oropharyngeal anesthesia including Lidocaine has been studied in several trials with the results showing that the use of the Lidocaine spray or gel with IV sedation increased the tolerability and ease of the procedure and reduced the risk of discomfort during the procedure. [13,25]

The action of local oropharyngeal anesthesia is achieved mainly by inhibiting the gag reflex which is one of the most important factors affecting the tolerability and ease of the procedure.[13, 23] So in order to perform the procedure without possibly using IV sedation, an effective local agent that suppresses the gag reflex should be used.

A study by Soweid et al. revealed that Lidocaine gel is applied to the posterior lingual area, is an effective mode of local anesthesia for local endoscopy, effectively suppresses the gag reflex, significantly increases the patient tolerability to the procedure, improves endoscopist satisfaction of the procedure, and considerably decreases the need for IV sedation. This approach can lead to reduction in the use of IV sedatives (and potentially their complications) and may decrease the overall cost of the procedure. [26]

Amornyotin et al. [27] compared lidocaine spray and its viscous form found out that the spray form increased patient and physician satisfaction, decreased pain, and made intubation easier; however, combined usage was not compared in this study. The study also showed that anxiety scores measured before endoscopy had a significant effect over tolerance. [28] Similarly, Cam et al.[29] discussed that the application of the spray or gel form alone did not provide a significant difference but when used together, these drug forms increased compliance and anesthetization and decreased anxiety scores in patients. It is believed that the gel's lubricating effect is also important for this satisfaction. Our study reveals that combination lidocaine spray and gel improved overall level of gagging and tolerability of procedure with no significant difference in the duration of the procedure, satisfaction after being spray before the procedure, ease of procedure reported by the endoscopist, willingness to choose the same anesthetic for the next procedure and complication between the two groups.

In clinical practice in our setting, incorporating this combination pre-procedural modality would be advantageous in terms of level of gagging, tolerability of procedure and decreasing the cost for sedation compared to Lidocaine spray alone and/or general anesthesia to eligible patients who would undergo EGD.

CONCLUSION: The combination of Lidocaine spray and Lidocaine gel lubrication is safe and effective technique to improve patient comfort and tolerability of unsedated EGD procedure.

RECOMMENDATIONS: The combination of Lidocaine spray and lidocaine gel lubrication should be offered as treatment option to eligible patients. A larger prospective clinical trial is recommended for further investigation of clinical parameters (e.g. Duration of the procedure, satisfaction after being spray before the procedure, ease of procedure reported by the endoscopist, willingness to choose the same anesthetic for the next procedure and complication) with regards to this combination pre-procedural modality. Increasing the Lidocaine spray instead of adding Lidocaine gel is also an area that could be explored in future studies.

REFERENCE

1. Hedenbro JL, Lindblom A. patient attitude to sedation for diagnostic upper endoscopy. Scand J Gastroenterol 1991;26:1115-1120.
2. Arrowsmith JB, Gerstman BB, Fleischer DE, et al. Results from American society for gastrointestinal endoscopy/U.S. food and drug administration collaborative study on complication rates and drug use during gastrointestinal endoscopy. Gastrointest Endosc 1991;37:421-427
3. Frohlich F, Gonvers JJ, Fried M, Concious sedation, clinical relevant complication and monitoring of endoscopy; results of a nationwide survey in Switzerland. Endoscopy 1994;26:231-234
4. Scott BB. Gastroenterology in the trent region in 1992 and a review of changes since 1975. Gut. 1995;36:468–72
5. Arrowsmith JB, Gerstman BB, Fleischer DE, Benjamin SB. Results from the American Society for Gastrointestinal Endoscopy/U.S. Food and Drug Administration collaborative study on complication rates and drug use during gastrointestinal endoscopy. Gastrointest Endosc. 1991;37:421–7
6. Tan CC, Freeman JG. Throat spray for upper gastrointestinal endoscopy is quite acceptable to patients. Endoscopy 1996; 28:277-282
7. Pereira SP, Hussani SH, Hanson PJV, et al. Endoscopy; throat spray or sedation? J R Coll Physician Lond 1994; 28:411-414
8. Mosca S, Balzano A, Amitrano N, et al. Is routine sedation and/or local anesthesia necessary for diagnostic esophagogastroduodenoscopy? Endoscopy 1988; 20:51
9. Beavis AK, La Brooy S, Misiewicz JJ. Evaluation of one-visit endoscopic clinic for patients with dyspepsia. BMJ 1979; 1:1387-1389
10. Bonta PI, Kok MF, Bergman JJ, Van den Brink GR, Lemkes JS, Tytgat GN, et al. Conscious sedation for EUS of the esophagus and stomach: A double-blind, randomized, controlled trial comparing midazolam with placebo. Gastrointest Endosc. 2003;57:842–7
11. Garg PK, Singh AP, Jain BK, Bansal A, Mohanty D, Agrawal V. Safety and acceptance of non-sedated upper gastrointestinal endoscopy: a prospective observational study. *J Laparoendosc Adv Surg Tech A*. 2012;22(4):315–318.
12. al-Atrakchi HA. Upper gastrointestinal endoscopy without sedation: a prospective study of 2000 examinations. *Gastrointest Endosc*. 1989;35(2):79–81.
13. 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(4): 786–793.
14. Çam H, Pehlivan S, Dağ MS, Yılmaz N, Demir U, Gülşen MT.. Study of ideal topical pharyngeal anesthesia in upper gastrointestinal system endoscopy: A double-blind, randomized, controlled trial. *Turk J Gastroenterol* 2016; 27(2):103-107. https://www.ncbi.nlm.nih.gov/pubmed/26853792 (accessed 17 March 2017).
15. Ristikankare M, Hartikainen J, Heikkinen M, Julkunen R. Is routine sedation or topical pharyngeal anesthesia bene cial during up- per endoscopy? Gastrointest Endosc 2004; 60: 686-94
16. Ayoub C, Skoury A, Abdul-Baki H, Nasr V, Soweid A. Lidocaine lollipop as single-agent anesthesia in upper GI endoscopy. Gas- trointest Endosc 2007; 66: 786-93.
17. 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.
18. 18. 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.
19. al-Altrakchi HA. Upper gastrointestinal endoscopy without sedation: a prospective study of 2000 examinations. Gastrointest Endosc 1989; 35: 79-81.
20. 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.
21. 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.
22. 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.
23. Campo R, Brullet E, Montserrat A, Calvet X, Moix J, Rué M, Roqué M, Donoso L, Bordas JM. Identification of factors that influence tolerance of upper gastrointestinal endoscopy. *Eur J Gastroenterol Hepatol* 1999; 11: 201-204

24. Mulcahy HE, Kelly P, Banks MR, Connor P, Patchet SE, Farthing MJ, Fairclough PD, Kumar PJ. Factors associated with tolerance to, and discomfort with, unsedated diagnostic gastroscopy. *Scand J Gastroenterol* 2001; 36: 1352-1357
25. 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: 14-18
26. Soweid AM et al. Posterior lingual lidocaine swab and EGD *World J Gastroenterol* 2011 December 21; 17(47): 5191-5196
27. 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.
28. 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.
29. Çam et al. Pharyngeal anesthesia in gastrointestinal endoscopy *Turk J Gastroenterol 2016; 27: 103-7*
.

APPENDIX 1: QUESTIONAIRE/VISUAL ANALOGUE SCALE

Name				Age		Sex		Date	
Height		Weight		BMI					
Smoker	Yes	No		Alcohol		Yes	No		
Prior EGD	Yes	No		Indication for EGD					
QUESTION (Patient)									
1. I am satisfied with the Lidocaine spray anesthetizing my throat.									
Strongly Disagree		Disagree		Neutral		Agree		Strongly Agree	
1		2		3		4		5	
2. What was your pain level in your throat during the procedure of the scope?									
None				Moderate					Severe
1	2	3	4	5	6	7	8	9	10
3. What was the level of overall discomfort during the procedure?									
None				Moderate					Severe
1	2	3	4	5	6	7	8	9	10
4. What was your level of gag during the procedure?									
None				Moderate					Severe
1	2	3	4	5	6	7	8	9	10
5. The Upper endoscopy procedure was tolerable									
Strongly Disagree		Disagree		Neutral		Agree		Strongly Agree	
1		2		3		4		5	
5. Are you willing to use the same anesthetic for the next EGD procedure?								Yes	No
ENDOSCOPIST ASSESSMENT									
1. The procedure was easy to performed									
Strongly Disagree		Disagree		Neutral		Agree		Strongly Agree	
1		2		3		4		5	
2. Are you willing to use the same anesthetic for the next EGD procedure?								Yes	No

APPENDIX 2 ENGLISH INFORMED CONSENT

INFORMATION SHEET

Title of the Clinical Research:

"Effectiveness of Lidocaine jelly lubrication as an adjunct to Lidocaine spray for adults undergoing Esophagoduodenoscopy: a randomized double-blind placebo-controlled trial"
"

Investigators:

Alex Pang, M.D., Internal Medicine - Gastroenterologist.
East Avenue Medical Center, East Avenue, Quezon City, Philippines
Contact number: 09199932613

This document is to certify that I hereby freely agree to participate as a volunteer in a research study as an authorized part of the educational and research program of East Avenue Medical Center under the supervision of Dr. Alex Pang Jr.

Please √ Initial Box

1. I have been given sufficient information about this clinical research. The purpose of my participation in this research has been explained to me and is clear. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason. ☐
3. I confirm that my participation involves being interviewed from East Avenue Medical Center. I allow the researcher to take written notes during the interview. It is clear to me that in case I do not want the interview to be noted, I am at any point of time fully entitled to withdraw from participation. ☐
4. I agree that my health information related to this study may be used or disclosed in connection with this clinical research by the investigators, EAMC IERB and any other unit of EAMC.
5. I have been given the explicit guarantees that, if I wish so, the researcher will not identify me by name or function in any reports using information obtained from this interview, and that my confidentiality as a participant in this research will remain secure. ☐
6. I have been given guarantee that this research project has been reviewed and approved by East Avenue Medical Center Institutional Ethics Review Board. For research problems or any question regarding the research project, East Avenue Medical Center Institutional Ethics Review Board may be contacted through (contact person at IERB). ☐
7. I confirm that I have read and understood the points and statements of this form. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study. ☐
8. I have been given a copy of this consent form signed by the investigator. ☐

Name of participant _____ Age: ___ Gender: _____

Address: _____ Phone #:_____

_____ _____

Signature of Participant Date

_____ _____ _____

Name of Researcher/Interviewer Date Signature

Title of the Clinical Research:

"Effectiveness of Lidocaine jelly lubrication as an adjunct to Lidocaine spray for adults undergoing Esophagoduodenoscopy: a randomized double-blind placebo-controlled trial"

Investigators:

Alex Pang, M.D., Internal Medicine - Gastroenterologist.
East Avenue Medical Center, East Avenue, Quezon City, Philippines
Contact number: 09199932613

Ang dokumentong ito ay upang patunayan na ako sa pamamagatin nito ay malayang sumasang-ayon upang lumahok bilang isang boluntaryo sa isang pag-aaral at pananaliksik sa East Avenue Medical Center sa ilalim ng pangangasiwa ni Dr. Alex Pang Jr.

		Please √ Initial Box
9.	Ako ay nabigyan ng sapat na impormasyon tungkol sa klinikal na pananaliksik na ito. Ang layunin ng aking paglahok sa pananaliksik na ito ay ipinaliwanag sa akin at ito ay malinaw.	☐
10.	Naiintindihan ko na ang aking paglahok ay boluntaryo at ako ay malaya na bawiin sa anumang oras na walang ibinibigay na dahilan.	☐
11.	Kinukumpirma ko na ang aking paglahok ay nagsasangkot ng pakikipanayam mula sa East Avenue Medical Center. Pinapahintulutan ko ang mananaliksik na magtala sa panahon ng pakikipanayam. Ito ay malinaw sa akin na kung sakaling hindi ko gusto ang panayam na itala, ako ay may karapatan na bawiin ang aking pakikilahok sa anumang oras..	☐
12.	Ako ay sumasang-ayon na ang aking impormasyong pangkalusugan na may kaugnayan sa pag-aaral na ito ay maaaring gamitin o isiwalat na may kaugnayan sa ganitong klinikal na pananaliksik sa pamamagitan ng mga mananaliksik, EAMC IERB at anumang iba pang yunit ng EAMC.	☐
13.	Ako ay nabigyan ng malinaw na garantiya na, kung nais ko, ang mananaliksik ay hindi ibubunyag ang aking pagkakakilanlan sa pamamagitan ng pagbibigay ng pangalan o tungkulin sa anumang mga ulat na gamit ang mga impormasyon na nakuha mula sa pakikipanayam na ito, at ang aking pagiging kompidensyal bilang isang kalahok sa pananaliksik na ito ay mananatiling ligtas.	☐
14.	Ako ay nabigyan ng garantiya na ang pananaliksik na ito ay sinuri at inaprubahan ng East Avenue Medical Center Institutional Ethics Review Board. Para sa mga problema sa pananaliksik o anumang mga katanungan tungkol sa proyektong pananaliksik na ito, maaaring makipag-ugnayan sa East Avenue Medical Center Institutional Ethics Review Board sa pamamagitan ng telepono bilang (632) 928.0611 local 739.	☐
15.	Kinukumpirma ko na nabasa ko at naintindihan ang mga puntos at mga pahayag ng pahintulot na ito. Ang lahat ng aking katanungan ay nasagot sa aking kasiyahan, at ako ay boluntaryong sumang-ayon na lumahok sa pag-aaral na ito.	☐

16. Ako ay binigyan ng kopya ng form ng pahintulot na may lagda ng mananaliksik. ☐

Pangalan_____ Edad: _____ Kasarian: _____

Tirahan: _____ Telepono:_____

_____ _____

Lagda sa itaas ng pangalan Petsa

_____ _____ _____

Pangalan ng Mananaliksik Petsa Lagda