Research Article
Open Access

Adverse event rate of unsedated esophagogastroduodenoscopy:a comparison between healthy adults and cirrhotic patients

Abstract

This study was aimed to evaluate and compare the adverse event rate of pharyngeal anesthesia when the topical lidocaine is used as a single agent for unsedated esophagogastroduodenoscopy (UEGD) between healthy adults and cirrhotic patients. Retrospectively analyzed the patients on whom UEGD procedures had been performed during the period of June, 2008 to December, 2009 in Siriraj Hospital. Patients were categorized into two groups. Group A was the healthy adults. Group B was the cirrhotic patients. The primary outcome variable was the adverse event rate. Secondary outcome variables were anesthesia and procedure–related adverse events, and mortality rate. There were 1,398 patients who underwent UEGD procedure during the study period. After matching age, gender, weight, height and duration of procedure, there were 131 patients in group A and 129 patients in group B. All pharyngeal anesthesia was given by residents or anesthetic nurses directly supervised by staff anesthesiologist in the endoscopy room. There were no significant differences in age, gender, weight, height, duration of procedure, and overall adverse event rate between the two groups. Hypertension in group B was significantly greater than in group A. However, tachycardia and hypertension in group B was significantly lower than in group A. All adverse events were transient, easily treated, with no adverse sequelae. UEGD in healthy adults and cirrhotic patients was safe and effective. Although, overall adverse event rate was relatively high, however, all adverse events in both groups were comparable, mild degree, transient and easily treated. No serious adverse events were observed in these two groups.

Keywords: Esophagogastroduodenoscopy; Unsedated; Adverse event; Cirrhosis; Healthy

Volume 5 Issue 3 - 2016

Somchai Amornyotin, Wiyada Chalayonnawin, Siriporn Kongphlay
Department of Anesthesiology and Siriraj GI Endoscopy Center, Mahidol University, Thailand

Correspondence: Somchai Amornyotin, Department of Anesthesiology and Siriraj GI Endoscopy Center, Faculty of Medicine Siriraj Hospital, Mahidol University, 2, Siriraj, Bangkoknoi, Bangkok 10700, Thailand, Tel +662 419 7990, Fax +662 411 3256, Email somchai.amo@mahidol.ac.th

Received: June 17, 2016 | **Published:** September 16, 2016

Abbreviations: UEGD; Unsedated Esophago Gastro Duodenoscopy, ASA; American Society of Anesthesiologists, SD; Standard Deviation, %; Percentage

Introduction

Cirrhosis is a common cause of mortality worldwide. The role of endoscopy in liver cirrhosis is of increasing value in the diagnosis and management.[1] Esophagogastroduodenoscopy (EGD) procedure is commonly utilized for the patients with liver cirrhosis. Generally, unsedated EGD procedures are used even in these cirrhotic patients. Several previous studies suggested that many patients who received adequate information about the procedure select not to have sedation.[2,3] In Thailand, most of diagnostic EGD procedures are accomplished with topical pharyngeal anesthesia. Topical pharyngeal anesthesia before these procedures is demonstrated to increase patient tolerance and completion of procedure.[4-6] There have not been any studies directly comparing the adverse events of UEGD procedure between healthy adults and cirrhotic patients.

Materials and methods

Patients

The study was accomplished from June 2008 to December 2009 at a World Gastroenterology Organization Endoscopy Training Center, Siriraj Hospital, Thailand. Patients with age at least 18 years of age who presented for diagnostic EGD were eligible for the study. Exclusion criteria included procedure requiring intravenous sedation, patients with clinical evidence of hepatic encephalopathy, and American Society of Anesthesiologists (ASA) physical status of class IV or V.

Study design

This study was a retrospective study. Patients were categorized into two groups. Group A was the healthy adults. Group B was the cirrhotic patients. Pharyngeal anesthesia either with topical viscous lidocaine solution and/or lidocaine spray was performed in the pre–procedure room. The primary outcome variable was the adverse event rate. The secondary outcome variables were anesthesia and procedure–related adverse events, and mortality rate. Successful endoscopic procedure was defined as completion of the procedure as intended without additional intravenous sedation once the procedure started.

The procedure was performed by either gastroenterology fellow supervised by staff attending physician or by the staff endoscopist. Olympus video esophagogastroduodenoscope (GIF–Q 180, Olympus Corporation, Tokyo, Japan) was used for all EGD procedures. All patients were monitored in standard manner for noninvasive blood pressure, heart rate, electrocardiogram, and oxygen saturation with pulse oximetry. No other premedications were administered before the procedure. Pharyngeal anesthesia was administered by the nurse anesthetist or resident in anesthesiology supervised by the staff anesthesiologist in the pre–procedural room.

The alteration in hemodynamic profiles was considered as adverse event if any of the following was detected:hypertension or hypotension (increase or decrease in blood pressure by 25% from baseline), tachycardia or bradycardia (increase or decrease in heart rate by 25% from baseline), and oxygen desaturation (SpO_2 < 90%).

©2016 Amornyotin et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and build upon your work non-commercially.

Copyright: ©2016 Amornyotin et al.

Additionally, other symptoms such as sore throat, nausea, or vomiting were also recorded as adverse event. The procedure–related adverse events were classified as in British Society of Gastroenterology.[7]

Statistical analysis

Results were expressed as mean ± standard deviation (SD) or percentage (%), when appropriate. Comparisons between group A and B were compared by using χ^2 tests (for categorical variables), χ^2 square tests for trend (for ordinal variables), and two–sample independent t–test (for continuous variables). The statistical software package SPSS for Windows (Version 18; SPSS, Inc, Chicago, IL) was used to analyze the data. All statistical comparisons were made at the two–sided 5% level of significance.

Results

A total of 1,398 UEGD procedures were performed during the study period. After matching age, gender, weight, height and duration of procedure, there were 131 patients in group A and 129 patients in group B. Table 1 summarized the patients' characteristics, duration of procedure and endoscopy success rate of the two groups. All UEGD procedures in both groups were successfully completed. There were no significant differences in age, gender, weight, height, duration of procedure and endoscopy success rate between the two groups. All patients in group A had ASA physical status I. All patients in group B had ASA physical status II and III.

Table 1 Characteristics of patients, duration of procedure and endoscopy success (mean, SD and percentage)

	Group A (n=131)	Group B (n=129)	*P* value
Age (yr) (mean, SD)	43.3 (11.6)	50.0 (8.6)	0.33
Gender (%):Male	78 (59.5)	91 (70.5)	0.063
Female	53 (40.5)	38 (29.5)	
Weight (kg) (mean, SD)	58.7 (10.4)	61.3 (12.2)	0.173
Height (cm) (mean, SD)	161.8 (7.7)	161.7 (7.4)	0.743
ASA physical status (%)			< 0.001*
I	131 (100.0)	0	
II	0	69 (53.5)	
III	0	60 (46.5)	
Duration of procedure (min)			
(mean, SD)	10.3 (4.7)	11.2 (4.7)	0.429
Endoscopy success (%)	131 (100.0)	129 (100.0)	1

Group A:Healthy adults; Group B:Cirrhotic patients

*considered to be of statistical significance

Table 2 demonstrated anesthesia and procedure–related adverse events during and immediately after endoscopy, and the mortality rate. The overall adverse event rate occurred in 44 patients (33.7%) in group A and 32 patients (24.9%) in group B (p=0.120). Most of anesthesia–related adverse events were hemodynamic alterations including tachycardia and hypertension. Hypertension in group B occurred more frequently than in group A. Tachycardia and hypertension in group A was significantly higher than in group B. However, the overall adverse event rate in both groups was comparable. These alterations were transient, mild degree and did not require any specific interventions. In addition, there were no procedure–related adverse events and the mortality rate in both groups.

Table 2 Anesthesia and procedure–related adverse events during and immediately after endoscopy, and mortality rate (n, %)

	Group A (n=131)	Group B (n=129)	P value
Overall	44 (33.7)	32 (24.9)	0.12
Anesthesia–related	44 (33.7)	32 (24.9)	0.12
Tachycardia	23 (17.6)	13 (10.1)	0.081
Hypertension	5 (3.8)	18 (14.0)	0.004*
Tachycardia and hypertension	16 (12.3)	1 (0.8)	< 0.001*
Procedure–related	0	0	
Mortality rate	0	0	

Group A:Healthy adults; Group B:Cirrhotic patients

*Considered to be of statistical significance.

The hemodynamic parameters including systolic and diastolic blood pressure, heart rate and oxygen saturation were showed in Table 3. There were no significant differences in systolic and diastolic blood pressure as well as heart rate at all time points between the two groups. Oxygen saturation in 5 min after insertion of the endoscope in the cirrhotic patients was significantly lower than in the healthy adults (p=0.005). However, oxygen saturation at the other periods in both groups was not significantly different.

Discussion

UEGD is considered to be safe, feasible, quick, and well tolerated procedure. Additionally, the unsedated procedure is well accepted as demonstrated by patients' willingness to repeat the procedure under similar conditions.[4,6,8] Several advantages of UEGD have been reported. However, the potential benefit from the use of topical anesthetic preparations in the cirrhotic patients for UEGD procedure remains controversial. The primary outcome variable of this study was the adverse event rate. The secondary outcome variables were anesthesia and procedure–related adverse events, and mortality rate. Overall adverse event rate in the healthy group was relatively high. However, there was not significantly different between the two groups. Hypertension in the cirrhotic group was significantly greater than in the healthy group. In contrast, tachycardia and hypertension in the healthy group was relatively higher than in the cirrhotic group. These alterations were anesthesia–related adverse events. The procedure–related adverse events and mortality rate in both groups were none.

To date, the data regarding the safety of UEGD procedure in the cirrhotic patients are limited, and there are no large prospective studies that address safety. In addition, there are limited studies comparing of UEGD in the healthy adults and the cirrhotic patients. The present study is the first study comparing the adverse event rate during and immediately after UEGD procedure between healthy adults and cirrhotic patients. A previous study evaluated whether UEGD procedure could be used to screen for varices and to assess the tolerance of this procedure in the patients with hepatic dysfunction. The result of this study confirmed that all patients tolerated the procedure without significant discomfort. Topical pharyngeal anesthesia then became important in facilitating patient's tolerance to this procedure. UEGD procedure was a safe and cost–effective technique for variceal screening.[9]

An impact of topical pharyngeal anesthesia for UEGD procedure in the cirrhotic patients had been evaluated in our previous study.[10]

Citation: Amornyotin S, Chalayonnawin W, Kongphlay S. Adverse event rate of unsedated esophagogastroduodenoscopy:a comparison between healthy adults and cirrhotic patients. *Gastroenterol Hepatol Open Access.* 2016;5(3):78–81. DOI: 10.15406/ghoa.2016.05.00142

The study demonstrated the efficacy of topical pharyngeal anesthesia for UEGD procedure in the cirrhotic patients. All UEGD procedures were successfully completed. The use of topical pharyngeal anesthesia was safe with rare serious adverse events. Although, anesthesia–related adverse events were relatively high, however, these adverse events were mild, transient, with no specific interventions. Topical pharyngeal anesthesia might be a worthy technique for diagnostic UEGD procedure in the cirrhotic patients.[10]

For hemodynamic profiles, several previous reports have been demonstrated that the alteration of hemodynamic profiles during UEGD procedure was transient and did not require any specific interventions. The previous studies also confirmed that oxygen desaturation during UEGD procedure happened both in the cirrhotic group and in the control group. The cirrhotic patients did not have an increased risk of oxygen desaturation during this procedure.[11]. In this present study, the alteration of hemodynamic parameters including systolic and diastolic blood pressure, heart rate and oxygen saturation in both groups was comparable to the previous studies. Although, mean oxygen saturation at 5 min after the insertion of endoscope in the cirrhotic patients was significantly lower than in the healthy patients, however, these alterations were mild, transient and easily managed without adverse sequelae. These hemodynamic alterations are probable a result of the procedural stress. Our previous study evaluated and compared the anesthesia–related adverse event rate and the alteration of blood pressure and heart rate in UEGD procedure between elderly patients and younger patients. Anesthesia–related adverse event rate and alterations of blood pressure and heart rate during and immediately after UEGD procedure in the elderly patients are relatively high. However, these adverse events and the alterations of hemodynamic parameters in the elderly (aged ≥ 65 years) patients did not higher than in the younger (aged < 65 years) patients. All of these events are mild and transient.[12] The result of the previous study was comparable to the present study.

Table 3 Clinical and biochemical variables of individuals with overweight–obesity

	Group A (n=131)	Group B (n=129)	P value
Baseline			
SBP, DBP	127.2 (14.8), 76.4 (11.4)	123.1 (13.2), 72.3 (11.6)	0.276, 0.052
HR, SpO_2	76.2 (10.5), 99.1 (1.2)	72.1 (11.3), 99.0 (1.3)	0.208, 0.524
At insertion			
SBP, DBP	136.7 (18.4), 80.7 (16.8)	132.6 (19.0), 76.4 (14.9)	0.305, 0.068
HR, SpO_2	89.5 (15.8), 99.0 (1.4)	81.1 (14.6), 98.6 (1.5)	0.163, 0.179
5 min after insertion			
SBP, DBP	136.8 (20.5), 78.9 (14.3)	133.2 (19.9), 74.3 (13.5)	0.634, 0.275
HR, SpO_2	88.8 (16.1), 99.3 (1.2)	81.6 (14.1), 98.8 (1.4)	0.082, 0.005*
10 min after insertion			
SBP, DBP	134.2 (21.1), 76.8 (13.9)	126.9 (19.3), 72.6 (13.6)	0.456, 0.221
HR, SpO_2	85.1 (15.5), 99.1 (1.3)	78.9 (14.3), 99.0 (1.2)	0.224, 0.181
15 min after insertion			
SBP, DBP	126.5 (14.9), 76.1 (17.2)	126.0 (16.8), 74.5 (13.4)	0.629, 0.809
HR, SpO_2	87.6 (12.2), 98.7 (1.5)	77.6 (13.8), 99.0 (1.2)	0.525, 0.611
20 min after insertion			
SBP, DBP	119.4 (13.9), 72.8 (11.1)	131.3 (21.7), 75.4 (11.4)	0.634, 0.711
HR, SpO_2	81.6 (13.5), 99.1 (1.1)	82.3 (11.1), 98.9 (1.2)	0.415, 0.329

SD; Standard Deviation, BMI; Body Mass Index, WC; Waist Circumference, AC; Abdominal Circumference, HC; Hip Circumference, RER; Respiratory Exchange Ratio, HR; Hear Rate.

Several factors associated with successful completion of UEGD procedure have been described. These included older age, male gender, lower level of pre–endoscopic anxiety, smaller endoscope diameter, and history of previous unsedated endoscopy.[13,14] In our previous study, the type of topical lidocaine was also a factor related with successful completion of UEGD procedure. The use of lidocaine spray in UEGD procedure was presented to result in a higher procedural completion rate, better ease of intubation, and superior patient and endoscopist satisfaction compared with the use of viscous lidocaine solution. In addition, a procedural completion rate in both types of topical lidocaine was more than 90%.[4] All UEGD procedures in the present study were successfully completed. These might be due to we selected patients who presented for diagnostic EGD procedures.

There are several limitations in this study. First, our study is a retrospective study. Some limitations might be occurred. Second, the authors did not assess pre–procedure anxiety which has been shown to be a factor that had been influenced the outcome of the study. Third, the UEGD procedures were performed by variety of endoscopists including fellow in training. Therefore, the varied experience may have biased the result including the adverse event rate and the successful completion rate. However, this effect might be small because of high successful completion of the procedures and equivalent amount of time used for the completion of the procedures in both groups. Overall, despite these limitations, we are confident, however, that these findings are generalizable to the practice of topical pharyngeal anesthesia for UEGD procedure in the cirrhotic patients.

Conclusion

UEGD procedure in healthy adults and cirrhotic patients was effective and safe with rare serious adverse events. Its efficacy in the cirrhotic patients was not different or worse than in the healthy adults. Topical pharyngeal anesthesia might be a worthy technique for use in UEGD procedure even in the cirrhotic patients.

References

1. Krystallis C, Masterton GS, Hayes PC, et al. Update of endoscopy in liver disease:more than just treating varices. *World J Gastroenterol.* 2012;18(5):401–411.
2. Early DS, Ben–Menachem T, Decker GA, et al. Appropriate use of GI endoscopy. *Gastrointest Endosc.* 2021;75(6):1127–1131.
3. Periera SP, Hussaini SH, Hanson PJV, et al. Endoscopy:throat spray or sedation. *J R Coll Physicians Lond.* 1994;28(5):411–414.
4. Amornyotin S, Srikureja W, Chalayonnavin W, et al. Topical viscous lidocaine solution versus lidocaine spray for pharyngeal anesthesia in unsedated esophagogastroduodenoscopy. *Endoscopy.* 2009;41(7):581–586.
5. Amornyotin S, Pranootnarabhal T, Chalayonnavin V, et al. Anesthesia for gastrointestinal endoscopy from 2005–2006 in Siriraj Hospital:a prospective study. *Thai J of Anesthesiology.* 2007;33(2):93–101.
6. Amornyotin S, Chalayonnavin W, Kongphlay S. Topical pharyngeal anesthesia for unsedated esophagogastroduodenoscopy procedure in sick patients. *Journal of Anesthesia & Critical Care:Open Access.* 2016;4(2):1–5.
7. Dr Jonathan Green. British Society of Gastroenterology. Guidelines in Gastroenterology:Complications of gastrointestinal endoscopy, 2006;p. 1–30.
8. Evans LT, Saberi S, Kim HM, et al. Pharyngeal anesthesia during sedated EGDs:is "the spray" beneficial? A meta–analysis and systematic review. *Gastrointest Endosc.*2006;63(6):761–766.
9. Darwin P, Zangara J, Heller T, et al. Unsedated esophagoscopy for the diagnosis of esophageal varices in patients with cirrhosis. *Endoscopy.* 2000;32(12):971–973.
10. Amornyotin S, Kongphlay S. Unsedated esophagogastroduodenoscopy in cirrhotic patients:An impact of topical pharyngeal anesthesia. *J of Anesthesia Critical Care Open Access.* 2015;3(4):1–5.
11. Iwao T, Toyonaga A, Harada H, et al. Arterial oxygen desaturation during nonsedated diagnostic upper gastrointestinal endoscopy in patients with cirrhosis. *Gastrointest Endosc.* 1994;40(3):281–284.
12. Amornyotin S, Kongphlay S. Anesthesia–related adverse event rate and alteration of blood pressure and heart rate during and immediately after unsedated esophagogastroduodenoscopy in elderly patients. *Journal of Gastroenterology Hepatology Research.* 2015;4(2):1474–1477.
13. Mulcahy HE, Kelly P, Banks MR, et al. Factors associated with tolerance to, and discomfort with, unsedated diagnostic gastroscopy. *Scand J Gastroenterol.* 2001;36(12):1352–1357.
14. Mulcahy HE, Greaves RR, Ballinger A, et al. A double–blind randomized trial of low–dose versus high–dose topical anesthesia in unsedated upper gastrointestinal endoscopy. *Alimentary Pharmacology Therapeutics.* 1996;10(6):975–979.

Citation: Amornyotin S, Chalayonnawin W, Kongphlay S. Adverse event rate of unsedated esophagogastroduodenoscopy:a comparison between healthy adults and cirrhotic patients. *Gastroenterol Hepatol Open Access.* 2016;5(3):78–81. DOI: 10.15406/ghoa.2016.05.00142