Turk J Gastroenterol *2015; 26: 224-7*

Lidocaine versus lidocaine plus benzydamine as a topical anesthesia regimen for unsedated upper gastrointestinal endoscopy: A comparison study

UPPER GI

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Original Article

ABSTRACT

Background/Aims: The aim was to assess the efficacy of adding benzydamine (B) spray to standard treatment with a lidocaine (L) spray before upper gastrointestinal endoscopy (UGE) as a topical anaesthetic regimen.

Materials and Methods: A total of 118 adult patients undergoing outpatient UGE were randomly assigned to receive L (n=44), LB (n=38) or B (n=36) before the procedure. The primary outcome was the patient tolerance score, which represents a summative evaluation of the taste of the anesthetic agent, the intensity of pharyngeal numbness, the amount of coughing or gagging and the degree of discomfort during oesophageal intubation.

Results: The median (min-max) patient tolerance scores were comparable between groups LB (10.5; range 5-12) and L (10; range 4-13) (p=0.235) and significantly lower in group B (7.5; range 3-12) (p<0.01). LB improved several secondary outcomes. Oesophageal intubation was less difficult (5 [range 2-10] vs 3 [range 0–8], p<0.001), and a lower proportion of patients developed postprocedural sore throat (4 [10.5%] vs 15 [34.1%], p=0.011) in LB compared to L.

Conclusion: LB is not superior to L in terms of overall patient tolerance, but LB may be preferred over L in cases with difficult oesophageal intubation or a previous history of postprocedural sore throat.

Keywords: Benzydamine, endoscopy, lidocaine, oral sprays, topical administration

INTRODUCTION

Upper gastrointestinal endoscopy (UGE) is a minimally invasive medical procedure that is widely used to facilitate the diagnosis of various benign and malignant conditions of the upper gastrointestinal tract. It also enables physicians to perform therapeutic procedures. UGE is a safe procedure, with an overall complication rate ranging from 1 in 200 to 1 in 10,000 and mortality rates ranging from zero to 1 in 2000 (1-4). The variability in rates of adverse events may be explained by several factors, mainly by the method of data collection and the definitions of adverse events. Cardiopulmonary complications related to sedation and analgesia are responsible for up to 60% of upper gastrointestinal endoscopy adverse events (1-3).

The practice of using sedation for UGE shows remarkable geographical variation. For example, most procedures in the United States and Europe are performed with patients under sedation, whereas in Finland, sedation is seldom used (5,6). Despite the evidence that UGE can be performed without sedation, it is a common practice to administer topical pharyngeal anaesthesia and/or parenteral sedative medications because UGE may cause considerable discomfort for patients (7,8).

As a topical pharyngeal anaesthesia, lidocaine (L) is the most frequently preferred agent, but there is controversy about its efficacy in improving patients' tolerance for the procedure (9,10). In this study, we aimed to compare the effectiveness of L alone versus L plus benzydamine (LB) for topical anaesthesia in unsedated UGE.

MATERIALS AND METHODS

From January 2011 to December 2013, consecutive adult patients (18 years) who underwent UGE at a single endoscopy centre with informed consent were enrolled in this study, which was approved by the lo-

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Received: March 24, 2015 **Accepted:** March 26, 2015

cal ethics committee. Patients with any of the following were excluded: sedated endoscopy neuropsychiatric impairment, a history of stroke with impaired swallowing reflex, past medical history of head and neck cancer or surgery, active oropharyngeal infection, asthma, using a steroid inhaler, known allergic reaction to local anaesthesia and an allergy or intolerance to L and/or B. Eligible patients were randomised into one of three groups: the L group, LB group or B group.

The patients in group L received four doses of 10% lidocaine spray (Xylocaine pump spray 10%; Astra AB Södertalje, Sweden, 10 mg lidocaine per dose) to their pharynx, whereas two doses of 10% lidocaine spray and two doses of benzydamine spray (Tantum verde spray; Santa Farma, İstanbul, Turkey, 0.25 mg benzydamine per dose) were sequentially administered via the same route in group LB. Patients in group B received only four doses of benzydamine spray. The sprays were given in 3 consecutive 30-second intervals, and UGE was performed 1 min after the last spray dose.

Experienced endoscopists, who had experience with more than 500 UGEs, performed the procedure. The same model (Fujinon) was used to perform UGEs in all groups. No sedative drugs were administered to any patient.

After the procedure, all the patients swallowed sips of warm water every 5 min for assessment of the time until recovery of pharyngeal sensation. Subsequently, the patients were interviewed by independent healthcare personnel and completed a questionnaire.

As a primary outcome, the patient tolerance score was used as previously described by Chan et al. (11). Accordingly, the following parameters were combined to calculate the total score, ranging from 0 to 12: taste of the anaesthetic agent, intensity of pharyngeal numbness, the amount of coughing or gagging and the degree of discomfort at oesophageal intubation (Table 1). Secondary outcome measures included patients' and endoscopists' satisfaction with the procedure according to a visual analogue scale (VAS) ranging from 0 (unsatisfied) to 10 (very satisfied); difficulty with oesophageal intubation, graded by the endoscopists according to a VAS ranging from 0 (very easy) to 10 (very difficult); procedure time; development of postprocedural sore throat; and time until recovery of pharyngeal sensation.

All statistical analyses were performed with Statistical Package for the Social Sciences version 15.0 for Windows (Publisher: Chicago, Illinois. USA). Normality was assessed using the Shapiro–Wilks test. Normally distributed data were expressed as mean±SD, and an unpaired t-test and one-way ANOVA were used to compare the relevant groups. Non-Gaussian data were expressed as median (min-max), and Mann-Whitney and Kruskal-Wallis tests were used to compare the relevant groups. A two-sided p value of 0.05 or less was considered statistically significant.

RESULTS

The number of patients in groups L, LB and B were 44, 38 and 36, respectively. There were no significant differences between the three groups with respect to baseline characteristics (Table 2). The median (min-max) patient tolerance scores were comparable between groups LB (10.5; range 5-12) and L (10; range 4-13) (p=0.235) but significantly lower in group B (7.5; range 3-12). In terms of each individual component of the patient tolerance score, group B was inferior to groups L and LB, whereas the only difference between groups L and LB was in the intensity of pharyngeal numbness, which was significantly higher in group L (Table 3). Regarding secondary outcomes, both the endoscopists and patients were similarly satisfied with the procedure using L or LB, but the patients in group LB had significantly easier oesophageal intubation, and a lower

Table 1. Characteristics of the patients

	0	1	2	3
Taste of topical anesthetic	Very bad	Bad	Good	Very good
Intensity of Pharyngeal Numbness	Nil	Mild	Moderate	Severe
Instensity of cough or gagging	Severe	Moderate	Mild	Nil
Degree of discomfort at esophageal intubation	Severe	Moderate	Mild	Nil

Table 2. The parameters included in the patient tolerance score

	Lidocaine n=44	Lidocaine+Benzydamine n=38	Benzydamine n=36	p value
Age (years)*	44.8±14.6	46.6±12.6	42±13.9	0.455
Gender (M/F)	22/22	19/19	18/18	1
Previous EGD	12	11	13	0.672
Biopsy	15	14	11	0.849

Expressed as mean±SD. EGD: esophagogastroduodenoscopy

Table 3. Patient tolerance score as the primary outcome

	L	LB	B	p value
Taste of topical anesthetic	1.5 (0-3)	2 (1-2)	2 (1-2)	L vs B p<0.001 L vs LB p=0.123 LB vs B p=0.007*
Intensity of Pharyngeal Numbness	3 (1-3)	2 (1-3)	1 (0-3)	L vs B p<0.001 L vs LB p=0.029 LB vs B p<0.001
Instensity of cough or gagging	3 (0-3)	3 (1-3)	2 (0-3)	L vs B p=0.04 L vs LB p=0.076 LB vs B p<0.001
Degree of discomfort at esophageal intubation	4 (1-4)	4 (2-4)	3 (1-4)	L vs B p=0.012 L vs LB p=0.089 LB vs B p<0.001
Total Score	10 (4-12)	10.5 (5-12)	7.5 (3-12)	L vs B p=0.003 L vs LB p=0.235 LB vs B p<0.001

All values expressed as median (min-max). L: xylocaine, B: benzydamine, LB: lidocaine+benzydamine. *B was better than LB.

Table 4. Secondary outcomes of the study

	L	LB	B	p value
Endoscopist satisfaction*	8 (3-10)	9 (5-10)	7 (3-10)	L vs B p<0.001 L vs LB p=0.144 LB vs B p<0.001 L vs B p=0.049
Patient satisfaction*	9 (3-10)	9 (3-10)	7 (3-10)	L vs LB p=0.131 LB vs B p=0.003 L vs B p=0.085
Difficulty with intubation *	5 (2-10)	3 (0-8)	4.5 (1-8)	L vs LB p<0.001 LB vs B p=0.062
Duration of procedure (min)	4 (3-12)	5 (3-10)	5 (2-8)	p=0.809
Recovery of pharyngeal sensation (min)	10 (1-20)	10 (5-15)	7 (0-15)	L vs B p<0.001 L vs LB p=0.535 LB vs B p<0.001 L vs B p=0.08
Sore throat n (%)	15 (34.1)	4 (10.5)	17 (47.2)	L vs LB p=0.011 LB vs B p<0.001
Duration (min)	10 (4-15)	3 (2-4)	5 (2-20)	p=0.122

All values expressed as median (min-max). L: xylocaine, B: benzydamine, LB: lidocaine+benzydamine. *B was better than LB.

proportion of patients developed postprocedural sore throat in this group (Table 4).

DISCUSSION

Patient comfort during UGE is important, and compliance remains one of the major concerns, especially for patients undergoing unsedated procedures. While topical anaesthesia is widely used in clinical practice, aiming at better patient tolerance and compliance, the use of topical pharyngeal anaesthesia for UGE has been debated since its inception. Several studies found no benefit for topical pharyngeal anaesthesia in terms of ease of intubation, patient comfort, gagging or coughing (9,12,13); however, patient discomfort was significantly reduced following the topical administration of relevant medications in some other studies (11,14,15). Conflicts arise mainly due to the lack of a standard definition and assessment of tolerance. Nevertheless, it seems that topical anaesthesia will continue to be used in the near future unless thinner, newer generation endoscopes become widely available.

Although lidocaine spray is commonly preferred as a treatment modality, the optimal regimen for topical anaesthesia is not clear. B hydrochloride is a topical nonsteroidal agent that has anti-inflammatory, analgesic/anaesthetic and antimicrobial effects. In this study, we aimed to assess the efficacy of adding B spray to standard treatment with L.

Our results indicated that: (i) The L only regimen used in the present study was found to be effective in achieving a reasonable level of comfort, as shown by the patient tolerance score, which was 10 on a scale of 0-12; (ii) Adding B to L did not provide any advantage in terms of patient tolerance; (iii) B alone is, at most, a modestly effective treatment strategy and should not be preferred alone when L is available. The only additional benefits of combining L and B were that oesophageal intubation was less difficult and a lower proportion of patients developed postprocedural sore throat compared to L only. The anti-inflammatory and analgesic properties of B may account for these effects.

This study design does have some limitations. We did not include a placebo group. For this reason, we cannot conclude that B alone is an option when L is contraindicated or not available, although we also observed some degree of improvement in tolerance subsequent to the use of B. Furthermore, our study was not blinded.

In conclusion, lidocaine plus benzydamine is not superior to lidocaine in terms of overall patient tolerance, but lidocaine plus benzydamine may be preferred over lidocaine in cases with difficult oesophageal intubation or a previous history of postprocedural sore throat. This unique modality is quite promising but requires further study. In addition, larger trials are warranted to verify these results.

Ethics Committee Approval: Ethic committee approval was received for this study.

Informed Content: Written informed content was obtained from patients who participated in this study.

Peer-review: Externally peer-review.

Author contributions: Concept- M.İ., M.A.; Design - M.İ., İ.K.Ö., T.İ.; Supervision - M.A., Ö.G.U.; Materials - T.İ., H.E.; Data Collection &/or Processing - M.İ., H.E., T.İ.; Analysis &/or Interpretation - M.İ., İ.K.Ö., M.A.; Literature Search - T.İ., H.E.; Writing - M.İ., M.A.; Critical Reviews - İ.K.Ö., Ö.G.U.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: No financial support was provided for this study.

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