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A NOVEL STUDY ON LOCAL ANESTHETIC FORMULATION OVER UPPER- GIT ENDOSCOPY

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ABSTRACT

An endoscopic procedure that examines the upper gastrointestinal tract but often caused severe discomfort for many patients due to gag reflexes, was examined as a pharyngeal anesthetic using lidocaine lozenges and viscous oral solutions. A blinded, randomized, controlled study of 110 adult patients. Patients were randomized either to receive lidocaine lozenges or lidocaine viscous oral solution 2%, either with 100 mg or 5 mL. In case of need, midazolam was injected intravenously. During UGE, lidocaine lozenges and lidocaine oral solution were tested to determine which reduced patient discomfort, including gag reflexes. Results: Sixty-four percent of patients in the lozenge group report an acceptable gag reflex, compared to only 33 percent in the oral solution group (P = 0.0072). A lozenge group of 69% evaluated UGE as acceptable compared with a group of 39% evaluating it as acceptable (P <0.0092). In the lozenge group, 78% found the taste of the lozenge to be good (P<0.0001), while 82% found the texture of the lozenge to be good (P<0.0001). It was evaluated as tasty and have a good texture as well as reducing gag reflexes and reducing patient discomfort during UGE. Patients were more accepting of UGE after taking the lozenge.

Key words: A pharyngeal anesthetic, a lidocaine lozenge, and an upper gastrointestinal endoscopy.

INTRODUCTION

When the endoscope passes through the pharynx, a strong gag reflex occurs, which can cause discomfort during upper gastrointestinal endoscopy (UGE). An alternative to an intravenous sedative is to administer a topical pharyngeal anesthesia. The most common form of topical pharyngeal anesthesia for UGE is sprays or viscous solutions [1]. Spray devices trigger gag reflexes, and viscous solutions have a bitter taste and are difficult to swallow [2]. UGE patients can be reluctant to accept lidocaine because of its bitter taste. [3,4] In this study, the goal was to determine if a new lidocaine lozenge would make UGE more acceptable. During the procedure, the lozenge was expected to reduce gag reflexes and make the local anesthetic formulation more appealing in taste and texture [5]. The study assessed whether the new lidocaine lozenge as a topical pharyngeal anesthetic before UGE was more effective and accepted by patients than the lidocaine viscous solution.

METHODS

Formulation of lidocaine lozenges

Lidocaine hydrochloride was used as the active ingredient in the lozenges. Several additional ingredients were added, including a sweetener, a glidant, and a binder. Using liquorice powder to mask lidocaine's bitter taste. During the ten-minute release period, lidocaine was released into the pharynx through the lozenges.

Oral solution containing lidocaine

In the past, Lidocaine viscous oral solution in 2% (w/w) with liquorice flavor was the standard topical anesthesia.

Inpatients

A patient must have had UGE at Hospital within the past three months to qualify for participation. A woman must have been using safe contraception for three months

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before undergoing UGE (applies only to fertile women) and be between 18 and 80 years old. Moreover, they must be able to read, speak, and understand local language; and verbally and in writing they must give consent. Lidocaine allergy as well as pregnancy or breastfeeding were exclusion criteria. Neither ambulatory nor inpatient treatment was available for patients with severe liver impairments in the study. When a patient has severe liver impairment, lidocaine should not be administered**.**

Conceptualization of the study

A one-blinded, randomized, and controlled design was used in this study. Good Clinical Practices at Hospital monitored the data throughout the study. Clinical Trials was registered for the study in accordance with the Helsinki Declaration and national ethical guidelines for biomedical research.

Procedure

As a result standard procedure, an IV cannula was inserted into the patient's hand. UGE procedures require monitoring of blood pressure, heart rate, and oxygen saturation before and during the procedure. Research assistants opened sealed opaque envelopes to carry out the randomization. The patient was then anesthetized with pharyngeal anesthesia by the research assistant without knowledge of the randomization by the endoscopist. After pharyngeal anesthesia was administered, patients and nurses were advised not to discuss it. Lozenges or oral solutions containing 100 mg lidocaine were administered to patients. In contrast, the solution was swallowed after the lozenge had been swallowed until it had dissolved completely. The patients were ready to undergo UGE 10 minutes after receiving pharyngeal anesthesia. The intravenous administration of midazolam (1.25–5 mg) was used if awake sedation was required. In addition to the time it took for the endoscope to pass through the pharynx, the research assistant noted if IV midazolam had been administered. There were 15 endoscopists who performed more than 500 UGEs using a video esophago-gastroduodenoscopy.

Patient assessment

A questionnaire was completed by the patient after the UGE and when he or she was fully alert. A gag reflex acceptance questionnaire included questions regarding taste perception, texture, and local anesthetic effect. An uncomfortable rating scale of 0-10 was used during the procedure, In the scale of 0 to 10, no discomfort is indicated by 0, mild discomfort is indicated by 2, moderate discomfort is indicated by 3, and severe discomfort is indicated by 4.

Analyses performed by endoscopists

A scale from 1 to 4 was used to evaluate the difficulty of the UGE: 1 meant very easy, 2 meant easy, 3 meant difficult, and 4 meant extremely difficult. As a follow-up to the procedure, an endoscopist used the same scale to evaluate the UGE complete impression.

Statistical analysis

With these criteria in mind, the sample size was calculated: Discomfort scale based on visual analogues, at least 1.50 is considered relevant clinically, a standard deviation of 2.00 is expected, the significance level is 0.05, and the power is 80%. We included 110 patients to account for dropouts since each group included 50 patients.

Lozenge and solution categorical variables were analyzed using the chi-square test. The difference between the two groups was analyzed using Student's t-tests on two samples. We measured statistical significance using a P value of 0.05. SAS software was used for all statistical analysis (SAS Institute Inc, Cary, NC).

RESULTS

The inclusion criteria were met by 110 of the 300 consecutive patients screened over an eight-week period. Age (27%) and missing or canceling UGE (26%) were the main reasons for patients not being included. Randomly assigned to the L and S groups were 55 patients each. The L group had eight withdrawn patients, and the S group had four. In six patients, sedation left them amnesic (six patients), UGE suspensions (two patients), changes in the endoscopic procedure (one patient), or refusals to fill out the questionnaire left them without any recollection (one patient). L group patients completed the study 49 times, while S group patients completed it 51 times. The demographics of both groups, including age, gender, BMI, ASA physical status classification system, and number of UGEs previously performed, were similar as well.

Patient assessment

Observations of non-sedated patients were conducted shortly after the procedure (52 patients) or after the patients had completely recovered from sedation (48 patients). Patients in the two groups received the same amount of sedation (P = 0.16) and there was no significant difference between them.

There was a greater acceptance of discomfort among patients in the L group (59% versus 39%) and a greater acceptance of discomfort among patients in the S group (12% versus 6%). In both groups, significant differences were found (P = 0.046).

Endoscopist assessment

In terms of how easy it was to introduce the endoscope and move it through the pharynx, there was no significant difference between the two groups (P = 0.54). Neither group's endoscope passage through the pharynx or UGE took longer than the other's (P. pharynx + 0.53 and P. total + 0.41). Prior to Endoscopists, the UGE discussed the patient's condition with him. The endoscope was evaluated

again after the UGE. The two groups did not differ significantly (P. before 0.67 and P. after 0.57), for both assessments.

DISCUSSION

This study is the first to consider the taste of the lidocaine solution when comparing it to the lozenge's overall performance and acceptance. A higher level of acceptance has not been demonstrated in any other trials. There have been a few other studies that have evaluated lidocaine lozenges as a topical anesthetic before UGE. [6, 7,8] These studies, however, use different active agents or dosages of lidocaine, rendering the results incomparable. The same dose of anesthetic (20 mg oxybuprocaine) was administered to 110 consecutive patients in 110 different combinations. Heuberger and Mulcahy HE *et al* [9, 6] reported that topical anesthesia administered in spray form was significantly more accepted by patients than anesthesia administered in lozenges. The effects of a benzocaine/tyrothricin lozenge (3.5 mg benzocaine and 2 mg tyrothricin) with conscious sedation on UGE patients were compared with conscious sedation alone on 174 patients. Both studies showed no improvement in clinical outcome when lozenges were used in conjunction with conscious sedation, according to Ayoub *et al* [10]. Both studies used drugs other than lidocaine, with oxybuprocaine being more potent and benzocaine less potent.8 Additionally, both studies were conducted under conscious sedation, which causes antegrade amnesia. Spray and lozenge groups received significantly different total lidocaine doses, with lozenge receiving only 20 mg of lidocaine while spray receiving 60 mg.

In two studies, patients in the L group were twice as likely to report discomfort associated with UGE as those in the S group when compared to those in the L group. Patients in the L group searched twice as often for an acceptable gag reflex as those in the S group in this study. As a result, the anesthetic effect of the lozenge might reduce patient discomfort during UGE. A discomfort assessment conducted by the L group of patients revealed that they found discomfort more acceptable than the S group. Since the L group accepts UGE more readily, this may indicate that discomfort influences patient acceptance. Lozenges help patients accept UGE more easily. It has been demonstrated by Amornyotin *et al* [11] that patient comfort has a direct impact on patient acceptance.

Probably because lidocaine lozenges remain in contact with the mouth for a longer time and penetrate better into the mucosa of the pharynx, the lozenge is superior. Through sucking on a lozenge and swallowing saliva containing the local anesthetic, lidocaine is continuously released, allowing for a slow, homogenous spread. It can then exert its anesthetic effects on both Upon the pharyngeal mucosa and on the soft palatal third of the tongue. Sedation was administered to the same number of patients in both groups without a significant difference. Most patients receive sedation before UGE begins, so they were not able to evaluate the topical anesthesia's effect before the procedure. Patients who weren't sedated showed that sedation didn't affect their evaluations. Therefore, we used 100 mg of lidocaine in this study. There is probably a correlation between topical anesthesia effectiveness and lidocaine dosage. The dose of lidocaine administered before an UGE was found to be effective at 100 mg in other studies [12]. By making the lozenge taste and feel better than the solution, liquorice flavor and aspartame can effectively disguise Lidocaine's bitter taste. Some patients who received the lozenge may have responded better to the UGE because the lozenge had a better taste and texture. There are some limitations to this study. It may have been better to require sedation. To include only patients who are not sedated after local anesthetic, because sedation would not affect their assessments. Several endoscopists performed the procedures in the study, which could have also impacted the results. Having fewer endoscopists perform the UGEs might have resulted in more uniform results. In spite of this, the procedures were only performed by experienced endoscopists.

CONCLUSION

As a local anesthetic, the lozenge was effective and well accepted by patients, with its mild taste and texture helping patients to accept the gag reflex during UGE. Patients' acceptance of UGE appears to be improved by using the lozenge to reduce discomfort during the procedure. UGE is a highly uncomfortable procedure for many patients around the world if the lozenge is incorporated into the procedure.

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