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Original Research Article

Comparative Study of Lidocaine Spray and Lidocaine Lozenges on Propofol Requirements during Upper GI Endoscopy

Shailendra Raghunath Shiravadkar[1], Pratibha Matche[2], Surekha Chavan[3], Anju Paul[4], Mahendra Bangar[5], Daniel Saji[6], Amruta Kagdelwar[7], Kuldeep Kumar[8]

[1]Ex-Assistant Professor, SSPM Medical College, Sindhudurg, Maharashtra, India
[2]Associate Professor, Incharge Head Pain Medicine Unit, Dept. of Anaesthesiology, JSS Medical College & Hospital, JSS AHER, Mysuru, Karnataka, India
[3]Professor Trauma Care Centre BJGMC & SGH, Pune, Maharashtra, India
[4]Assistant Professor, Department of Anaesthesiology and Critical Care, Government Medical College, Jalgaon, Maharashtra, India
[5]Junior Resident, Department of Anaesthesiology, BJGMC & SHH, Pune, Maharashtra
[6]Assistant Professor, Department of Community Medicine Government Medical College, Jalgaon, Maharashtra, India
[7]Junior Resident, Department of Anaesthesiology, Government Medical College, Jalgaon, Maharashtra, India
[8]Junior Resident, Department of Anaesthesiology and Critical Care, Government Medical College Jalgaon, Maharashtra, India

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Corresponding author: Dr. Anju Paul
Conflict of interest: Nil

Abstract

Introduction: Lidocaine spray is used before upper gastrointestinal endoscopy (UGE) routinely. A lozenge formulation with ease of administration, palatable taste and improved compliance could be preferred topical anesthesia. This study was conducted to evaluate the efficacy of lidocaine lozenges versus lidocaine spray on propofol requirement in diagnostic gastroduodenal endoscopy.

Materials and Methods: Prospective study with two hundred patients undergoing diagnostic UGE were randomized either to lidocaine lozenge or spray groups. Ease of application, ease of procedure, level of gag reflex and investigators and patient's global assessment were noted along with total dose of propofol administered. Comparison was done by using appropriate statistical test.

Results: Significantly less dose of propofol ($P < 0.0001$) required along with less procedural difficulty and gag reflex during UGE with lidocaine lozenges compared to spray. Global assessment by patient and physician was favorable toward lozenges.

Conclusions: Lidocaine lozenges significantly reduced propofol requirement with advantages of easy application, better suppression of gag reflex, better patient and endoscopist satisfaction compared with lidocaine spray.

Keywords: Lidocaine Lozenge, Lidocaine Spray, Upper Gastrointestinal Endoscopy.
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Introduction

Esophagogastroduodenoscopy (UGE) is most common daycare screening, diagnostic, and therapeutic procedure. Patient discomfort interferes with the endoscopist's examination sometimes evokes cardiac arrhythmia, myocardial ischemia, aspiration, and hypoxemia. [1] Topical local anesthetic agents (Lidocaine or bupivacaine spray or viscous gargles), before UGE widely used as alone or with intravenous anesthetics (propofol, fentanyl, etomidate, ketamine, dexmedetomidine). There are disadvantages of lidocaine use as spray or viscous gargles as dosing variability, bitter taste, improper dispensing or technique. [2]

Lozenge is a solid, single-dose preparation dissolves over 5-10 min and releases drug in saliva which carries it multi-directionally into oral cavity and pharyngeal mucosa with extended time of contact.[3] This study was conducted to evaluate efficacy of Lidocaine Lozenges against spray on requirement of propofol along with advantages like

ease of administration, palatable taste and patient and endoscopist compliance during UGE.

Methods

Prospective, randomized study was conducted (from May, 2022 to December, 2024) after hospital ethical committee approval and patients' written, informed consent. The sample size was calculated to detect difference of 0.46 in propofol (mg/kg) used to standard deviation of 1.1 to achieve 90% power at significance level of 0.05. This gave required sample size of 100 patients in each group.200 patients aged 18–60 years, of the American Society of Anesthesiologists (ASA) physical status 1, undergoing elective diagnostic UGE lasting <5minutes (endoscope insertion till removal), in whom only intravenous propofol was used, were included. Patients were randomly allotted into two equal groups, labelled A and B, based on computer-generated random sequence of numbers. Patients with any medical illness, age (<18 & >60years), allergic to amides, pregnant, lactating, morbidly obese, therapeutic or emergency UGE and requiring use of anesthetic agents apart from Propofol were excluded. Group A received lidocaine lozenge 200 mg (Xynova 200, manufactured by Troika Pharmaceuticals Ltd, India) placed in the mouth 15 min prior to procedure and was instructed to roll it side to side till it dissolves while Group B received 20 sprays lidocaine 10% spray (LOX 10%, manufactured by Neon Labs) (equivalent to 200 mg lidocaine) were administered 15 min before the procedure.

With standard monitoring and supplemental O_2 by Hudson's mask patients were anesthetized using propofol bolus injection (1mg/kg) till becomes unresponsive to noxious stimulus (supraorbital pressure). Diagnostic UGE performed by same gastroenterologist with standard protocol. Further bolus propofol loads given between 20 to 30 mg as needed. After procedure patients shifted to recovery till become awake. Investigator filled questionnaire evaluating (1) Total dose of propofol (mg/kg)-Primary endpoint. And Secondary endpoints as (2) Ease of procedure: on scale from 0 (easy) to 5 (difficult).

The criteria were presence of excessive gags, retching, restlessness and combativeness. (3) Level of Gag reflex: on a scale 5 - strong to 0 -absence and (4) Ease of application of local anesthetic as easy, adequate or difficult. (5) Patient's and Endoscopist's global assessment on scale (satisfactory 0 to unsatisfactory-5). Statistical analyses done using SPSS20.0.

Results

Both groups were comparable (Table-1)in mean age, weight, distribution of sex, duration of procedure.

Table 1: Comparison of parameters

Parameter	Group A	Group B	P-Value
Continuous Variables (Mean±SD)			
Age (Years)	49.4±10.5	47.5±12.5	0.125
Weight (Kg)	70.5±10.7	71.2±6.5	0.154
Procedure time (secs)	375.2±21.2	350.5±20.8	0.142
Propofol Dose (mg/kg)	0.8±0.04	1.2±0.21	<0.001
Level of Gag reflex	3.79±0.45	3.21±0.82	<0.001
Ease of procedure	0.95±0.02	1.7±0.12	0.002
Categorical Variables, n (%)			
Gender			
Male	55(55%)	52(52%)	0.554
Female	45(45%)	48(48%)	

Compared to Group B, significantly lower propofol required in Group A ($P < 0.001$). Also, level of gag reflex was significantly suppressed Group A ($P < 0.001$). Ease of procedure, ease of application of local anesthetic and investigators and patient's global assessment were much better in Group A than Group B.

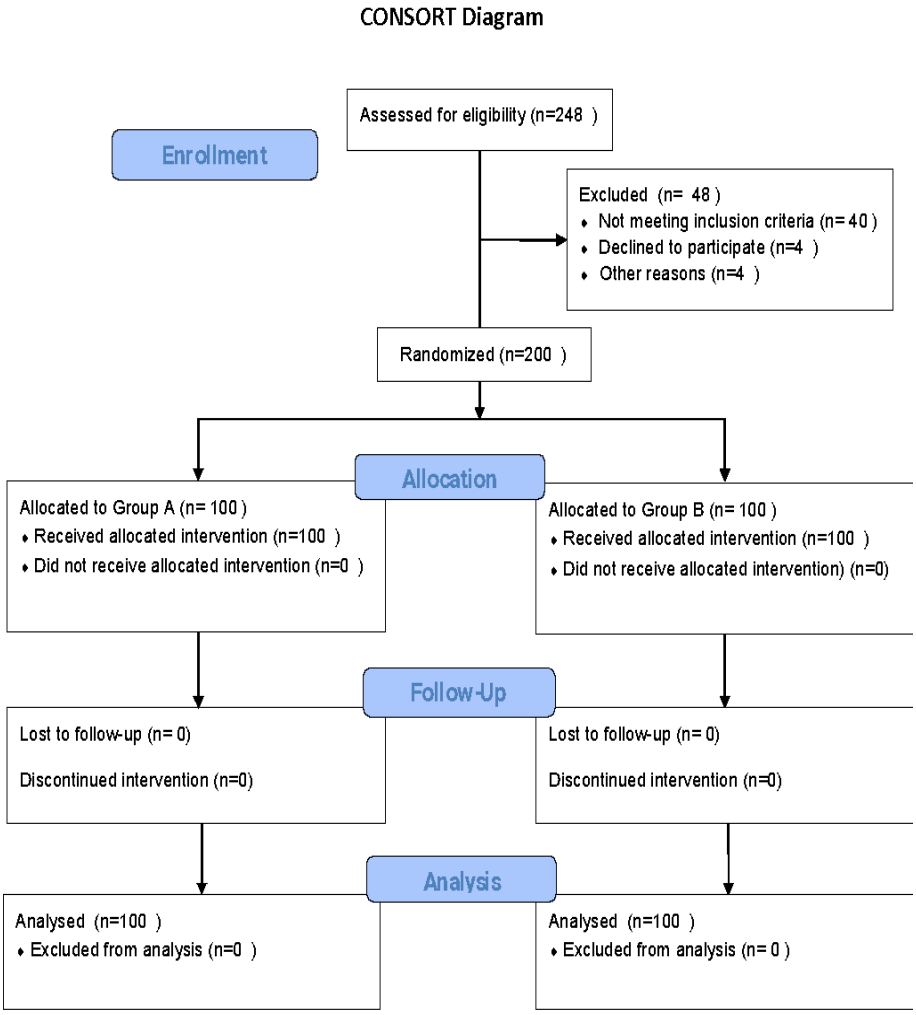

Figure 1: CONSORT Diagram

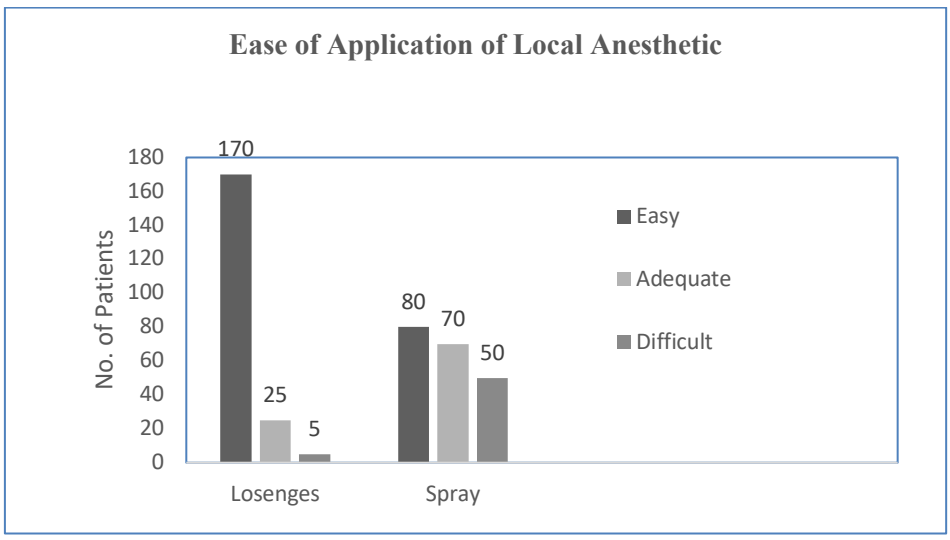

Figure 2: Comparison of ease of application

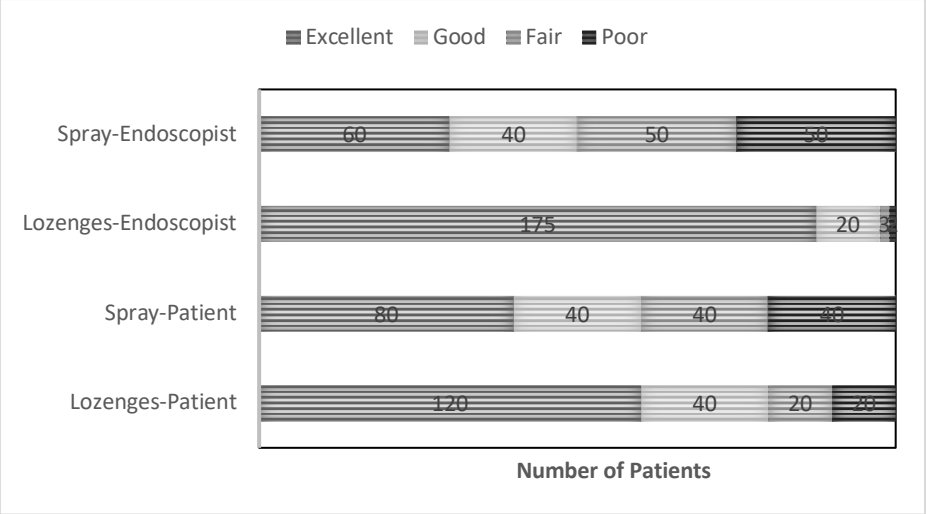

Figure 3: Comparison patients and endoscopist global assessment

Discussion

Gastrointestinal endoscopy is a daycare valuable screening, diagnostic, and therapeutic procedure for the gastrointestinal tract, which is usually done after spraying local anaesthetics to the upper GI tract, sometimes in combination with sedation to reduce patient discomfort.[6] Patient discomfort may lead to difficult endoscopist's examination and can cause aspiration, cardiopulmonary complications like cardiac arrhythmia, myocardial ischemia and hypoxemia[7]. Use of Local anesthesia in UGE is beneficial in reducing the gag reflex and thereby improves patient satisfaction.[8] And most commonly used local anaesthetic for upper airway is lidocaine which decrease cough, gag reflex and overall airway hyper-reactivity, enhancing patient compliance and practitioner satisfaction.[9]

Lignocaine is an amide local anesthetic agent and a Class 1b antiarrhythmic. Lignocaine is a one of the essential drug on World Health Organisation list. It is considered as an efficacious, safe and cost effective drug for any healthcare system.[10] The mechanism of action of lignocaine is to block the sodium channel and thereby preventing the neuronal transmission.[11] It can be administered through different routes, such as local infiltration, Intravenous, spinal, epidural, spray, lozenges, lollipops and gargle.

It has been reported in the literature that 200 mg of lidocaine spray is a safe and effective local anesthesia for diagnostic endoscopic procedures. The main disadvantages of the lignocaine spray are bitter taste, inconsistent coverage, and cross infection because of usage in multiple patients.[12] Further search led to the discovery of lidocaine lozenges to overcome this. In over study we used lignocaine lozenges 200mg and spray 200 mg to standardize the treatment dose.[3] Topical lignocaine reduces propofol requirement during UGE studied by Hung et al. we found that significantly lower dose of propofol required with use of lozenges than spray.

Procedure reported as easy in significantly more number of patients ($P = 0.0007$) in the lozenge group when compared to the spray group. Similar results were also reported by Ayoub et al.[4]

It was reported that, gag reflexes were significantly suppressed ($P < 0.0001$) in lozenge group as compared to the spray group. This could be due to the mechanism of drug delivery in which the lozenge dissolves, mixes with saliva and spreads to produce a local anesthetic effect. Moreover, lozenge releases the drug steadily for a prolonged period in the oral mucosa and hence form a coat of the anesthetic mixed with mucus on wider surface of the pharyngeal mucosa providing an improved local anesthetic effect. It is also reported by Mogensen et al.[2] that the lozenge formulation provides its local anesthetic effect on the soft palate and posterior third of the tongue (in addition to the pharyngeal mucosa), which contains deep pressure receptors for the gag reflex.

In Study by Chakib Ayoub et al Lidocaine lollipop is a promising form of local oropharyngeal anesthesia for EGD. Its use resulted in sparing the use of intravenous sedation. It is well tolerated and safe and may be particularly important in the elderly, patients with comorbidities, and office-based endoscopy.

Ease of application assessed by the investigator was reported to be easy in greater number of patients in lozenge group as compared to the spray group ($P = 0.001$). The spray must be administered at precise area of the throat and cannot be self-administered. There is also a factor of inconvenience as the patient must hold mouth wide open until an assistant could apply the lidocaine spray. The lozenge formulation with appropriate instructions can be readily self-administered

without any assistance or supervision. The lozenge formulation of a local anesthetic is easier and convenient method to deliver a topical anesthetic as the patient must simply suck the lozenge for 15-20 min prior to the procedure. The sweet and flavored lozenge masks bitter taste of lidocaine as well as makes the formulation more palatable and acceptable for the patients.[5]

Global assessment by the patient and the investigator was favorable for lozenge mainly because of ease of procedure and application of the lozenge for the investigator and due to suppression of gag reflex, pleasant flavor of lozenge and improved acceptance of the procedure for the patients. Similar results were obtained in study done by Supe et al.[3]

The adverse events reported were cough, nausea, vomiting and mild throat irritation similar in both groups.

Cost difference between spray and lozenge used for each patient is not significantly different. Using a spray bottle for a single patient causes a lot of wastage and reusing the remaining poses a risk of cross contamination by same nozzle. Lozenges are unit dosage form and used for a single patient, they do not pose risk of cross contamination hence hygienic and cost-effective.

Kacker et al.[12] conducted a study to evaluate the efficacy of lidocaine lozenges in awake diagnostic direct laryngoscopy and reported lesser procedural difficulty and suppressed gag reflex with lidocaine lozenges compared to spray.

A limitation of study was that the study was open-labeled, the results may be affected by patient or endoscopist bias.

Conclusion

The study suggests that less dose of propofol required during UGE with use of lidocaine lozenges with benefits of easier way of application, better suppression of gag reflex and makes the procedure easier when compared to lidocaine spray

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