AN OPEN LABEL COMPARATIVE STUDY BETWEEN XYLOCAINE LOZENGES AND XYLOCAINE SPRAY IN PATIENTS UNDERGOING UPPER GASTROINTESTINAL ENDOSCOPY IN A TERTIARY CARE CENTER

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Abstract:
Aim - To determine the efficacy safety and ease of use of lidocaine lozenges for endoscopy as compared to Lidocaine spray.
Methods- Total of 50 patients were taken and separated randomly in to Group A and Group B each containing 25 patients. Group A was given Lidocaine lozenge 200 mg to suck 15 minutes before and Group B was given Lidocaine Spray just prior to the upper GI endoscopy. Efficacy was assessed by Ease of the procedure, Gag refluxes in a 0 to 5 point scale. Physicians and Patients global assessment of topical analgesia were obtained. All the procedures were done by single experienced endoscopist. Comparison was made by SPSS version 17.
Results- Lidocaine lozenge showed less difficulty in intubation (P 0.0001) and less gag reflux (P0.0001). Group A had 7 (29) patients with staining of mucosa with the lozenge which may pose difficulty in assessing the fine detail of the mucosa. In Group A 4 patients (16) said the analgesia was excellent 15 (62) said it was good and 5 (20) said the analgesia was fair. None said it was poor. In Group B 11 patients (42) said the analgesia was good, 13 (50) patients said the analgesia was fair and 1 (0.03) patient said it was poor.
Conclusion- Lidocaine lozenge was more efficacious than lidocaine spray for topical analgesia before upper GI endoscopy. Lozenge stained the mucosa which may interfere with fine details of mucosa. This may be avoided by creating colorless lozenges in the future.

Keyword:
Lidocaine spray, Lidocaine lozenges, upper GI endoscopy

Introduction:
Upper gastrointestinal endoscopy or EsophagoGastroDuodenoscopy is an important diagnostic and therapeutic tool in Clinical Gastroenterology. It is considered to be a safe and painless procedure but significant complications like bleeding, perforation and infection can occur in 0.1% of patients. Cardiopulmonary complications account for more than 50% of reported
complications which can occur due to aspiration, oversedation, hypoventilation vasovagal episodes and airway obstruction. Providing adequate sedation and analgesia is an integral part of GI endoscopy. Variety of drugs are used for this purpose. Topical pharyngeal anesthetic agents are (lidocaine, benzocaine or tetracaine) are often used for endoscopic procedures. These agents are used mainly to suppress the gag reflex during procedures involving the upper GI tract. Lidocaine sprays are being used for this purpose. Here we want to assess how lidocaine lozenges in our population is useful compared to lidocaine spray when given prior to upper GI endoscopy.

**Justification for this study:**

Medicine is an ever evolving field of science and we always search for better therapeutic options. Xylocaine spray although provide some patient comfort and ease of the procedure we felt difficulty with some of our patients and intravenous conscious sedation is not always possible due to severe limitation of manpower as it requires a qualified anesthsiolist for monitoring. Hence we thought of comparing xylocaine spray with lozenge. Lozenges can be sucked by the patient themselves and it is more appealing to the patients in a study.

**Aim:**
To determine the efficacy, safety and ease of use of lidocaine lozenges for endoscopy as compared to Lidocaine spray.

**Methods:**
Total of 50 patients were taken and separated randomly in to Group A and Group B; each containing 25 patients each using a computer generated randomization sheet.

**Inclusion criteria:**
1. Patients of either sex aged 18-80 years.
2. Patients undergoing diagnostic gastroduodenal endoscopy.

**Exclusion criteria:**
1. Hypersensitivity to lidocaine or any component of the formulation.
2. Any contraindication to the lidocaine.
3. Application on breached mucous membrane.
4. Patients with medical history of asthma, bronchitis or chronic obstructive pulmonary diseases.
5. Use of another topical product at the application site.
6. Unwilling patients.
8. H/O alcohol or drug abuse.
9. Clinically significant impairment of hepatic/ renal/ cardiac function.
10. Pregnant women and lactating mothers.
11. Women of child bearing age not practicing contraception.
12. Participation in a clinical study involving an investigational agent within past 30 days. Written and informed consent obtained from the patients before including them in the study.
Institute ethical committee clearance obtained before starting the study. Approval date 22/10/2010.

Sample size:
Total 50 patients included, 25 each for group A and group B. Patients undergoing upper GI endoscopy in our department for diagnostic purposes are included in the study according to the inclusion and exclusion criteria described above.

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Total 50 patients included, 25 each for group A and group B. Patients undergoing upper GI endoscopy in our department for diagnostic purposes are included in the study according to the inclusion and exclusion criteria described above.

Sex distribution of lozenge group A (group A) and spray group (group B) are given as pie charts in Figure 1 and Figure 2 respectively.

Group A was given Lidocaine lozenge 200 mg to suck 15 minutes before the upper GI endoscopy and Group B was given Lidocaine Spray just prior to the upper GI endoscopy.

Efficacy was assessed by ease of the procedure, gag refluxes in a 0 to 5 point scale. Ease of the procedure was assessed by both the patient and physician. Physician's and patient's global assessment of topical analgesia were obtained. All the procedures were done by a single experienced endoscopist. Comparison was made by SPSS version 17 (Student t test). Figure 2A, 2B, 2C show the scales used for ease of the procedure, gag reflux and tolerability of the procedure respectively.

Results:

Figure 2D shows the patient characteristics of the 50 patients included in the study.
Lidocaine lozenges and lidocaine topical spray were compared for ease of the procedure. Both physician and patient assessments are compared. Ease of the procedure was assessed by physician in a 1 to 5 point scale 1 being the easiest to 5 being the most difficult one. Table 1 and Table 2 show respectively the ease of procedure and gag reflux scale mean and 95% confidence interval between the two groups. Both physician and patient rating showed Lidocaine lozenge group had less difficulty in intubation ($P < 0.0001$). This trend was also seen in gag reflux ($P < 0.0001$) which was assessed by physician alone. Table 3 shows the mean, 95% confidence interval and P value between the two groups of patient's rating of the procedure.

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<th>GROUPS</th>
<th>MEAN 95% CONFIDENCE INTERVAL OF SCORES</th>
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<td>GROUP B</td>
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<td>GROUP B</td>
<td>2.19/1.949-2.371</td>
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GROUP B 2.52/2.272-2.768 Figure 3 shows comparison between group A and group B of the physician's rating of ease of the procedure and gag reflex and patient's rating. Interestingly comparison between sexes in a particular group showed no significant differences in spray group (Group B) and Lozenge group (Group A).
Group A had 7 (29%) patients with staining of mucosa with the lozenge which may pose difficulty in assessing the fine detail of the mucosa. As the lozenge was blue in color it stained the mucosa blue. The mucosa of tongue, esophagus and some cases gastric mucosa were stained blue but it was washable when flushed with water. In Group A 4 patients (16%) said the analgesia was excellent; 15 (62%) said it was good and 5 (20%) said the analgesia was fair. None said it was poor. In Group B 11 patients (42%) said the analgesia was good, 13 (50%) patients said the analgesia was fair and 1 (0.03%) patient said it was poor. There were no significant adverse reactions of the drugs in both the groups.

Discussion:
Adequate patient tolerance is essential for successful completion of a safe examination and compliance with subsequent follow up. As a result endoscopists have developed skills in administering variety of sedative and analgesic agents to facilitate procedures and enhance patient comfort. Most endoscopies are performed with the patient under moderate sedation and analgesia which is also known as 'conscious sedation'. Endoscopies are performed using intravenous sedation with opioid narcotics (Meperiden, Fentanyl, Naloxone), Benzodiazepines (Diazepam, Midazolam, Flumazenil), Propofol or Ketamine; and topical agents like Benzocaine, Tetracain and Lidocaine. Endoscopic sedation also minimizes the risk of physical injury to the patient during the examination and provides the endoscopist with an ideal environment for a thorough examination. There are some problems with sedation like cardiopulmonary complications, delaying the patient recovery and discharge, requirement of close monitoring and finally added costs. Upper GI endoscopy is performed with out sedation in many countries. Unsedated patients experience more discomfort during endoscopy than sedated patients, but few studies have examined factors which could be modified to minimize discomfort during the procedure. A meta analysis of five randomized controlled trials found that patients who received pharyngeal anesthesia were significantly more likely to have rated their procedures as associated with no or minimal discomfort and that endoscopists were significantly more likely to rate the procedure as not difficult. Our study compared the efficacy of both the drugs and their safety profile. Both the groups did not show any significant adverse events. One thing we observed was staining of mucosa in lozenge group which may interfere with the fine details of the mucosa. But patient's assessment of difficulty of the procedure and physician's assessment of ease of procedure and gag reflux showed lozenge group being significantly better than spray group. Xylocaine has anesthetic properties by membrane stabilizing effect. The possible reasons for this better outcome could be 1) Prolonged contact time of the study drug with the mucosa as the patient tastes it and he/she can swallow as well; 2) Patient feels it is self administered and appealing as it is sucked rather than sprayed; 3) The drug is applied uniformly from tongue, pharynx, cricopharynx rather than over the oropharynx by the xylocaine spray; and 4) as the patient swallows it it reaches beyond the cricopharynx as well in to the proximal esophagus as well. A similar study conducted by Ayoub et al used Lidocaine lollipop as a single agent anesthesia before esophagogastro duodenoscopy and the came out with intravenous agent sparing effect of this form of local anesthesia before upper GI endoscopy.
Each lozenge costs around INR 20. The problem of staining can be circumvented by development of colorless lozenges in the future.

Conclusion:
Lidocaine lozenge was more efficacious than lidocaine spray for topical analgesia before upper GI endoscopy. No significant differences observed between males and females in both lidocaine lozenges and sprays. Lozenge stained the mucosa which may interfere with fine details of mucosa. This may be avoided by creating colorless lozenges in the future. There was no serious adverse events in both the groups.

Conflicts of interest:
In this study Xylocaine Lozenges (Xynova) were supplied by Troikaa pharmaceuticals.

References:


