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Original Research Article

Nebulized lidocaine an effective and safe topical anaesthetic agent to upper aero digestive tract prior to nasogastric intubation: a randomized, double-blind, placebo-controlled trial

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Abstract: Nasogastric intubation is a common painful procedure performed in emergency department that physicians rarely consider need for topical anaesthetic agent prior to the procedure. This study investigated the effectiveness and safety of nebulized Lidocaine as topical anaesthetic agent to upper aero-digestive tract prior to nasogastric tube insertion. The study prospectively randomized 78 adult patients in emergency department of a tertiary health institution with indications for nasogastric tube insertion. The study consisted of two groups, the nebulized group (NEBG) whose each nostril and oropharynx were nebulized with 1% to 4% Lidocaine and placebo group (PLAG) whose each nostrils and oropharynx were also nebulized with normal saline. The sociodemographic characteristics and the indications for Nasogastric (NG) tube insertion for the two groups were similar. The mean change in pulse rate was lower in NEBG (5.4 vs 10, p <0.001) as well as mean change in respiratory rate (2.6 vs 5, p <0.001) and both showed statistical significant difference. The mean discomfort score on VAS, mean difficulty level on likert scale, mean insertion time and failure rate were all lower in NEBG compared to the PLAG (3.4 vs 6.7, p< 0.001), (1.3 vs 3.8 p < 0.001), (96.4 sec vs 246.90sec p < 0,001) and (13.3% vs 46.7% p =0.011) respectively. The NEBG group experienced more tracheal intubation though not statistically significant (8 (20.5%) vs 3(7.7%), p = 0.1932). We thus concluded that nebulized lidocaine is safe and effective topical anaesthetic agent to upper aero-digestive tract prior to nasogastric tube insertion, with clinical evidence and statistical significant decrease in discomfort associated with the procedure.
Keywords: nasogastric tube, insertion, topical, lidocaine, nebulize, upper aero digestive tract

INTRODUCTION

Nasogastric (NG) intubation is a common procedure often performed for various reasons in emergency department with the aim of removing stomach contents, for diagnostic, therapeutic, prophylactic purposes and for instillation of materials (medication, food) into the stomach. This procedure is often distressing, unpleasant with some degree of pain / discomfort and attendant risk of complications [1]. The procedure has been described by patients as the most painful procedure, even worse than fracture reductions, incision and drainage [2]. Despite this, many physicians are often reluctant to use any form of local anesthetic agent to reduce this discomfort [3]. The procedure is often attended with complications such as trachea intubation, regurgitation, pulmonary aspiration, traumatic injury to upper aero digestive tract [4]. Previous studies have shown a higher rate of failure and other complications without the use of any form of local anaesthetic agent prior to the procedure [5, 6]. Most of these complications often result from poor patient's compliance as a result of discomfort / pain and irritation to upper aero digestive tract in a patient with persevered gag reflex. Some other studies have shown the efficacy, safety and improved patients' tolerance during the insertion of NG tube following pre-administration of local anesthetic agent(s) in form of topical anaesthesia to upper aero digestive tract, [1,7] topical lidocaine spray is routinely used by the ear, nose and throat surgeons for minor procedures and to aid examination of upper aero digestive tract, a practice also employed by upper gastrointestinal (GIT) endoscopist prior to upper GIT endoscopic studies. The aim of this study is to determine the effectiveness, efficacy and safety of nebulized lidocaine as upper aero digestive anesthetic agent prior to insertion of NG tube,

in improving patients' comfort and reduction of attendant complications.

MATERIALS AND METHODS

Setting

The study was a prospective, randomized double- blind placebo- controlled trial carried out in accident and emergency department (AED) of Ladoke Akintola University of Technology Teaching Hospital (LTH) Ogbomosho. Ladoke Akintola University of Technology Teaching Hospital (LTH) is a tertiary health care centre whose accident and emergency department received an average of 10,000 patients per annum. Ethical approval was obtained from the Hospital ethical committee unit while, informed consent was obtained from each patient.

Patients

The study randomized a total of 78 adult patients with 39 patients in each group (power=0.8, alpha=0.05) for statistical significant difference of 2cm on visual analog scale (VAS) scores. The inclusion criteria were patients greater than 18 year old, appropriate indication for nasogastric (NG) tube insertion with intention to treat, no contraindication to NG tube insertion, Glasgow Coma Score of 15, exclusion criteria were all patients with history of reactive airway, patients with history of hypersensitivity to local anaesthetic agent (lidocaine), lack of consent, facial injury, pregnant women, previous NG tube insertion, and lactating patients.

Randomization

The study consisted of two groups, the nebulized group (NEBG) whose each nostril and oropharynx were nebulized with 1% to 4% Lidocaine (≤4mg/kg, not to exceed 200mg per dose) and placebo group (PLAG) whose each nostril and oropharynx were also nebulized with normal saline.

Randomization was by balloting from 78 sealed opaque and tamper-proof envelopes that contain integer numbers from 1-78, which were randomly assigned in equal proportion into NEBG and PLAG by the researchers. Once the selection is made the patients then received the nebulized medication according to the group the patient integer corresponds to. The medications were all supplied by the researcher in a similar bottle. The selection of ballot was by a doctor who was blinded to the study and the procedures were carried out by registrars in emergency department who were also blinded to the content of the nebulizer.

The protocol

The procedure was carried out using standardized method [8]. The pre passage protocol involved nebulization of 1% to 4% lidocaine (≤4mg/kg, not to exceed 200mg per dose in adult) using nebulizer (Omron ^{R}) and a delay of 5 to 10 minute prior to the passage of plain KY jelly ^{R} (Johnson and Johnson US) lubricated size 16 fr gauge NG tube to allow the local anaesthetic agent to fix/take effect [9]. Correct positioning of the NG tube was established through test of the aspirate by litmus paper, insufflations of air and simultaneous auscultation of the epigastrium.

Data

The following data were entered into a pre formed paper proforma: age, sex, diagnosis, indication, initial vital signs, number of attempt prior to success, outcome (success of failure procedure is considered failure if patients required more than 3 attempts before success) vital signs after passage, patient satisfaction on previously validated visual analog scale (VAS) score of 0 to 10cm [9,10] with no satisfaction at 0 end and complete satisfaction at 10 end, patients' level of discomfort/ pain on visual analog scale (VAS) score of 0 to 10 with no discomfort at 0 end and worst possible imaginable discomfort at 10 end, insertion time in seconds, patient willingness to re-accept similar procedure in future and complication(s) from the use of agent and the procedure proper.

STATISTICAL ANALYSIS

Test of significance were done using student t-test for VAS score analysis [11,12] Mann-Whitney rank-sum test and Chi-square test; a p value less than 0.05 was considered to be statistically significant and greater than 2cm difference in VAS score was considered to be clinically meaningful based on Kelly et al study [13].

RESULTS

A total of 78 patients were recruited into the study over a six month period. Our patients' demographic characteristics were similar in both groups with no statistical significant difference in age and sex distribution between the two groups Table 1, while Table 2 shows the spectrums of indications for passage of NG tube.

Table 1 Showing the Sociodemographic characteristics of our patients

Patient demographic characteristics	NEBG group	PLAG group	P value
Age range	18 - 76	20 -71	
Mean age(SD)	38.5 (±14.214)	36.97(±16.81)	0.6655
Sex: Male: Female	21:18	23:16	0.8194

Table 2 showing diagnosis and indication for passage of NG tube

Diagnosis	Indication for passage Of NG tube	NEBG	PLAG
Intestinal obstruction	Decompression and vomiting	14	13
Perforated PUD	Decompression	6	8
Upper GIT bleeding	Monitoring	6	7
Pancreatitis	decompression	0	1
Trauma	Vomiting	6	7
Cholecystitis	Vomiting	3	1
Gastric outlet obstruction	Decompression and vomiting	4	2

P=0.7907

The mean change in patients vital signs in response to passage of NG tube between the two groups are as shown in table 3, with pulse rate and respiratory rate showing a statistical significant difference between the two groups.

Table 3 mean changes in vital signs associated with passage of NG tube

Mean change in vital signs and Oxygen saturation	NEBG	PLAG	P value
Pulse rate (beats/minute)	5.4(±2.76)	10(±5.04)	<0.001
Systolic blood pressure (mm Hg)	4.1(±2.42)	4.9(±1.79)	0.1016
Respiratory rate (cycle/minute)	2.6(±2.07)	5.0(±2.16)	<0.001
Oxygen saturation (%)	-1.51(±2.31)	-1.39(±3.38)	0.8540

Discomfort VAS score in NEBG ranges from 2 to 6 with mean discomfort VAS score of 3.4(±1.28) while that in PLAG ranges from 4 to 10 with mean discomfort VAS score of 6.87(±1.55) which was found to be statistically significant (p<0.001) with a meaningful clinical significance difference of 3.47. Sixteen (53.33%) patients in NEBG groups had discomfort VAS score of less than 4 as compared to none in PLAG. None of the patients in NEBG has discomfort score greater than six on discomfort VAS score. Figure 1 shows the mean discomfort VAS score, mean Likert score, and mean number of attempts and failure rate.

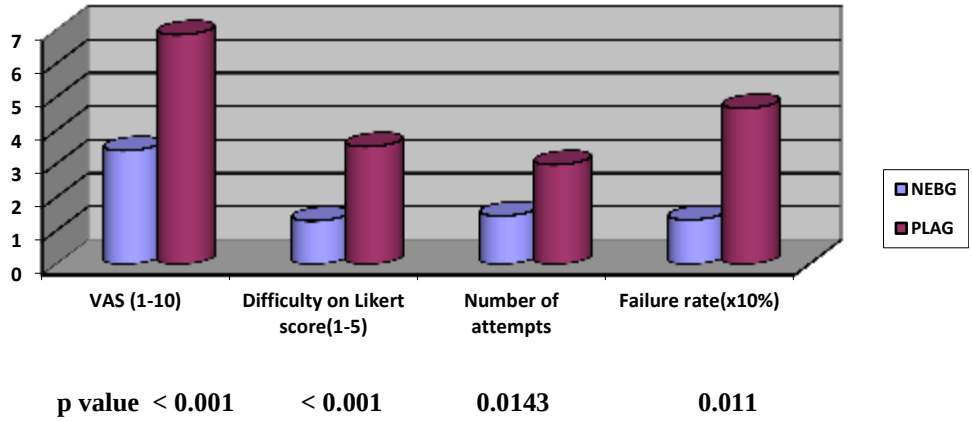
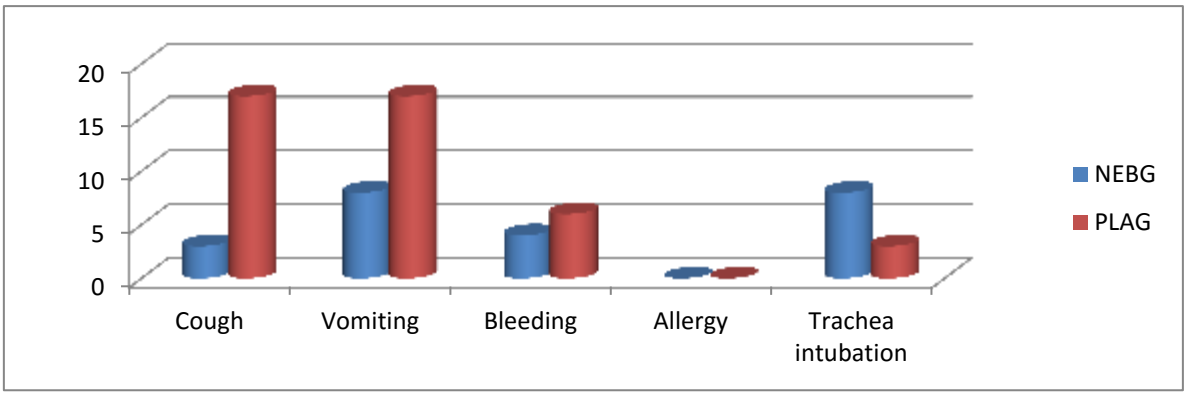


Fig 1: Showing the mean discomfort VAS score, mean Likert score, and mean number of attempts and failure rate.

The mean insertion time in NEBG was 96.4 (±19.08) seconds while in the PLAG was 246.90 (±72.79) seconds, (p<0,001). This shows a statistically significant difference between the two groups. The mean level of satisfaction on VAS score in NEBG was 6.90(±1.20) while that in the PLAG group was 2.80(±1.81) (p < 0.001). Four patients (10.25%) in NEBG suffered traumatic passage while 6 (15.38%)

patients in PLAG experienced a similar complication this is not statistically significant. The other patterns of complications between the two groups are as shown in figure 2.



p value	<0.001	0.0317	0.7348	1.000	0.1932

Fig 2: Showing pattern of complications between the two groups and the p-values

DISCUSSION

The passage of NG tube is a common but distressing procedure often performed for various reasons in emergency department [2]. Current evidence has shown that any form of topical anaesthetic agent in form of spray, nebulized aerosol and jelly applied to upper aero-digestive tract ease the passage of NG tube and reduces the patients' discomfort [1, 7]. Most of the patients are often anxious and scared of this procedure and often not tolerated.

This study showed significant improvement in patient tolerance with use of nebulized lidocaine as topical anaesthetic agent prior to passage of NG tube. A similar report obtained from other study demonstrates the effectiveness of topical anaesthetic agents to reduce pain prior to NGT insertion [14] The discomfort visual analog scale score was also lower in NEBG with significant clinical and statistical difference between the two groups, a finding similar to previous reports [13, 15]. Also noted in the study was statistically significant difference in mean change in pulse rate and respiratory rate between the two groups. This reaffirms the stress passed through by the patients during the procedure. However, no statistical significant difference in the blood pressure (with marginal higher mean arterial systolic blood pressure change in placebo group), and SPO2 findings. There is no statistical significant difference in traumatic passage in the two groups. Simple explanation for this is that passage of NG tube in PLAG induces stress that resulted in poor cooperation and tolerance, as a result of intact sensation and preserved gag reflex in these patients, while loss of sensation of nasal cavity and oropharynx in NEBG increased the likelihood of injury from persistent attempt in insensate patients. This finding is comparable to some other studies [13,14,16] though in contrary to Singer and Konia finding whose report has a higher incidence of tracheal intubation in patients with topical anaesthetic agents [17], while Spector et al found lower incidence of inadvertently trachea intubation with use of lidocaine as compared to placebo [18]. The number of attempts and success rate also show statistical significant difference between the two groups with lower number of attempt and higher success rate in the NEBG with about 87% success rate compared to about 53% success rate in PLAG which was in support from other studies reports [5, 6].

The mean likert score for difficulty level is 1.3 for the NEBG and 3.52 for the PLAG which shows a statistically significant difference between the two groups. Patients in NEBG experienced shorter mean insertion time of 2.5 minutes. Tubes were pushed in with ease compared to patients in PLAG. This observation is comparable to finding of Chan and Lau study [19].

CONCLUSION

The study demonstrates that the use of nebulized lidocaine significantly improves patients' tolerance to passage of NG tube and reduction in failure rate and mean insertion time. Though the theoretical risk of trachea intubation should not preclude the use of topical anesthetic agent prior to placement of nasogastric tube as this can be easily recognized and corrected. We therefore recommend the use of topical lidocaine in form of nebulization prior to nasogastric tube insertion.

LIMITATIONS OF THE STUDY

- The taste of the agent used may make the study not to be completely blinded
- The difficulty level may be affected by the attending physicians' expertise

- Failure to use independent observer to measure the outcomes

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DECLARATION OF CONFLICT OF INTERESTS

No conflict of interests were declared by the authors

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