

Comparing Efficacy of Lignocaine Plus Adrenaline Nebulization against Std Bronchodilator Therapy

Varun Ramamurthy¹, J. Hari Babu²

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Abstract

Materials and Methods: A total of 100 patients who fulfilled the inclusion criteria and consented were included in the randomized double blinded trial and divided into two groups; Group 1 received lignocaine combined with adrenaline nebulization and Group 2 received standard nebulized bronchodilators. The treatment response was monitored. Patient's respiratory secretion was assessed by number of suction for tracheal toileting per 8 hours and cough severity was assessed by Cough symptom score (CSS). additionally day to weaning from ventilator was documented.

Data Collection: Data will be collected at baseline and regularly throughout the study period by google forms filled by care taking staff and investigators team of doctors Respiratory parameters were assessed 8th hourly followed by regular assessments and emergency intervention as and when needed were done.

Statistical Analysis: We applied independent sample t-test. p-value less than 0.05, so there is a significant difference in average cough [p value of 0.0001], average secretion toileting frequency [p value of 0.0001] between loxicard and control groups. Mean of control group is always more as compare to loxicard group for average cough, average secretion and ventilator weaned days [p value of 0.0001]. Though expected, there was no gender variation among the study or control group and with a p-value of 0.27 hence statistical significance of variation among men and women were null.

Ethical Considerations: Informed consent was obtained from all participants or their legally authorized representatives. Any deterioration warranting a shift from the current medications were duly undertaken and no patient was released from the study group due to unforeseen complications.

Objective: To investigate the effectiveness of Lignocaine in combination with adrenaline

Author's Affiliation: ¹H.O.D, ICU, ²Senior Resident, Department of Critical Care Medicine, Velammal Medical College, Madurai 625009, Tamil Nadu, India.

Corresponding Author: J. Hari Babu, Senior Resident Department of Critical Care Medicine, Velammal Medical College, Madurai 625009, Tamil Nadu, India.

E-mail: dr.varunramamurthy@gmail.com

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nebulization as a therapeutic intervention in the treatment of tracheostomized head injury patients over standard bronchodilator therapy, thereby demonstrating better upper respiratory symptom mitigation.

Conclusion: This study aims to contribute valuable insights into the potential benefits of Loxicard combined with adrenaline nebulization in tracheostomized head



injury patients. Trying other combinations such as ropivacaine with or without adrenaline can be tested in the future. The findings may guide future clinical practice and research in optimizing respiratory and neurological outcomes in this specific patient population.

Keywords: Lignocaine Nebulization; Head Injury; Tracheostomy; Adrenaline nebulization.

INTRODUCTION

Bronchospasm and excessive tracheal secretions pose significant challenges in the management of tracheostomized head injury patients, often leading to compromised respiratory function and prolonged mechanical ventilation.¹ While various bronchodilators have been employed to address these issues, the search for optimal therapeutic strategies that enhance patient comfort and improve clinical outcomes continues. This prospective randomized study seeks to explore the efficacy of lignocaine plus adrenaline nebulization as a novel approach to address bronchospasm and tracheal secretions in tracheostomized head injury patients.

Tracheostomy, a common intervention in severe head injuries, disrupts the natural airway defense mechanisms, rendering patients susceptible to bronchospasm and impaired mucociliary clearance.^{2,3} The presence of tracheal secretions further complicates the clinical course, leading to increased airway resistance and heightened risk of respiratory complications.^{4,5} While various bronchodilators have been utilized to alleviate these challenges, their effectiveness in simultaneously ensuring patient comfort remains a subject of ongoing investigation.

Lignocaine, a local anesthetic, has demonstrated its ability to anesthetize the airway, offering potential benefits in reducing bronchospasm, cough and enhancing patient comfort during mechanical ventilation.^{6,7} Adrenaline, with its bronchodilator properties, may complement lignocaine by providing additional relief from airway constriction.⁸ The nebulization of lignocaine plus adrenaline represents a novel therapeutic avenue that holds promise in tackling the multifaceted challenges of bronchospasm and tracheal secretions in tracheostomized head injury patients.

While various bronchodilators have been traditionally used to topicalize the airway in this patient population, the unique combination of lignocaine and adrenaline, delivered through nebulization, presents an innovative approach. This study aims to contribute to the existing body of

knowledge by evaluating the comparative efficacy of lignocaine plus adrenaline nebulization against standard bronchodilator therapy, with a primary focus on airway resistance, oxygenation, and overall patient comfort. The potential benefits of this intervention extend beyond mere bronchodilation, offering a comprehensive solution to the complex respiratory challenges faced by tracheostomized head injury patients.

METHODS

This study is designed as a prospective, randomized controlled trial with double blinding to systematically investigate the efficacy of lignocaine plus adrenaline nebulization compared to standard bronchodilator therapy in tracheostomized head injury patients. Study was started after obtaining clearance from the institutional ethical committee.

100 Participants were recruited among tracheostomized head injury patients meeting the inclusion criteria. Informed consent was obtained from patients or their legal representatives.

Inclusion criteria are Adult patients (Age 18-65) with a confirmed diagnosis of head injury requiring tracheostomy, Within 48 hours post-tracheostomy placement and Stable hemodynamic status.

Exclusion criteria include Known contraindications to Lignocaine or adrenaline, Unstable cardiovascular status, and Severe co-existing medical conditions impacting the study outcomes.

Participants will be randomly assigned to either the experimental group (lignocaine plus adrenaline nebulization) or the control group (standard bronchodilator therapy) using computer-generated random numbers 50 members in two groups. Randomization will be stratified based on relevant clinical factors.

Experimental Group

Lignocaine Plus Adrenaline Nebulization was given 2ml of 2% Lignocaine plus 2ml of Adrenaline (1:1000) Plus 1ml sterile distilled water given 8th hourly.

Control Group

The combination of ipratropium bromide with salbutamol available as Duolin and budesonide hydrochloride available as a commercial product Budecort forms the predominant bronchodilator therapy in many institutions including ours, and it is chosen as the therapy for the control groups.

Double blinding was effected by the duty staff incharge of neuro ICU who mixed either lignocaine 2 ml (loxicard is the commercial preparation, which is devoid of preservatives that are potential irritant to the airway) with 2 ml adrenaline or 2 ml duolin plus 2 ml budecort as per study allotment. 1 ml distilled water added to both group to get 5 ml in the nebulizer kit.

Outcome measured are Frequency of tracheal toileting, severity of cough, no days from tracheostomy to ventilator weaning. Though other parameters such as rescue reconnection to ventilator were studied, there was a lot of subjective variations depending on the caregivers observed and hence was not studied further.

As no standard methods are in practise for evaluating tracheal secretion, a simple frequency of secretion score was formalised after discussing with neurosurgery consultants and neuro staff incharges it was decided that if [<2 suction / 8 hr shift is score 1, $2-6$ suction/8 hr is 2, >6 suction is 3], this scoring

Table 1: Total group comparison

| Group Statistics | | | | | | |
|-------------------|----------|----|--------|----------------|-----------------|----------------------|
| | group | N | Mean | Std. Deviation | Std. Error Mean | T statistic, p-value |
| Average cough | Loxicard | 50 | 2.3400 | .34582 | .04891 | -9.798, |
| | Control | 50 | 3.0200 | .34817 | .04924 | 0.0001 |
| Average secretion | Loxicard | 50 | 1.5120 | .28330 | .04007 | -8.299, |
| | Control | 50 | 1.9640 | .26089 | .03690 | 0.0001 |
| weaned | Loxicard | 50 | 4.3800 | .87808 | .12418 | -3.703, |
| | Control | 50 | 5.0600 | .95640 | .13525 | 0.0001 |

in average cough, average secretion and weaned between loxicard and control groups. Mean of control group is always more as compare to loxicard group for average cough, average secretion and weaned.

We applied independent sample t-test. p-value less than 0.05, so there is a significant difference in average cough, average secretion and weaned

was tested in our unit and found to be a useful tool in deciding the appropriateness of shifting a patient to ward from high dependency unit.

Cough symptom score is a tested questionnaire format used in assessing the severity of coughs during day and night shifts.

Excel was used to enter the data, and SPSS was used to analyse it (Version 21). For quantitative variables, descriptive statistics were generated, including mean, standard deviation, and proportions (percent). To verify the theory Chi Square, Independent Sample T-tests and ANOVA were applied. Statistics were judged significant at $P < 0.05$.

RESULTS

A total of 100 patients were enrolled in this study as 50 patients in two groups. We applied independent sample t test. p-value less than 0.05, so there is a significant difference in average cough [p value of 0.0001], average secretion toileting frequency [p-value of 0.0001] between loxicard and control groups. Mean of control group is always more as compare to loxicard group for average cough, average secretion and ventilator weaned days [p-value of 0.0001]. table 1

We applied independent sample t test. p-value less than 0.05, so there is a significant difference

between loxicard and control groups. Mean of control group is always more as compare to loxicard group for average cough, average secretion and weaned for female.

We applied independent sample t-test. p-value less than 0.05, so there is a significant difference in average cough, average secretion and weaned between loxicard and control groups. Mean of

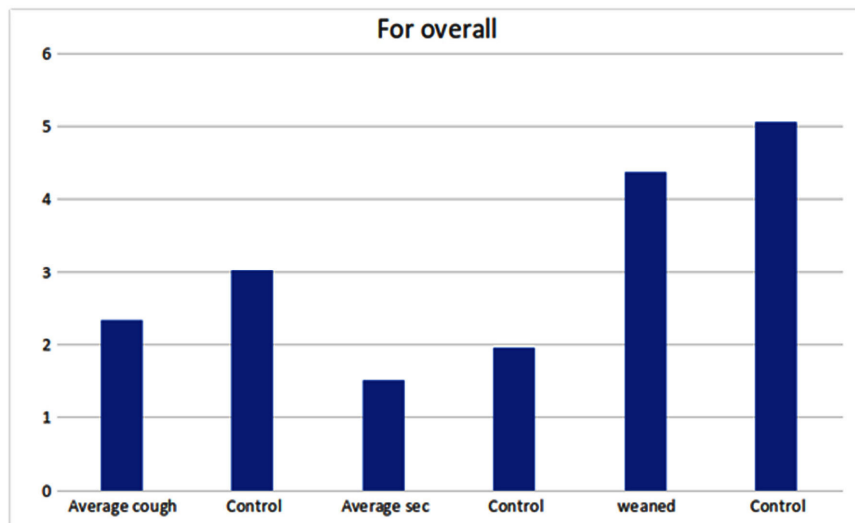


Fig. 1: Average cough, Average secretion and weaned between loxicard and control groups

Table 2: Comparison between two groups among female gender

| | Group Statistics ^a | | | | | |
|-------------------|-------------------------------|----|--------|----------------|-----------------|----------------------|
| | group | N | Mean | Std. Deviation | Std. Error Mean | T statistic, p-value |
| Average cough | Loxicard | 16 | 2.4000 | .33466 | .08367 | -5.210, |
| | Control | 16 | 3.0125 | .33040 | .08260 | 0.0001 |
| Average secretion | Loxicard | 16 | 1.5000 | .34254 | .08563 | -3.508, |
| | Control | 16 | 1.9000 | .30111 | .07528 | 0.001 |
| Weaned | Loxicard | 16 | 4.0625 | .99791 | .24948 | -2.744, |
| | Control | 16 | 5.0625 | 1.06262 | .26566 | 0.010 |

a. gender = Female

control group is always more as compare to loxicard group for average cough, average secretion and weaned for male.

p-value more than 0.05 so no significant difference in for average cough, average secretion and weaned between male and female.

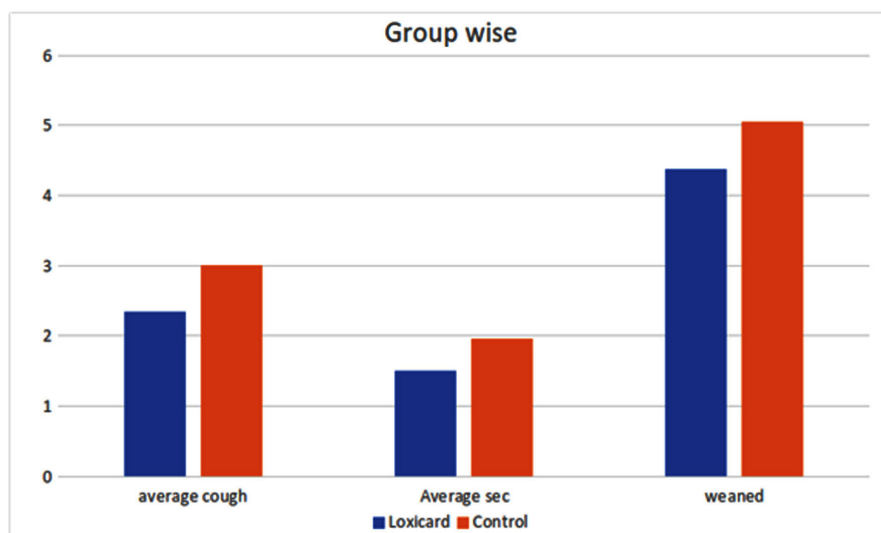


Fig. 2: Comparison of study versus control group

Table 3: Comparision between two groups among male gender

| | Group Statistica | | | | | |
|-------------------|------------------|----|--------|----------------|-----------------|----------------------|
| | gp | N | Mean | Std. Deviation | Std. Error Mean | T statistic, p-value |
| Average cough | Loxicard | 34 | 2.3118 | .35228 | .06042 | -8.228, |
| | Control | 34 | 3.0235 | .36102 | .06192 | 0.0001 |
| Average secretion | Loxicard | 34 | 1.5176 | .25640 | .04397 | -7.932, |
| | Control | 34 | 1.9941 | .23861 | .04092 | 0.001 |
| Weaned | Loxicard | 34 | 4.5294 | .78760 | .13507 | -2.550, |
| | Control | 34 | 5.0588 | .91920 | .15764 | 0.013 |

a. gender = male

Table 4: Comparision among male and female genders

| | Group Statistics | | | | | |
|-------------------|------------------|----|--------|----------------|-----------------|----------------------|
| | Gender | N | Mean | Std. Deviation | Std. Error Mean | T statistic, p-value |
| Average cough | Female | 32 | 2.7063 | .45148 | .07981 | 0.369 |
| | Male | 68 | 2.6676 | .50385 | .06110 | 0.713 |
| Average secretion | Female | 32 | 1.7000 | .37674 | .06660 | -0.736 |
| | Male | 68 | 1.7559 | .34355 | .04166 | 0.464 |
| Weaned | Female | 32 | 4.5625 | 1.13415 | .20049 | -1.109 |
| | Male | 68 | 4.7941 | .89039 | .10798 | 0.270 |

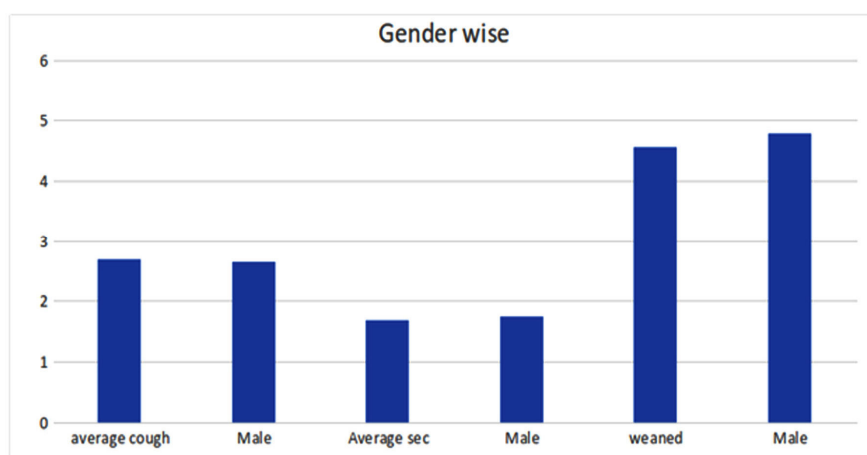


Fig. 3: Gender wise comparison

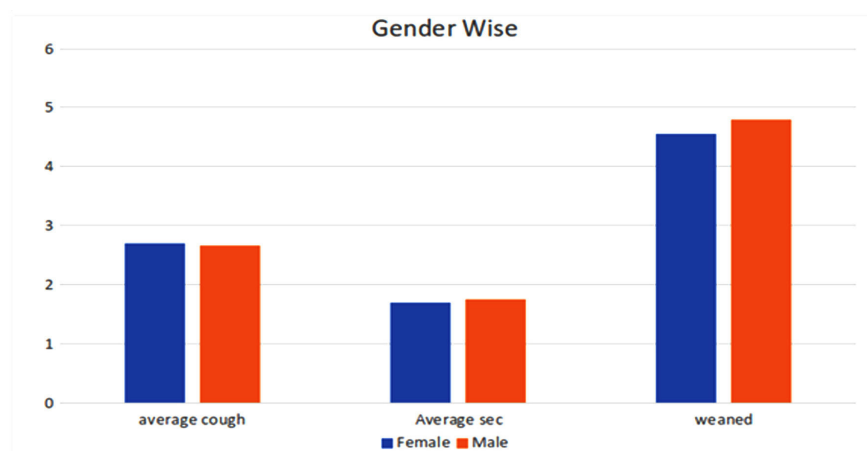


Fig. 4: Gender Wise

SUB GROUP ANALYSIS

Though expected, there was no gender variation among the study or control group and with a p value of 0.27 hence statistical significance of variation among men and women were null.

DISCUSSION

There are a lot of brain lung interactions not well studied in head injury patients, unexplained tachypnea and central breathing are well documented but increased infective inflammatory tracheal secretions as a direct result of head injury is not well studied.⁹ As a high volume centre treating more than 3000 to 5000 patients per year, we observed that tracheal secretion was one of the major factors causing inconvenience to the recovering patient and delaying their time to step down care. The ICP variations that occur due to cough and patients strain during toileting of secretions can be detrimental to recovery of patients.^{10,11}

The lignocaine nebulization used in anesthesia and endoscopy suites have made instrumentation of airway easier along with regional blocks.¹² The concern that lignocaine can negate the airway preventive reflexes and thereby increasing the aspiration risk is theoretically well documented. But already tracheostomised patients are protected by cuffed tracheostomy tubes and hence usage of lignocaine in these patients is not contraindicated.

The fact that most road traffic accidents occur in male population under the influence of alcohol and most of the victims are exposed to tobacco usage (smoking) makes their airway hyperreactive, during the cessation of smoking period, while in ICUs.¹³

The adrenaline being a potent bronchodilator is well known to reduce mucosal congestion and thereby theoretically prolong the effects of lignocaine was studied previously.¹⁴

The adrenaline reduced the mucosal bleeding both iatrogenic and trauma related¹⁵, thereby helping in reducing the bleeding that is witnessed during tracheal toileting in some patients.

Nebulization with lignocaine plus adrenaline proved to be beneficial when compared to other routine bronchodilator drugs. This prospective randomized study aims to provide valuable insights into the efficacy of lignocaine plus adrenaline

nebulization as an alternative or adjunct therapy for tracheostomized head injury patients. The findings could have implications for improving respiratory outcomes in this specific patient population. Being cost effective adds to the advantages already elicited.

This therapy though demonstrated superiority in respiratory symptom mitigation, the weaning from ventilator is dependent on various parameters like GCS, lung injury, previous history of respiratory illness, cardiac status and many more and hence may not be correlating directly to aiding in weaning from ventilator in all patients.

CONCLUSIONS

As was postulated, we found the respiratory symptom mitigation as reflected by decrease in average cough and average secretion was better in the loxicard group. There was no significant variation due to gender in both the groups.

Though statistically significant the days to be weaned from ventilator may not be reflective of the superiority of loxicard group, rather it might augment the weaning process. The weaning depends on a lot of factors such as respiratory comorbidity, central causes and GCS recovery.

Though it is safe to say that no harm in tracheostomy patients were noted because of the anesthetic property of the lignocaine. The synergistic effect of adrenaline in prolonging the benefits of lignocaine to be better evaluated in future studies by comparing local anesthetic with and without adrenaline.

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