Original article:

Comparison between conventional Ventimask Nebulization versus Micro pump Inhaler (AERONEB) for surface anaesthesia of upper airway to facilitate awake FOL guided intubation

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Abstract:

Introduction: Awake fibre-optic intubation is a specialised procedure used in difficult airway situations. Nebulisation with Local anaesthetic is one of the method used to achieve surface anaesthesia of airway. Micropump inhaler is a commonly used nebuliser with active nebulisation of drug used.

Material and Methods: After obtaining clearance from institutional ethical committee and institutional scientific committee, 40 patients were divided into 2 groups. Gp-A had 20 patients who were nebulized with 5ml of 4% Lignocaine solution using Micropump inhaler and Gp-B had 20 patients who were nebulized with 5 ml of 4% Lignocaine with standard ventimask nebulizer. Sedation and analgesia was provided by injection fentanyl 1 mcg/kg intravenous 15 minutes before starting the procedure. FOL guided intubation through oral route was attempted.

Observations and Results: Various parameters including Cough Reflex, Gag reflex, vocal cord mobility, hemodynamic parameters etc were studied and recorded as per observation proforma designed for the study. The data was statistically analysed. Gag reflex score and cough reflex scores were much lower in Gp-A (Micro-pump) as compared to Gp-B (Conventional ventimask) Gag Relex score (Mean 0.5 Vs 1.45, p-value 0.003) and Cough Reflex score (1.30 Vs 2.15, P-value-0.001)

Conclusion: Use of micropump nebuliser proved to be beneficial for nebulisation with local anaesthetic of upper airway as compared to conventional ventimask.

Key Words:- micro pump inhaler, ventimask, surface anaesthesia

Introduction

Intubation of the trachea is an essential step for administration of general anaesthesia in a patient undergoing surgical procedure. Anaesthesiologist is the key person to facilitate intubation of trachea. At times there are moments of anxiety when he lands up in a situation where he is not able to intubate the trachea. Fibre optic guided intubation of the trachea is a well established standard procedure to be followed in such difficult situations. This procedure can be performed either under general anaesthesia or under local anaesthesia of the upper airway. Awake intubation is a specialized procedure which is attempted in patients who have a difficult airway e.g. post burn contractures of the neck, tympano-mandibular joint ankylosis, oral cavity tumors, fractures of mandible and cervical spine etc.

Micro-pump inhaler (Aeroneb) is a hand held portable nebulization device which is micropump driven. According to its available literature the distribution of aerosol produced is of varying sizes and a very high proportion of which was deposited in the oropharynx that is the area needed to be anaesthetized to facilitate awake intubation. Most of the present day nebulizers are gas driven and they deliver drugs to bronchoalveolar level to relieve bronchospasm. They are not anaesthesia specific.

Micropump nebulizers (Aerosol generator) are used to nebulize medications in the treatment of Bronchial asthma, COPD, Cystic Fibrosis etc where prescribed liquid medicine is turned into a fine mist and then inhaled into lungs. When nebulizer is turned on it pumps the liquid medicine through the tiny holes in a wafer thin metal plate to create a soft mist aerosol.

Aims and Objectives

Primary Aim: To assess the efficacy of Micropump nebuliser for administration of surface anaesthesia of upper airway to facilitate awake intubation with FOL guided intubation.

Secondary aim: To compare Micropump nebuliser with conventional ventimask nebuliser for administration of surface anaesthesia of upper airway.

Materials and methods

Present study was conducted on patients belonging to either sex between the ages of 18 -65 years. Only ASA grade 1 & 2 patients posted for elective surgery were selected. The study was performed at Northern Railway Central Hospital, New Delhi. After obtaining clearance from institutional ethical committee and institutional scientific committee, a well informed written consent was obtained from the candidate of study and only those patients who voluntarily agreed to be part of this study were taken into consideration.

Our study was planned to be a blinded prospective study where observer was kept blinded about the group to which category the particular patient belongs to.

40 eligible patients were divided into 2 groups (Group-A and Group-B) of 20 patients each.

Group-A(N=20) were nebulized with 5ml of 4% Lignocaine solution using Micropump inhaler.

Group-B(N=20) were nebulized with 5 ml of 4% Lignocaine with standard ventimask nebulizer.

All patients remained fasting for 6 hours prior to the start of procedure..

On arrival in the operating room, the procedure was duly explained to the to the patient, monitors were then attached and after taking baseline readings of Noninvasive arterial Blood Pressure (NIBP), five leads Electrocardiogram (ECG) and digital pulse oxymetry(SpO_2). Continuous monitoring of these parameters was done for the duration of the study. An intravenous line was secured with 18/20 G cannula and intravenous fluid was started. After the measurement of baseline HR, NIBP and SpO2, all patients were premedicated with injection Glycopyrrolate 0.01mg/kg administered intramuscularly, injection Metoclopromide 0.2 mg/kg intravenously 30 minute before starting the procedure. Injection Ranitidine 50 mg intravenously was given 30 minutes prior to procedure to raise the pH of gastric contents.

A sealed envelope was opened to allocate patients randomly to one of two groups.

Sedation and analgesia was provided by injection fentanyl 1 mcg/kg intravenous 15 minutes before starting the procedure. Injection propofol 1-2 mg/kg intravenous was kept ready to provide additional sedation if required prior to railroading of the endotracheal tube over intubating fiberscope once it had reached inside the trachea up to the level of carina.

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The intubation was performed through oral route after putting a bite block between the upper and lower incisor teeth. Once larynx became visible, 1 ml of lignocaine 2% was sprayed over the vocal cords and waited for 60 seconds for the full effect of the drug before proceeding. Similar spray as you go was done once the intubating fiberscope had reached mid trachea and carina. Once carina was visible, a sleep dose of injection propofol was administered to facilitate the railroading of endotracheal tube over intubating fiberscope.

Following parameters were assessed

1. Cough reflex(score)
2. Gag reflex(score)
3. Vocal cord immobility (grading)
4. Blood pressure, Pulse rate, Oxygen saturation (Baseline after premedication, Highest and Lowest reading during the procedure, and immediately after intubation)
5. Time taken for intubation

Following scoring methods were used while recording observations (As shown in Table-1)

Cough reflex scale Score:	**Gag reflex scale Score:**
0 = No coughing in response to intubation 1= Mild coughing that did not hinder the intubation 2= Moderate coughing that interfered minimally with intubation 3= Severe coughing that made intubation difficult 4= Severe coughing that required additional local anaesthesia and/or other change in technique to achieve successful intubation	0 = No gagging in response to intubation 1= Mild gagging that did not hinder the intubation 2= Moderate gagging that interfered minimally with intubation 3= Severe gagging that made intubation difficult 4= Severe gagging that required additional local anaesthesia and/or other change in technique to achieve successful intubation
Vocal cord mobility Score :	**Patient discomfort Score**
0= Completely immobile 1=Mild movement not hindering intubation 2=Moderate movement making intubation difficult 3=Completely Mobile making intubation impossible	0= No discomfort 1=Mild discomfort 2=Moderate discomfort 3=Severe discomfort

Table-1: Cough reflex scale Score, Gag reflex scale Score, Vocal cord mobility Score, Patient discomfort Score

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Observation and results

After collecting the data obtained from our study cases, all the available proformas were tabulated and statistical analysis was done with the help of a biostatistician using computer software (SPSS-Version -16). The results were as follows.

Parameter	Group-A	Group-B	P-Value
Mean age (years	45.50	50.00	0.311
HEIGHT	1.61	1.62	.753
WEIGHT	66.05	63.25	.440
BODY MASS INDEX	25.34	24.02	.191

Table-2: Demographic profile. Patients in both the the groups were comparable (p value > .05)

Table-2- Demographic profile. Patients in both the groups were not significantly different and were comparable (p value > .05)

	Mean Heart Rate/min			Mean **Systolic BP**			Mean **Diastolic BP**		
	Gp-A	Gp-B	P-value	Gp-A	Gp-B	P value	Gp-A	Gp-B	P value
Baseline	92.70	81.50	0.050	**133.95**	**135.05**	0.882	**78.90**	**12.049**	0.562
Highest during the procedure	97.30	97.95	0.904	**140.45**	**144.90**	0.540	**78.00**	**10.242**	1.00
Lowest during the procedure	83.05	82.05	0.847	**114.50**	**109.95**	0.596	**64.40**	**15.274**	0.130
After the procedure	82.25	86.00	0.406	**113.35**	**108.95**	0.588	**72.15**	**13.990**	0.61

Table-3: Comparison between Mean Heart Rate, Mean Systolic BP, Mean Diastolic BP

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GROUP		Gag Reflex Scale Score	Cough Reflex Scale Score	No. of attempts required for intubation
GROUP A (MICRO PUMP INHALER)	Minimum	0	0	1
	Maximum	2	3	1
	Mean	**.50**	**1.30**	**1**
GROUP B (CONVENTIONAL VENTIMASK NEBULIZATION)	Minimum	0	1	1
	Maximum	4	3	4
	Mean	**1.45**	**2.15**	**1.4**
	P-Value	**0.003**	**0.001**	**0.019**

Table-4 :- Comparison between Gag Reflex and Cough Reflex Score

The mean gag reflex score according to scale in group A (micropump group) was 0.5 which was significantly less than gag reflex score(mean 1.45) of group B(conventional ventimask group) (P Value-**0.003)**. Also the cough reflex score in group A was 1.3 as compared to 2.15 in group B (P- **0.001)**. Thereby group A patients had less of gagging and coughing during the procedure which helped in proceeding the procedure further much more easily in group A patients.

While proceeding for laryngoscopic intubation, upon visualization of vocal cords a scoring was done as per the score described in the literature and shown in methodology. In our study in group A vocal cords were found to be completely immobile in 6 patients (30%) and making the awake fiberoptic intubation easier as compared to 3 patients (15%) in group B. The vocal cords showed mild movement (score 1) in 12 patients (60%) in group A as compared to 5 patients (25%) in group B. Vocal cords had moderate movement making intubation difficult in 2 patients(10%) in group A and 9 patients (45%) in group B. In group A the mean score was 0.80 as compared to mean score of 1.60 in group B which was highly significant and thereby indicating less vocal cord movement in group A patients and helping the intubation easier.

Patient discomfort was also noted and scoring was done according to the patient discomfort scale mentioned in the literature and methodology. In group A 2 patients (10%) did not have any discomfort during during the procedure as compared to this there was no patient in no discomfort scale in group B(ventimask). In group A 13 patients (65%) had mild discomfort (score of 1) compared to 5 patients(25%) in group B. 5 patients of group A (25%) experienced moderate discomfort (score of 2) as compared to 11 patients(55%) of group B. None of the patients belonging to group A had severe discomfort (score of 3) as compared to 4 patients (20%) in group B. Out of these 4 patients of group B one patient could not be successfully intubated due to extreme discomfort and in two cases endotracheal tube could not be railroaded due to inadequate relaxation of larynx and extreme coughing by the patients.

Number of times the 4% lignocaine sprayed to relax the larynx and vocal cords were also more in group B. It was sprayed only once in 6 cases(30%) in group A as compared to 1 case (15%) in group B . In 13 patients

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(65%) lignocaine was required to be sprayed twice for adequate relaxation in both the groups. While it was sprayed three times in one case(5%) of group A as compared to 6 cases(30%) of group B. We found that in group A (micropump), additional requirement of 1 ml of 4% lignocaine spray was less as compared to that in group B.

Number of attempts required for successful fiberoptic laryngoscope insertion beyond the vocal cords, were significantly more in group B as compared to group A. Fiberoptic laryngoscope was inserted twice in 19 patients (95%) to perform intubation in group A as compared to 11 patients (55%) in group B. In group A in one patient (5%) fiberoptic laryngoscope was inserted thrice for successful intubation as compared to 6 patients (30%) of group B. In three patients (15%) of group B fiberoptic was inserted 4 times and three patients out of these 4 still could not be intubated as one patient complained extreme discomfort. In two other patients of group B, even after successful insertion of fiberoptic laryngoscope beyond vocal cords, endotracheal tube could not be railroaded due to inadequate relaxation of larynx of patients.

Number of attempts required for intubation were significantly higher in group B as compared to group A. All the patients in group A were successfully intubated in one attempt(100%) as compared to 15 patients(75%) belonging to group B.Three patients(15%) required two attempts

Discussion

There are various techniques practised for facilitating the procedure of intubation using fiberoptic laryngoscope. Different researchers have used various combination of drugs for general anaesthesia and local anaesthesia of the upper airway for this facilitation.

We decided to use a new devise available in our department, a micropump inhaler (Aeroneb) for nebulization of upper airway with local anaesthetic and analyse the results obtained. We also decided to compare the quality of nebulisation by using this equipment against the commonly available conventional ventimask used for nebulisation.

On literature review (user manual of the product) it was found that micropump nebulizer(Aerosol generator, brand name Aeroneb) is primarily used to nebulize medications for the treatment of Bronchial Asthma, COPD, Cystic Fibrosis etc where prescribed medications are administered. These liquid medications are turned into fine mist (Aerosol) by the use of micropump which pumps the liquid through the tiny holes in a wafer thin metal plate to produce soft mist aerosol. This device is found to be very simple to operate and easy to handle.

Figure-1: The vibrating mesh two different magnifications.

Further literature review revealed that the size of the particles in an aerosol strongly influences its deposition in the lungs. The aerosols are almost always a mix of different particle sizes.

The mass median diameter (MMD) is the median size of the particle in an aerosol (that is one half of the mass of the aerosol is smaller than the MMD and other half of mass of aerosol is of larger than MMD. The amount of drug that can be delivered is affected by not only MMD but also the measure of wide dispersal of particles over the range of sizes.

It is also mentioned that the aerosol generated by using electronic micropump nebulizer have smaller MMD as compared to conventional ventimask nebuliuzer. The electronic micropump nebulizers generate a more hetrodisperse solution of aerosols.

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Size of Particle	Action
>10 µm	filtered by nose or deposited in oro-pharynx
5-10 µm	reach first six generations of respiratory tree
0.5-5 µm	best for peripheral deposition
<0.5 µm	may be expired as do not settle effectively

Table-5 :- Action of mist particle size at different levels of upper airway

Denise[13] et al in their study mentioned that size of mist particles by conventional nebulisers vary from 1 – 20 µm. The smaller particles go into terminal bronchioles and larger particles get deposited on nasal and paharyngeal mucosa. For our purpose of achieving local anaesthesia of upper airway, we need aerosol particles of local anaesthetic to be deposited in the oral cavity , pharynx, trachea and first generation of respiratory tree. So according to the table an aerosol size of 5- 10 µ should be ideal for achieving the local anaesthesia of upper airway for the blunting of airway responses and hemodynamic changes associated with awake fiberoptic laryngoscope guided intubation. The figure shown below shows that using micropump inhaler the aerodynamic size of aerosol was ranging from 1-10 µ for nearly 80% of the liquid used. This helped in deposition of around 80% of the aerosol in the oropharynx, trachea and first generation respiratory tree as shown in diagram. When we look at the deposition of aerosol by ventimask, we find that very less amount is deposited in the oropharynx. Majority of the aerosol remain within the ventimask device or got exhaled

Figure-2 :- It shows distribution of aerosols in micro-pump mist (1-10Micron size has nearly 80% mist particles

Based on above explanation after our study, the observation and results confirmed our presumptions to show that the use of micropump nebulizer was significantly better as compared to use of conventional ventimask nebulizer for administration of local anaesthesia of upper airway.

Conclusion:

From our study, we conclude that using a simple devise i.e. micropump nebuliser for the purpose of nebulisation of upper airway with the local anaesthetic has proved to be very beneficial. Also it is less time consuming, easy to use and with better results as stu for nebulisation with local anaesthetic of upper airway as compared to conventional ventimask.

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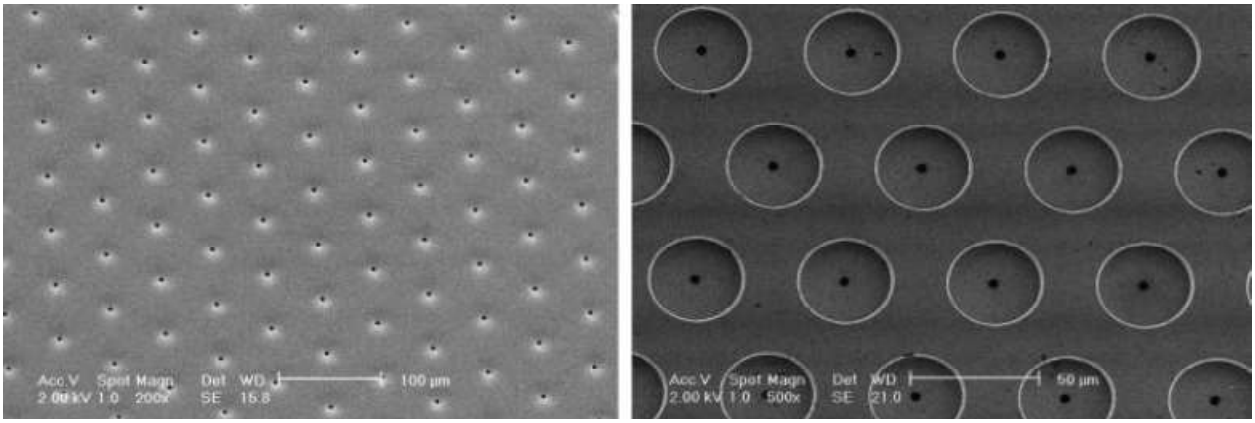

Figure-1: The vibrating mesh two different magnifications.

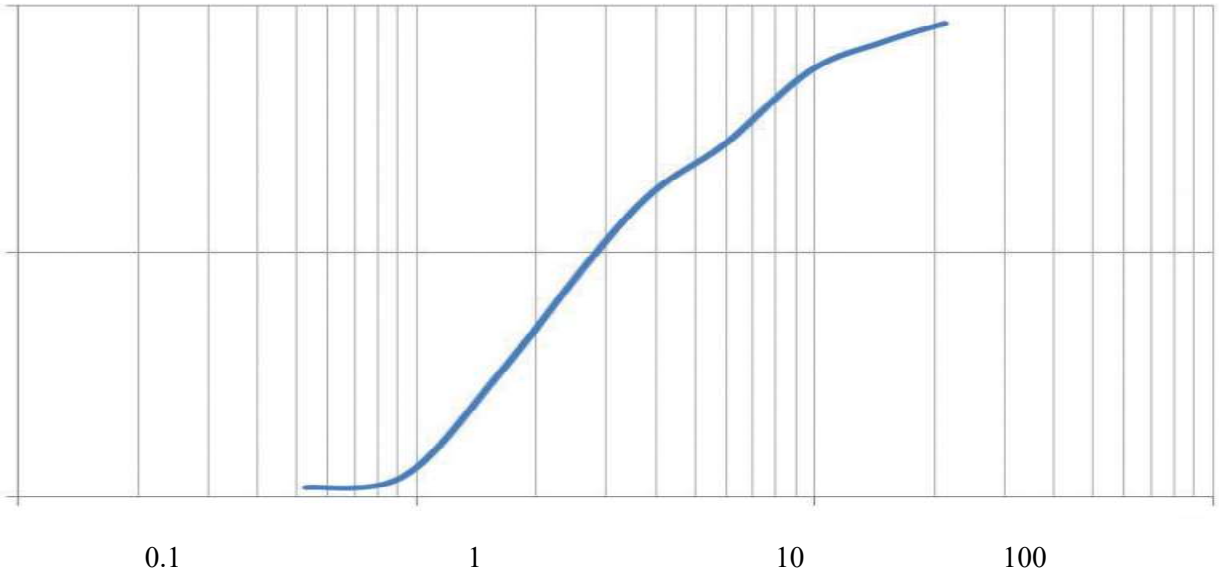

Figure-2 :- AeroDynamic size(µm). It shows distribution of aerosols in micro-pump mist (1-10Micron size has nearly 80% mist particles

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