INTRODUCTION

Fibreoptic intubation is indicated for patients with anticipated difficult airway because of airway pathology, anatomical variations, airway trauma, morbid obesity or unstable cervical spine.\(^1\) Awake fibreoptic intubation (AFOI) is technically challenging even for the experienced anaesthesiologists and often uncomfortable for the patients. Inadequate topical anaesthesia of the airway may make the intubation impossible or lead to crisis from aspiration or breath holding leading to desaturation. The key element of a successful awake intubation depends on adequate topical anaesthesia of the airway. In this study we aimed to compare efficacy of two topical anaesthesia techniques, atomised local anaesthetic versus transtracheal topical anaesthesia for AFOI.

METHODS

A prospective, randomised controlled study was designed. Thirty-three patients with anticipated difficult airway requiring AFOI were consented and studied. The study was approved by the institutional ethics committee. The patients with an American Society of Anesthesiologists’ physical status 1–3 with anticipated difficult airway requiring AFOI were included. The primary objective was to compare the patient comfort after topical anaesthesia of the airway using atomiser with transtracheal injection of the local anaesthetic agent for AFOI in patients with anticipated difficult airway. The secondary objectives were to compare the ease of intubation, time required to intubate and the haemodynamic changes during intubation.

After topical anaesthesia of nostrils, patients in Group T received transtracheal injection of 4 ml of 4% lignocaine whereas Group A patients received 4–5 mL of 4% atomised lignocaine using DeVilbiss atomiser before AFOI. Patient comfort assessed objectively by the anaesthetic assistant during the procedure, ease of intubation assessed using cough and gag reflex score, time taken to intubate and the haemodynamic changes during the procedure were compared. Results: Ease of intubation, patient comfort and the time taken to intubate were significantly better in Group T patients, with \(P = 0.001\), 0.009 and 0.019, respectively, compared with the patients in Group A. There were no significant changes in haemodynamic parameters.

Conclusion: Topical anaesthesia by transtracheal injection in patients with anticipated difficult airway made AFOI easier and faster with better patient comfort compared to atomiser with no clinically significant untoward side effects.

Key words: Atomisation, awake fibreoptic intubation, local anaesthetic, patient comfort, transtracheal
difficult airway requiring AFOI were recruited for the study after obtaining the Institutional Ethics and Scientific Committee approval and patient consent.

The primary objective of our study was to evaluate the patient discomfort in AFOI, based on patient comfort, cough and gag scores, on topical anaesthesia of airway by single transtracheal injection of local anaesthetic agent (LA) compared with the LA atomiser in patients with anticipated difficult airway intubation. The secondary objectives included comparing the ease of intubation process, time required to secure the endotracheal tube and the cardiorespiratory effects during the procedure with these two techniques. Patients aged 18 years and above, of American Society of Anesthesiologists’ physical status grade 1–3, with anticipated difficult airway suitable for topical anaesthesia by both transtracheal injection and atomiser methods were included in the study. Pregnant patients, those with coagulopathy and those on anticoagulants or antiplatelet agents were excluded from this study.

Patients were allotted by computer-generated random sequence series into two groups. Group T was randomised to receive transtracheal injection of lignocaine and Group A was randomised to receive atomised lignocaine. Patients were explained about the anaesthesia procedure and the informed consents were obtained. All patients had their airway assessed by experienced anaesthesiologists and identified to have difficulty in intubation by conventional laryngoscopy. The tools used for assessment for difficult airway were Mallampati classification, thyromental distance and temporomandibular joint and neck mobility. The history regarding the illness, surgeries and comorbidities were also assessed.

After fasting for 6 h or more, the selected patients were given glycopyrrolate 0.2 mg intravenously (IV) 15 min pre-operatively. Patients received fentanyl 1–2 μg/kg IV in incremental doses to obtain a Ramsay sedation scale of 2, (1- Anxious, agitated or restless, 2- Co-operative, oriented and tranquil, 3- Responds to command only, 4- Brisk response to light glabellar tap or loud auditory stimulus, 5- Sluggish response to light glabellar tap or loud auditory stimulus, 6- No response to light glabellar tap or loud auditory stimulus) that is, a cooperative, oriented and tranquil patient. Patients in both groups were given two sprays of 10% lignocaine into each nostril and 1 mL of 2% lignocaine jelly. Patients in Group T were given transtracheal injection of 4 ml of 4% lignocaine whereas Group A patients were given 4% atomised lignocaine using DeVilbiss Model 163 atomiser [Figure 1, DeVilbiss Healthcare PTY Ltd., Somerset, Pennsylvania, USA]. This atomiser works on Venturi principle and has a glass reservoir and metal top. It is used to deliver the atomised LA in a controlled fashion during inspiration with all the advantages of fine particle size and low-dosage requirement in addition to better and rapid action.

The atomiser was sterilised by autoclaving or plasma sterilisation for every use. The glass reservoir was filled with 10mL of 4% lignocaine and was connected to the oxygen tubing. Fine mist of the lignocaine obtained from the atomiser by intermittently blocking the pre-made perforation in the oxygen tubing, at a flow rate of 8–10 L/min, was directed towards the soft palate and posterior pharynx in a controlled fashion during patients’ inspiration to topicalise the airway. Patients were asked to take full vital capacity breaths of atomised lignocaine contained oxygen to anaesthetise the pharynx, glottis and subglottic structures. Change of voice to low pitch and/or back of tongue becoming numb was/were considered as sign(s) of adequate topical anaesthesia which was assessed after giving four puffs, rechecked thereafter every two puffs. At the end of the study, the volume of drug left in the atomiser was measured in each case in Group A to know the volume of local anaesthetic used.

Fibreoptic bronchoscopy was performed to secure the airway 3 min after obtaining optimal topical anaesthesia in both the groups. The time for intubation was calculated as the time taken from the beginning of the bronchoscopy from the nostril to the confirmation of the tube in the trachea by end-tidal capnography.
Ease of intubation process was assessed using cough and gag reflex score [Table 1]. The patient comfort score [Table 1] was assessed and documented by qualified specialist anaesthetist who helped the senior anaesthetist doing the procedure. The heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and oxygen saturation were noted initially as the baseline values and then at regular intervals. The haemodynamic and respiratory parameters were noted soon after giving sedation and then at 1 min and 5 min of intubation.

Based on a pilot study conducted in 16 patients, considering mean patient comfort during AFOI following topical anaesthesia with atomiser versus transtracheal injection (2.38 ± 1.30 vs 1.25 ± 0.463) as primary objective, with effect size of 1.283, with error % (α) = 5%, statistical power (1-β) % = 80% and 2 sided test, we have found the required sample size per group as 12. But we recruited 33 patients in our study with 16 patients in Group A and 17 in group T. Data were collected and compiled by using Microsoft Excel 2010 and analyzed by using SPSS 20.0 version. The quantitative variables were analyzed by using Student’s t – test or Mann-Whitney U–test wherever it was applicable. The categorical variables were analyzed by using Chi-Square test. P value < 0.05 was considered statistically significant.

RESULTS

There were 17 patients in Group T and 16 patients in Group A, with four and two females in each and with mean age of 50.9 ± 10.7 and 58.5 ± 17.1 years, respectively. Gender and age had no statistically significant differences between the two groups (P = 0.412 and 0.135, respectively).

Group A had higher cough and gag scores, affecting twelve patients, while in Group T, only two patients were affected (P = 0.001) [Table 1]. Two patients in Group A had prolonged cough but none in the Group T. The patient comfort scoring was significantly better in Group T with nine calm patients whereas in Group A two patients were calm during intubation. One patient in Group A showed poor comfort and none in Group T. Majority of the patients in the Group A showed good or moderate comfort with P value of 0.009 [Table 1]. Time taken for intubation in Group A was significantly longer, with a mean 80.8 s, compared with 48.5 s for Group T (P = 0.019) [Table 1].

The baseline values of all the variables other than blood pressure were comparable [Table 2]. SBP was significantly high in Group A patients (P = 0.002). Hence, subsequent comparison was made based on the percentage changes in the haemodynamic parameters from the baseline at various points of time to avoid errors in analysis. The baseline DBP, MAP and HR were comparable. However, there were no significant intergroup differences in the changes of blood pressure or saturation from baseline at any point during intubation [Table 3]. After sedation, the HR in Group T was noted to be significantly high (P = 0.019) during the transtracheal injection. Patients in Group A, who had more discomfort while undergoing intubation, did not show significant changes in blood pressure or HR from the baseline during the procedure. Oxygen saturation remained unchanged throughout in both groups.

On measuring the remaining volume of the local anaesthetic in the atomiser at the end of the procedure, it was found that approximately 4–5 mL was used for each case.

| Factors                          | Score                                                                 | Group T, n (%) | Group A, n (%) | P   |
|----------------------------------|-----------------------------------------------------------------------|----------------|----------------|-----|
| Cough and gag score              | 1. None                                                               | 15 (88.24)     | 4 (25.00)      | 0.001 |
|                                  | 2. Minimal coughing and gagging, <3 times, like clearing the throat  | 2 (11.76)      | 3 (18.75)      |     |
|                                  | 3. Mild cough and gag lasting for <1 min                              | 0              | 7 (43.75)      |     |
|                                  | 4. Persistent coughing and gagging                                    | 0              | 2 (12.50)      |     |
|                                  | 5. Need of rescue topical anaesthesia                                 | 0              | 0              |     |
| Comfort score                    | 1. Excellent, calm patient                                           | 9 (52.94)      | 2 (12.50)      | 0.009 |
|                                  | 2. Good, comfortable patient                                         | 8 (47.06)      | 7 (43.75)      |     |
|                                  | 3. Moderately comfortable, need to pacify the patient                | 0              | 6 (37.50)      |     |
|                                  | 4. Poor, uncomfortable                                               | 0              | 1 (6.25)       |     |
|                                  | 5. Agitated patient                                                  | 0              | 0              |     |
| Time taken for intubation in sec | (mean±SD)                                                             | 48.5±38.6      | 80.8±36.3      | 0.019 |

SD – Standard deviation

Table 1: Comparison of the cough and gag score, the patient comfort score and the time taken to intubate
**DISCUSSION**

The topical anaesthesia of airway mucosa using atomisers, nebulisers, ‘spray-as-you-go’ technique and transtracheal injections, is an alternative to the complex nerve block techniques for aiding AFOI in patients with anticipated difficult airway.[1] All of the patients in our study had anticipated difficult airway and most of them had head and neck malignancies affecting the airway directly or indirectly after a surgery with or without flaps or radiotherapy. We have observed that most patients of Group T showed a significant reduction in the cough reflex induced on passing the scope to the trachea (25% vs. 88.24%, \( P = 0.001 \), Table 1). The gag reflex and the discomfort on navigation at the level of hypopharynx were not different among the groups. Though most patients on both groups had narrow space in the pharynx due to airway pathology, topical anaesthesia was not efficient in group A as the raining-down effect of local anaesthetic into trachea during atomisation might have been suboptimal. This might have been the reason for lesser comfort observed in the patients of Group A.

Cough and gag reflex scoring was used in this study to assess the effectiveness of the block. Several other researchers also have used cough and gag reflexes as a tool to study the efficiency of topical anaesthesia.[4-6] Regional block was considered adequate if there was no event of cough or gag during the procedure and was considered the best with a score of 1. Need for rescue topical anaesthesia spray was considered as the worst in the efficiency of the topical anaesthesia with a score of 5. This scoring was close to what Malcharek et al.[4] had used. Most of the patients in both groups scored 1–3 and no one in either group required rescue measures [Table 1].

Some studies had patient’s comfort assessed through feedback by contacting them at a later date after the procedure. Since many of our study patients had tracheostomy or laryngectomy as part of surgery, it was hard to get clear reply from all patients uniformly regarding their experience. Hence, objective assessment of patient comfort levels was made by the anaesthetic assistants when the patients were undergoing awake intubation [Table 1].

AFOI after transtracheal injection was done faster in this study than after atomiser in difficult airways. This may be because of better topical anaesthesia in Group T compared to that in Group A. The time taken for topical anaesthesia was not included unlike in certain studies where the time for topical anaesthesia was also included in the intubation time.[5]

Atomisation has the advantage of rapid anaesthetising action in the airway as it produces LA particles finer than

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**Table 2: Comparison of the baseline haemodynamic variables**

| Variables | Group T (mean±SD) | Group A (mean±SD) | \( P \) |
|-----------|------------------|------------------|------|
| SBP (mmHg) | 137.9±19.2       | 165.4±27.3       | 0.002 |
| DBP (mmHg) | 92.8±16.3        | 103.4±16.1       | 0.069 |
| MAP (mmHg) | 109.9±17.1       | 119.1±26.2       | 0.239 |
| HR (/min)  | 92.9±16.2        | 85.2±17.5        | 0.198 |

SBP – Systolic blood pressure; DBP – Diastolic blood pressure; MAP – Mean arterial pressure; HR – Heart rate; SD – Standard deviation

**Table 3: Comparison of percentage changes of haemodynamic variables from baseline**

| Variables | Time | Group T (mean±SD) | Group A (mean±SD) | \( P \) |
|-----------|------|------------------|------------------|------|
| SBP (mmHg)| Post-sedation | 5.64±10.58 | 6.29±19.49 | 0.449 |
|           | Post-intubation | 13.32±15.06 | 10.12±22.59 | 0.829 |
|           | 1 min | 23.00±13.98 | 23.26±26.62 | 0.428 |
|           | 5 min | 23.87±15.94 | 13.50±20.21 | 0.130 |
| DBP (mmHg)| Post-sedation | 5.74±8.47 | 5.53±17.53 | 0.540 |
|           | Post-intubation | 5.83±23.04 | 7.28±23.66 | 0.801 |
|           | 1 min | 22.75±17.70 | 21.79±21.79 | 0.971 |
|           | 5 min | 23.13±18.56 | 26.89±18.87 | 0.377 |
| MAP (mmHg)| Post-sedation | 7.95±8.87 | −2.53±34.53 | 0.829 |
|           | Post-intubation | 12.02±18.67 | 1.44±30.40 | 0.468 |
|           | 1 min | 21.20±15.82 | 13.74±40.66 | 0.971 |
|           | 5 min | 23.44±16.49 | 22.60±37.62 | 0.26 |
| HR (/min) | Post-sedation | 1.27±9.24 | −8.79±13.28 | 0.015 |
|           | Post-intubation | −9.51±28.70 | −23.89±52.17 | 0.387 |
|           | 1 min | −7.64±27.18 | −8.98±22.84 | 0.627 |
|           | 5 min | 0.68±18.99 | −6.82±26.56 | 0.349 |

SBP – Systolic blood pressure; DBP – Diastolic blood pressure; MAP – Mean arterial pressure; HR – Heart rate; SD – Standard deviation
with nebulisation,\cite{7,8} with minimal drug wastage and good intubation conditions.\cite{7-11} Being non-invasive, patient acceptability is better with atomisers and nebulisers, but not with ‘spray-as-you-go’ technique.\cite{12}

Transtracheal injection of LA is widely practised and often proved to be superior to other techniques. However, being an invasive technique, transtracheal injection has certain concerns such as higher apprehension and lower acceptability among patients, bleeding from the trachea, accidental injection of LA into major vessels and LA toxicity.\cite{1,2}

Transtracheal injection with 4 ml of 4% lignocaine (Group T) or atomiser with 4% lignocaine (Group A) was used to anaesthetise the area supplied by superior and recurrent laryngeal nerves. Similar dose and concentration of lignocaine have been used by several others as well. Both 2% lignocaine and 4% lignocaine are shown to have equal efficiency for transtracheal injections.\cite{1-3,13} Similarly, there are studies showing that 2% lignocaine is as effective as 4% lignocaine for topical anaesthesia with atomisation.\cite{7,8} The total dose of local anaesthetic used in both groups was almost similar in our study.

Based on absorption of lignocaine during topical anaesthesia with different concentrations, it has been found that 1% lignocaine is adequate for awake intubation in patients scheduled for diagnostic flexible bronchoscopy.\cite{14} Most of the studies with lower-dose LA were in patients with normal airway. In this study, identical 4% concentration was chosen in both groups because of abnormal airway and the study intention was to have a better understanding of the comparative efficacy of the topical anaesthesia by two different methods.

The total dose of lignocaine always remained within the safety limits of 9 mg/kg body weight as suggested in a previous study on anaesthetists as study participants for AFOI using combined nebulisation and spray-as-you-go topical anaesthesia.\cite{15} No attempt was made to assess the blood levels of lignocaine in our study due to feasibility issues. However, several studies had reported safety with 4% lignocaine for topical anaesthesia. We did not observe any LA-related toxicity in any of our 33 patients.

Patients in both the groups had almost similar haemodynamic changes during intubation compared to the baseline levels. None of the patients had desaturation or laryngospasm or regurgitation during the procedure. Even though cough was more in Group A, no patient needed rescue topical anaesthesia with spraying of LA through the fibreoptic scope. One difference noticed among the groups was an increase in HR in Group T patients after the sedation, which coincided with the transtracheal injection, but it was not associated with any difference in any other parameters. Although the increase in HR was statistically significant, it did not bear any clinical significance.

All patients in our study were sedated to Ramsay sedation score of 2 using similar doses of fentanyl at 1–2 μg/kg body weight in both the groups. Midazolam or infusions of sedative agents were avoided due to the concern of increasing the risk of respiratory depression and subsequent hypoxia in patients with anatomically compromised airway.

The main limitation of the study was related to the difficulty in assessing the complexity of airway and the pharyngeal space of each patient beforehand, which often gives difficulty during navigation. The differences in the pharyngeal space might have influenced the atomised lignocaine reaching the desired area including the subglottic regions. Some of our patients in both groups had radiotherapy before the surgery which might have accelerated their discomfort or might have suppressed the sensation in case of already fibrosed tissue, which might have influenced our results. In those patients who underwent tracheostomy or laryngectomy, assessment of patient comfort levels was made by the anaesthetic assistants during awake intubation. We could have used a feedback form to be filled by the patient on a later date. This was another drawback of our study.

We had not reviewed pre-operatively the nasal endoscopy results of all of our patients as some of the previous surgical evaluation details and photographs were not available to study due to various reasons.

This may be the first study comparing these two techniques of airway topical anaesthesia in cases of anticipated difficult airway. All procedures were done by experienced anaesthetists who use both techniques routinely. This could be a reason for the absence of any notable complication or needing rescue technique in both the groups and may not be reproducible by novices.
We propose that transtracheal injection may be given preference, if necessary using ultrasound guidance for patients with difficult or vague anatomical landmarks, to topical anaesthesia with an atomiser to ensure better patient comfort during AFOI.

CONCLUSION

Topical anaesthesia of airway with transtracheal injection resulted in lesser patient discomfort, faster intubation and comparable haemodynamic parameters during AFOI in patients with anticipated difficult airway as compared to topical anaesthesia using atomiser.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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