Original Article

Effect of immobilised cervical spine on oropharyngeal sealing pressure with Ambu AuraGain™ Supraglottic airway: A randomised crossover trial

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ABSTRACT

Background and Aims: Ambu® AuraGain™ laryngeal airway (AuraGain) is one of the newer supraglottic airway device introduced in 2014. Cervical spine stabilisation with hard cervical collar makes insertion of supraglottic airways and tracheal intubation difficult. This study was conducted to investigate whether the presence of a cervical collar affects the oropharyngeal sealing pressure (OSP) and fibreoptic view of the glottis (Brimacombe score) in airways secured with the AuraGain. **Methods:** The study was a randomised crossover trial. Thirty five ASA 1-3 patients undergoing elective surgery under general anaesthesia were recruited for the study. In each patient AuraGain was inserted twice in a crossover manner once with and once without a hard cervical collar *in situ*, with the sequence of insertion randomised. During each insertion of AuraGain the OSP, fibreoptic view of the glottis, insertion parameters, ventilator data and complications were noted. **Results:** The mean OSPs in both the groups were similar with no significant difference (29.6 ± 3.7 cmH_2O without collar and 30.1 ± 3.1 cmH_2O with collar [$P = 0.310$]). The fibreoptic view of glottis was also similar in both groups. The insertion with collar was more difficult than without collar. The number of attempts for successful insertion was same in both the groups. The time taken for appropriate placement of LMA was significantly prolonged in patients with collar. **Conclusions:** We conclude that the Ambu AuraGain can be used to provide effective ventilation in patients whose cervical spine is immobilised with a hard cervical collar.

Key words: Ambu AuraGain, laryngeal airway, supraglottic airway, oropharyngeal sealing pressure, hard cervical collar

INTRODUCTION

Supraglottic airway (SGA) devices have been widely used for airway management in both hospital and pre-hospital settings.[1,2] Ambu® AuraGain™ is a newer intubating SGA device introduced in 2014, which promises to provide high oropharyngeal sealing pressures (OSPs) of up to 40 cmH_2O and a larger gastric access.[3]

Cervical spine immobilisation with the help of a hard cervical collar is a standard of practice in patients with cervical spine instability.[2] This application of hard cervical collar can make insertion of SGAs and tracheal intubation difficult, which is attributed to the restricted neck mobility and limited mouth opening caused by the presence of a hard collar. However, SGAs have been used for ventilation in patients with cervical collar in pre-hospital emergency settings.[2]

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The effectiveness of Ambu AuraGain™ (AuraGain) in patients with cervical collar has not yet been studied. This study was conducted to assess if the presence of a cervical collar affects the optimal placement and stability of the AuraGain. Primary objectives were to study the OSP and fibreoptic view of glottis with AuraGain in patients with and without a cervical collar. The secondary objectives were to study the insertion parameters (number of attempts for successful insertion, ease of insertion, time taken to insert the device and ease of passage of gastric tube), ventilation parameters (peak airway pressures [P_{aw}], end-tidal carbon dioxide [$ETCO_2$]) and complications (post-operative sore throat, bleeding, laryngospasm, and injury to airway) among the patients with and without a cervical collar.

METHODS

This study was a prospective, randomised crossover trial, with the patient serving as his own control. The study was conducted after obtaining approval from Institute Ethics Committee. The trial has been registered in Clinical Trials Registry – India (registration number CTRI/2016/03/006717). The study period was from March 2016 to May 2017, 1 year 2 months. American Society of Anesthesiologist (ASA) physical status class 1-3 patients, above 18 years of age, posted for elective surgery under general anaesthesia and planned airway management with AuraGain placement were included in the study. Patients with any pathology in the neck, upper respiratory tract or upper alimentary tract, predicted difficult airway, a body mass index >35 kg/m^2, patients with a history of obstructive sleep apnoea, history of lung diseases, potentially full stomach patients or history of oesophageal reflux were excluded from the study. The sample size was estimated to be 35. It was calculated based on a previous crossover study by Mann *et al*. with an expected proportion of subjects with sealing pressure <20 cmH_2O with collar as 6% and, proportion of subjects with sealing pressure <20 cmH_2O without collar as 32%, at 5% level of significance and 80% power using nMaster software 2.0.[4,5]

Written informed consent was obtained from all patients. All patients received oral ranitidine 150 mg in the night and morning before surgery. Standard anaesthetic monitors (pulse oximetry, non invasive blood pressure, electrocardiography) were connected. Intravenous access was secured and then patients received Midazolam 50 μg/kg and Fentanyl 2 μg/kg intravenously. After pre-oxygenation, anaesthesia was induced with Propofol 2 mg/kg, and after confirming the adequacy of mask ventilation, Atracurium 0.5 mg/kg was given and patient mask ventilated for 3 minutes.

In each patient, the AuraGain was inserted twice, once without cervical collar and once with cervical collar. The sequence of insertion was randomised using computer-generated random number either to sequence A: without cervical collar followed by with cervical collar or sequence B: with cervical collar followed by without cervical collar. The size of the laryngeal mask used was decided based on patient's weight (size 3: 30-50 kg; size 4: 50-70 kg; size 5: 70-100 kg). A Philadelphia cervical collar (TOPHIL Cervical Immobiliser, Dynamic TechnoMedicals, India) was used in this study.[6] Appropriate size was chosen for each patient based on neck circumference, as advised by the manufacturer. For patients belonging to sequence A, the patient's head and neck were in neutral position without cervical collar initially and the AuraGain was inserted following standard steps of SGA device insertion by the anaesthesiologist (with >1 year of experience). After measuring the study parameters, AuraGain was removed and mask ventilation done for 1 minute. Then the cervical collar was applied, and AuraGain was reinserted by the same operator, and the parameters assessed again. In sequence B, the steps were done with insertion with collar applied first followed by insertion without the collar.

In both the groups, the cuff was inflated according to the size of the device (maximum 20 ml for size 3 and 30 ml for size 4 AuraGain) and the intra-cuff pressure was measured with a calibrated aneroid manometer (VBM limited, Germany) and was kept below 60 cmH_2O by removing air after inflating to maximum volume.[7] After connecting the breathing circuit to AuraGain, appropriate placement and ventilation was determined by square wave $ETCO_2$ tracing. A well-lubricated gastric tube (12F) was inserted through the gastric port and confirmed by epigastric auscultation. Maximum three attempts were allowed for each group. Anaesthesia was maintained with 1-1.3 MAC sevoflurane in air and oxygen (50:50) and depth of anaesthesia was monitored with entropy. Patients were then mechanically ventilated with a tidal volume of 8 ml/kg and respiratory rate of 12/min.

The study parameters measured during each sequence were OSP which was determined by placing the anaesthesia workstation in manual mode with APL

valve fully closed with a fresh gas flow of 3 l/min (GE anaesthesia delivery system). The pressure at which audible leak (on auscultation of anterior neck) occurred was taken as the OSP,[8-10] fibreoptic view of the glottis (Brimacombe score) which was assessed by passing flexible fibreoptic laryngoscope (diameter 3.7 mm: Karl-Storz, Tuttlingen, Germany) through the airway tube of AuraGain, by placing the tip of the scope 1 cm proximal to the end of the tube. Brimacombe scoring system was used.[11] The scoring includes Score 4, only the vocal cords were visible; Score 3, the vocal cords plus the posterior epiglottis were visible; Score 2, the vocal cords plus the anterior epiglottis was visible; Score 1, the vocal cords were not visible, ventilation parameters (P_{aw}, $ETCO_2$), insertion parameters (number of attempts, ease of insertion, time taken for insertion, and ease of passage of gastric tube) and complications.

The appearance of a square wave capnogram was taken as the endpoint of successful insertion of AuraGain. The time taken to insert was defined from the time face mask was removed till appearance of square wave capnogram. The ease of insertion of AuraGain and nasogastric tube was assessed using Likert scale, 1 - very easy, 2 - easy, 3 - do not know, 4 - difficult, and 5 - very difficult.[12]

The cervical collar was removed after assessing the parameters and the surgery continued. Any complications during the procedure like laryngospasm, airway bleeding (noted in oral cavity, on the AuraGain or during suctioning), injury to airway, and so on, were noted. At the end of surgery, volatile anaesthetic was discontinued and neuromuscular blocking effect was antagonised with neostigmine (50 μg/kg) and glycopyrrolate (10 μg/kg). After confirming the adequate neuromuscular recovery clinically and making sure patient was awake, AuraGain was removed. All patients were followed up for 48 hours to assess for post-operative sore throat or any other complications.

Statistical Package for the Social Sciences (SPSS) version 18 (SPSS Inc., Chicago, IL, USA) was used for the analysis of the data. Descriptive and inferential statistical analysis has been carried out in this study. Results of continuous measurements have been presented as Mean ± SD and results of categorical variables as percentage (%) and median with interquartile range. The significance was assessed at 5% level of significance. Normality of distribution of data was determined using Kolmogorov-Smirnov tests of normality. Paired Student *t*-test (two-tailed, dependent) was used to find the significance of study parameters on a continuous scale with and without collar (OSP, the time taken to insert, P_{aw}, and $ETCO_2$). Wilcoxon Signed rank test was used to find the significance of the median scores (Brimacombe score, number of attempts, ease of insertion of LMA and ease of insertion of gastric tube). All statistical analyses were carried out at 5% level of significance and *P*–value <0.05 was considered significant.

RESULTS

A total of 35 patients were included in our study. Sequence A was done in 18 patients and sequence B in 17 patients. The demographic profile and patient characteristics namely age, sex and body mass index, ASA status and Modified Mallampati (MMP) scoring are given in Table 1. The results of statistical analysis of the OSP and fibreoptic view of glottis (Brimacombe score) of two groups are given in Table 2. There was no significant difference in the OSP (*P*–value = 0.31) and Brimacombe score (*P* value = 0.08) with or without cervical collar.

The analysis of the insertion parameters namely the number attempts taken for successful insertion of

Table 1: Demographics

Parameter	Patients (*n*=35)
Age (Mean and SD) (years)	40.4±11.3
Gender (%)	Male:16 (45.7%); Female:19 (54.3%)
Weight (kg)	63.9±8
Height (cm)	1.5±0.06
BMI (kg/cm^2)	24.9±2.9
MMP Class 1/2/3	9/18/8 (Median - 2)
ASA Class I/II/III	20/13/2
Sequence of insertion A/B	18/17

Parameter	Sequence A (*n*=18)	Sequence B (*n*=17)	Patients (*n*=35)
Age (Mean and SD) years	39.8±10.3	41±12.7	40.4±11.3
Gender (%)	Male:7 Female:11	Male:9 Female:8	Male:16 (45.7%) Female:19 (54.3%)
Weight (kg)	63.4±5.2	64.4±2.8	63.9±8
Height (m)	1.5	1.5	1.5
BMI (kg/m^2)	24.6±3.2	25.2±2.4	24.9±2.9
MMP Class 1/2/3	4/10/4	5/8/4	9/18/8 (Median - 2)
ASA Class 1/2/3	8/8/2	12/5/0	20/13/2

Table 2: Comparison of OSP and Brimacombe score

Variable	Without collar *n*=35	With collar *n*=35	*P*
Mean OSP (Mean±SD)	29.6±3.7	30.17±3.1	0.310
Brimacombe score 1/2/3/4	0/0/4/31	0/1/8/26	0.083

AuraGain, the ease of insertion, median time taken for insertion of AuraGain and the ease of insertion of nasogastric tube are given in Table 3. The number of attempts taken for successful insertion of AuraGain was almost similar with or without collar (*P* value = 0.7). We found a statistically significant difference in ease of insertion of the AuraGain (*P* value = 0.001) between the groups.

The ventilation parameters assessed were P_{aw} and $ETCO_2$. The mean P_{aw} in this study was 16.5 ± 3.6 cmH_2O in patients without collar and, 17.8 ± 3.7 cmH_2O in patients with collar which was statistically significant (*P* value = 0.026). The mean $ETCO_2$ in patients without cervical collar was 29 ± 2.9 mmHg and in patients with the collar on was 28.9 ± 2.5 mmHg. There were no airway-related complications during the course of study in any patient.

DISCUSSION

In our study, we found that AuraGain provides adequate sealing pressure without a cervical collar. In a study conducted by Shariffudin *et al.*, the OSP of AuraGain was 24.1 cmH_2O in 100 patients and it was 34 ± 5 cmH_2O in a study by Lopez *et al*. in 60 patients.[13,14] In a recent study by Singh *et al*., it was 28.7 ± 4.8 cmH_2O, which was similar to our study.[15] The sealing pressure of the commonly used ProSeal LMA is around 26 cmH_2O, and that of LMA Supreme is 21 cmH_2O as recorded in previous studies; hence AuraGain provided sealing pressure comparable to these SGA.[9,16]

This study shows that AuraGain provided effective sealing in patients with cervical collar *in situ* as well. There were no studies in assessment of OSP of AuraGain in patients with a cervical collar. However, there were studies comparing OSP of other LMAs in patients with a hard cervical collar. Mann *et al*. found that the leak pressure of LMA Supreme in patients with a cervical collar was 27 cmH_2O; which was comparable to the findings in this study.[4]

This study being a crossover study, inter individual variations are negated between the groups and hence providing more reliability to the results. Regarding the primary objective of this study, it was found that sealing pressure of AuraGain was comparable with or without the hard cervical collar. This shows that AuraGain provides adequate sealing pressure even when a hard cervical collar is in use. There were no studies in literature to reveal the efficacy of AmbuAuraGain in patients with hard cervical collars. On the contrary, Mann *et al*. found that OSP was higher in patients with cervical collar when compared with those without a collar (22 cmH_2O without collar and 27 cmH_2O with collar).

In this study, there was no significant difference in fibreoptic grading of glottis view in patients with and without cervical collar which shows that the presence of a cervical collar does not affect the fibreoptic visualisation of the glottis and hence adequate ventilation was possible with AuraGain in these patients. When we compare with previous studies, the results are quite similar. Komatsu *et al*. had studied the effect of manual in line stabilisation (MILS) of cervical spine on fibreoptic visualisation of glottis while placement of ILMA and noticed no significant difference in glottic view.[17] Similar results were found in a study by Kus *et al*., where they compared I-gel with LMA Supreme in paediatric patients with cervical collar.[18] On the contrary, Asai *et al*., found that the cuff position became suboptimal in patients with MILS.[19]

Coming to the secondary objectives, the number of attempts taken for successful insertion of AuraGain was similar in both the patient groups. On analysing the ease of insertion of LMA, there was significant difference between the two groups. This shows that the difficulty of insertion of AuraGain increased when a cervical collar was applied. Similar results have been found in past studies on SGA in patients with cervical collar.[17,20]

The time taken for successful insertion of an LMA is a good indicator of its difficulty of insertion. In a study by Kriege *et al*., the median time taken to insert AuraGain was 30 (18-41) seconds and in Shariffuddin *et al*.'s study of AuraGain, it was 33.4 ± 10.9 seconds.[13,21] In

Table 3: Analysis of insertion parameters

Parameter	Without collar *n*=35	With collar *n*=35	*P*
No of attempts:1/2	32/3	31/4	0.705
Ease of insertion of Ambu:1/2/3/4	25/8/0/2	14/12/1/8	0.001*
Ease of insertion of nasogastric tube 1/2	32/3	26/9	0.04*
Time taken to insert (seconds)	21.3±9.6	26.1±11.7	0.025*

*$P<0.05$

the former study, insertion time was measured from the moment the mouth was opened until the first ventilation. In our study, though there is a statistically significant increase in time for placement of AuraGain in the group with the cervical collar, the mean time difference was only 4.8 seconds, which may not be clinically significant in anaesthetic practice.

The ease of insertion of nasogastric tube was assessed using Likert score. The results were as per the previous research by Jagannathan *et al*., on AuraGain in normal patients.[15] There is a paucity of studies assessing ease of insertion of gastric tube through AuraGain in patients with cervical collar.

The mean P_{aw} and the $ETCO_2$ values in this study were comparable in both groups inferring that the AuraGain provides good ventilation even in patients with a cervical collar *in situ*. There were no complications such as bleeding, post-operative sore throat or voice change in this study.

A hard cervical collar is used in patients with suspected or proven cervical spine instability.[22] Managing airway in such patients can pose significant difficulty as discussed. This is more noteworthy in pre-hospital settings where emergency management of such airway is called for. Further, in such settings, availability of skilled personnel for airway management is a scarcity. LMAs require a shorter learning curve and are easier to insert when compared with endotracheal intubation.[23] From this study, it is evident that AmbuAuraGain laryngeal airway can be used to secure the airway and maintain adequate ventilation in patients whose cervical spines are immobilised with a hard cervical collar in both hospital and pre-hospital settings. One of the main limitations of our study is that, it was conducted on patients without any cervical spine injury, whereas in actual clinical settings whether the insertion of LMA will cause any cervical spine movement or spinal cord damage are yet to be studied. Further research is needed to analyse the effect of AmbuAuraGain insertion on cervical spine movement and damage. Blinding was not done during the study as the intervention (placement of cervical collar) could not be blinded. Another limitation is in each patient the AuraGain was inserted twice.

CONCLUSION

AmbuAuraGain laryngeal airway provides adequate OSP and maintains optimal cuff position in patients with immobilised cervical spine with a hard cervical collar. Hence, we conclude that AmbuAuraGain can be used in patients whose cervical spine is immobilised with a hard cervical collar.

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Conflicts of interest

There are no conflicts of interest.

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