INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing coronavirus disease (COVID)-19 emerged in December 2019. The virus rapidly swept across the world due to its high transmissibility as compared to other epidemic coronaviruses.[1] Aerosols, droplets and direct contact transfer had been implicated in transmission of coronaviruses.[2] Amongst the aerosol-generating procedures (AGPs), tracheal intubation was found to be consistently associated with transmission of the SARS-CoV in a systematic review.[3] The global scale and velocity of the COVID-19 pandemic led to several measures to protect health care workers (HCWs). These included use of negative pressure rooms, adherence to airborne precautions and personal protective equipment (PPE) and using barrier enclosures for tracheal intubation.[4] The aerosol box (AB) used during tracheal intubation is a transparent, semi-open, cuboidal barrier device used to shield the airway.

ABSTRACT

Background and Aims: The aerosol box (AB), an improvised device used during the coronavirus disease (COVID)-19 pandemic, has attracted both interest and controversy. Several simulated studies have examined its protective efficacy as well as intubation efficiency. The aim of this study was to evaluate the practical conduct of intubation using the AB in patients undergoing elective, oncological surgery during the pandemic. Methods: This prospective, observational study included adult patients undergoing oncological surgery. Thirteen anaesthesiologists performed 132 intubations using one of three ABs designated as AB 1, AB 2 and AB 3. The primary outcome was the difference in the time to intubation (TTI) between patients with Mallampati score MP I-II (Group 1) and MP III-IV (Group 2). Secondary outcomes included first-pass success rate, fall in peripheral oxygen saturation to < 95%, total number of attempts and failure to intubate using the AB. Results: The mean TTI was not significantly different in Group 1 and Group 2 (71.02 (61.66) s vs. 101.35 (121.94) s respectively, P = 0.119). Desaturation during intubation was seen in 20 patients (15.1%). First pass success rate was achieved in 109 patients (82.6%). Twenty-one patients (15.9%) needed more than one attempt to intubate and the box had to be removed in 8 patients (6.1%) for facilitating intubation. The Mallampati score did not significantly influence either desaturation or first pass success rate. Conclusion: There was a non-significant increasing TTI trend in patients with a higher MP score with the use of an aerosol box. However, this did not translate to a clinically significant difference in the overall intubation outcomes.

Key words: Aerosol, anaesthetists, COVID-19, intubation, prospective study

INTRODUCTIONS

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing coronavirus disease (COVID)-19 emerged in December 2019. The virus rapidly swept across the world due to its high transmissibility as compared to other epidemic coronaviruses.[1] Aerosols, droplets and direct contact transfer had been implicated in transmission of coronaviruses.[2] Amongst the aerosol-generating procedures (AGPs), tracheal intubation was found to be consistently associated with transmission of the SARS-CoV in a systematic review.[3] The global scale and velocity of the COVID-19 pandemic led to several measures to protect health care workers (HCWs). These included use of negative pressure rooms, adherence to airborne precautions and personal protective equipment (PPE) and using barrier enclosures for tracheal intubation.[4] The aerosol box (AB) used during tracheal intubation is a transparent, semi-open, cuboidal barrier device used to shield the airway.
Venketeswaran, et al.: Aerosol Box in patients with a difficult airway

manager from airborne particles. Canelli et al. in their study of the aerosol box demonstrated that the majority of the infectious secretions are contained within the box and the disposable gloves/sleeves of the anaesthetist[5] making it a useful adjunct to PPE. Guidelines state that caution should be exercised in patients with a difficult airway.[6]

Though the aerosol box is an ingenious device, its utility and performance have been questioned.[7] Majority of the studies pertaining to the AB are simulation-based and its clinical implications are being explored.[8,9]

There is a lingering fear of exposing a patient with a potentially difficult airway to hypoxia by using the AB, and with this in mind we planned a study aimed to document the intubation outcomes using the AB in a spectrum of patients including those with a potentially difficult airway in a clinical setting.

METHODS

This was a prospective, observational, single-centre study. The study was approved by our Institutional Ethics Committee and was registered in the Clinical Trials Registry of India (CTRI/2020/07/026610). Written informed consent was obtained from all the study participants for using the AB and the collected data for academic purposes. All patients above 18 years of age undergoing oncological surgeries under general anaesthesia by rapid sequence intubation from July to September 2020 were included. Both orotracheal and nasotracheal intubations were eligible. Only procedures performed by qualified anaesthesiologists with at least 1-year clinical experience, all of whom were familiar with the use of AB were included for this study. Anaesthesiologists were allowed to use the conventional Macintosh Laryngoscope (DL) or the C-MAC™ video laryngoscope (VL) (Karl Storz, Tuttingen, Germany) D-Blade based on the availability. Patients who did not fit within the aerosol box due to their body habitus, requiring fibreoptic guided intubation, undergoing emergency surgery with risk for gastric aspiration, or requiring double-lumen tube insertion were excluded.

Consecutive patients planned for surgery under general anaesthesia were screened during the pre-anaesthetic visit. Only those testing negative for SARS-CoV-2, were taken up for surgery. The institutional COVID standard operating procedure (SOP) for anaesthesia and operation theatre was followed.[6,10] Three different ABs were used during this period [Figure 1]. All boxes had a thick, transparent plastic drape covering the open end. AB1 and AB2 were commercially available and had, in addition to disposable sleeves mounted on the apertures, an in-built suction port for creating some negative pressure inside. The third box (AB3) which resembled the early-generation box was locally manufactured and we improvised it by adding the drape and placing the Yankauer suction tip inside the box during intubation and extubation. The AB was disinfected after each use as per our infection control policy.

The attending anaesthesiologist and anaesthesia assistant were donned in PPE for airborne precautions (N-95 mask, face shield, fluid-resistant jumpsuit with hood, and double gloves). An intravenous access and standard monitoring were established. Patient’s head was rested on a soft head-ring. One of the three available ABs was placed over the patient’s head and preoxygenation commenced with oxygen 5 l.min⁻¹ and adjustable pressure limiting valve set at 10 cm H₂O pressure for 5 minutes. Height of the operating room table was adjusted to facilitate clear vision through the AB panel. The laryngoscope was positioned within the box. Patients were then administered fentanyl 1–1.5 µg.kg⁻¹, propofol 2-3 mg.kg⁻¹ followed by a bolus of suxamethonium 1.5 mg.kg⁻¹ or rocuronium 1 mg.kg⁻¹. Simultaneously the assistant started the timer on the monitor and the trachea was intubated 60 s later using

![Figure 1: Specifications of the aerosol boxes used during the study](image-url)
a DL/VL. The assistant was instructed to pause the gas flows during the conduct of intubation and aid in giving the endotracheal tube (ETT), inflate the cuff and restore gas supply and commence mechanical ventilation. The assistant also performed additional manoeuvres as required by the anaesthesiologist. In the event of any difficulty, the use of intubation aids (bougie/stylet), change in approach (adjustment of the head position, external laryngeal manipulation, need for second assistant, nasotracheal vs orotracheal), plan modification (change of laryngoscope, tube, fibreoptic bronchoscopy, laryngeal mask airway) and removing the aerosol box were left to the discretion of the attending anaesthesiologist. The timelines were recorded by the backup anaesthesiologist. The attending anaesthesiologist documented his/her perception of ease of intubation using the AB in a specially prepared questionnaire. The AB was also used during extubation.

The primary outcome was the difference in the time to intubation[8] between patients with Mallampati score MP I-II (Group 1) and MP III-IV (Group 2) (defined as the time from when the laryngoscope blade passes between the patient’s incisors until the first upstroke on the capnograph trace). Secondary outcomes included first-pass success rate (defined as successful insertion of the DL or VL and ETT by an anaesthesiologist in the first-attempt without withdrawing from the mouth in no longer than 150 seconds), fall in saturation from the time of removal of the oxygen mask to delivering the first breath to peripheral oxygen saturation (SpO₂) <95%, total number of attempts at intubation and failure to intubate using aerosol box (defined as the need to remove the aerosol box in order to achieve successful intubation).

Prior to the commencement of this study, we undertook a retrospective audit of 47 patients who had received general anaesthesia using the AB, based on which a sample size of 30 patients each with MP I-II and MP III-IV was deemed necessary to detect an absolute difference of 20 s in the mean time to intubation using a two-sided Z-test of the difference in means with 80% power and a 5% significance level.

Continuous variables were reported as mean ± standard deviation (SD) or median (Interquartile range (IQR)) while categorical variables were reported as frequency (percentage). Variables influencing TTI were subjected to the student t-test and a multivariable linear regression model was created with factors that achieved significance. Logistic regression analysis was carried out to determine the relative importance of variables affecting the saturation. Differences in the TTI between AB were analysed using Analysis of Variance (ANOVA). Descriptive statistics was done for the other outcomes. A P value <0.05 was considered significant. Statistical analysis was done using the Statistical Package for the Social Sciences International Business Machines (IBM-SPSS) version 26.0 (IBM, Armonk, NY, USA).

**RESULTS**

One hundred and thirty-six eligible patients were anaesthetised using one of 3 ABs of which, 132 patients with complete data were included in this study. Thirteen anaesthesiologists participated in the study and 74 (56.1%) intubations were carried out by anaesthesiologists with ≥5 years experience. Patient demographics are depicted in Table 1. The mean age of the patients was 52.56 (10.95) years and the ratio of female to male patients were 100:32. Twenty-six patients (19.7%) had a body mass index (BMI) ≥30.

In all patients, the mean TTI was 81.59 (88.23) [Table 2] while the mean TTI in Groups 1 and 2 were 71.02 (61.66) s vs. 101.35 (121.94) s respectively, \( P = 0.119 \). The TTI did not follow a normal distribution and the analysis was repeated after removing the outliers (TTI >150s), but we were not able to demonstrate a significant difference in the mean TTI between Group 1 and Group 2 (56.27 (27.59) vs. 65.37 (30.57) s; \( P = 0.101 \)). This is depicted in Supplemental Table 1. Eighty patients were intubated in <60s, 110 in less than 120s, 119 patients within 150s and 13 patients in ≥150s. The mean TTI was significantly longer in AB2 (108.85 (127.32)) when compared to AB1 (63.86 (40.6); \( P = 0.014 \)) and AB3 (69.3 (60.8); \( P = 0.035 \)). On univariate analysis, factors found to significantly influence the TTI were the type of laryngoscope, Cormack-Lehane (CL) grade, and use of intubation aids, change of approach, plan modification and type of AB [Table 3]. However, on multivariable analysis, only AB2, use of intubation aids, change of approach and plan modification emerged as independent predictors of the TTI [Table 3].

Desaturation was observed only in 20 patients (15.1%) overall. BMI ≥30 kg.m\(^{-2}\) and a change of approach were independently associated with a risk of desaturation (Odds ratio (95%CI) 5.98 (1.43-25.00) and 6.023 (0.646-56.12) respectively) [Table 4]. First-pass
success rate, which is a measure of both the number of attempts and TTI <150 s, was achieved in 109 (82.6%) patients [Table 2]. Intubation at first attempt was achieved in 111 patients whereas 19 patients required two attempts and 2 patients required three attempts. A higher number of patients in AB2 required more than one attempt \((n = 13)\) when compared to AB1 \((n = 3)\) and AB3 \((n = 5)\). The AB was removed in 8 (6.1%) patients for facilitating intubation.

A qualitative feedback from the anaesthesiologists showed that in 72% of intubations the anaesthesiologists experienced varying degrees of stress while using the AB. The AB was reported by the anaesthesiologists to reduce their ability to access the laryngoscope, ability to introduce the ETT into the glottis and ability to view the chest movements in 22%, 12.8% and 15% of patients respectively.

**DISCUSSION**

We demonstrated that in a pandemic situation where an AB was used as part of other measures to reduce the risk of exposure to anaesthesiologists during tracheal intubation, the time to intubation was not significantly different between patients with MP I-II and MP III-IV. To the best of our knowledge, this is the first clinical study that has shown that the AB can be safely used even in patients with a potentially difficult airway. The outcomes using an AB have been mostly reported in simulated situations using manikins where it has been shown to prolong the TTI.[11-14] A Canadian manikin-based simulation study reported that the mean time to intubation in a difficult airway scenario was increased with an AB compared to without (34.4s vs 27.3s, mean difference 7.1%; 95%CI, –2.5 to 16.7).[14] The only clinical trial using the AB was a non-inferiority randomised trial which reported that the mean TTI in patients with and without an AB was 52.1 (95% CI, 26.1–78) vs. 42 (95% CI, 19.2–64.8) s, respectively \((P = 0.046)\).[9] The authors concluded that the delay in TTI with the AB was well within the safe period of apnoea tolerated by most patients. However, this study did not report outcomes specifically in patients with a difficult airway.

Factors predicting a longer TTI in our patients were use of intubation aids (bougie/stylet), use of AB2, change of approach and plan modification. Intubation aids can shorten the TTI if used appropriately. In our study, intubation aids were mostly used only after a failed first attempt at intubation, hence prolonging the TTI. Different ABs have been known to influence the TTI.[15] The AB2 used in this study, although a later generation one compared to AB3, had a higher number of patients with a difficult airway when compared to
Venketeswaran, et al.: Aerosol Box in patients with a difficult airway

The mandatory five minutes of preoxygenation could have increased the safe apnoea time of most patients. BMI ≥30 was independently predictive of desaturation whereas the TTI was not. It has been reported that patients with BMI ≥30 are at risk for arterial desaturation once they become apnoeic\[16\] and that the safe apnoea period in such patients is also lower than patients with normal weight (2-3 min vs. 8-10 min).\[17\] In spite of desaturation, none of the patients had an adverse outcome.

The first pass success rate in our study was 82.6%. Other studies using ABs in simulated and real patients had success rates between 38-100%\[10,11-14,18\]

Despite the longer TTI and the fact that the patients did not receive bag and mask ventilation while apnoeic, only 20 patients (15.2%) desaturated of which 13 patients had SpO₂ <90%. While some studies on apnoeic oxygenation have defined desaturation as SpO₂ ≤90%, we felt that a higher safety margin of SpO₂ <95% would be desirable. The mandatory five minutes of preoxygenation could have increased the safe apnoea time of most patients. BMI ≥30 was independently predictive of desaturation whereas the TTI was not. It has been reported that patients with BMI ≥30 are at risk for arterial desaturation once they become apnoeic\[16\] and that the safe apnoea period in such patients is also lower than patients with normal weight (2-3 min vs. 8-10 min).\[17\] In spite of desaturation, none of the patients had an adverse outcome.

The first pass success rate in our study was 82.6%. Other studies using ABs in simulated and real patients had success rates between 38-100%\[10,11-14,18\]

| Variable | All patients (n=132) | Mallampati score* | Aerosol Box |
|----------|----------------------|-------------------|-------------|
| Mean TTI (SD) in seconds | 81.5 (88.23) | 71.02 (81.6) | 101 (121.94) | 63.8 (40.6) | 108.8 (127.3) | 69.3 (60.8) |
| Median TTI in seconds (IQR[range]) | 51.5 (40-84) | 50 (39-70) | 59.5 (45-111) | 52.5 (40-67) | 60 (43-125) | 50 (39.5-60) |
| Intubation | | | | |
| Orotracheal | 123 (93.2) | 82 (95.3) | 41 (89.1) | 37 (84.1) | 46 (97.9) | 40 (97.6) |
| Nasotracheal | 9 (6.8) | 4 (4.7) | 5 (10.9) | 7 (15.9) | 1 (2.1) | 1 (2.4) |
| Intubation aids | | | | |
| Oral bougie | 13 (9.8) | 5 (5.8) | 17 (8.4) | 2 (4.5) | 7 (14.9) | 4 (9.8) |
| Nasal Bougie | 5 (3.8) | 4 (4.7) | 1 (2.2) | 4 (9.1) | 0 | 1 (2.4) |
| Styllet | 8 (6.1) | 3 (3.5) | 10 (9.9) | 3 (6.8) | 4 (8.5) | 1 (2.4) |
| Laryngoscope | | | | |
| Macintosh | 116 (88) | 77 (89.6) | 39 (84.8) | 36 (81.8) | 41 (87.2) | 38 (92.7) |
| C-MAC™ | 18 (13.6) | 10 (11.6) | 8 (17.4) | 8 (20.5) | 6 (12.8) | 3 (7.3) |
| Change in approach | | | | |
| Use second assistant | 20 (15.1) | 10 (11.6) | 10 (21.7) | 4 (9.1) | 11 (23.4) | 5 (12.2) |
| Readjust head position | 2 (1.5) | 1 (1.2) | 1 (2.2) | 0 | 2 (4.3) | 0 |
| BURP® | 53 (40.1) | 28 (32.6) | 25 (54.3) | 5 (34.1) | 22 (46.8) | 16 (39) |
| Change of plan | | | | |
| Use of LMA** | 1 (0.8) | 0 | 1 (2.2) | 0 | 1 (2.1) | 0 |
| Use of CMAC | 2 (1.5) | 1 (1.2) | 1 (2.2) | 0 | 2 (4.3) | 0 |
| Use of Macintosh | 3 (2.3) | 3 (3.5) | 0 | 1 (2.3) | 0 | 2 (4.9) |
| Use of another blade | 3 (2.3) | 1 (1.2) | 2 (4.3) | 0 | 2 (4.3) | 1 (2.4) |
| First pass success | 109 (82.6) | 72 (83.7) | 37 (80.4) | 40 (90.9) | 33 (70.2) | 36 (87.8) |
| Number of attempts | | | | |
| First attempt | 111 (84.1) | 74 (86) | 87 (80.4) | 41 (93) | 34 (72.3) | 36 (87.8) |
| Second attempt | 19 (14.4) | 12 (14) | 7 (4.3) | 3 (6.8) | 11 (23.4) | 5 (12.2) |
| Third attempt | 2 (1.5) | 0 | 2 (4.3) | 0 | 2 (4.3) | 0 |
| Removal of box | 8 (6.1) | 3 (3.5) | 10 (9.9) | 0 | 5 (10.6) | 3 (7.3) |

Values in parentheses indicate percentage except where otherwise specified. *Mallampati score: Group 1=MP Score I-II, Group 2=MP Score III-IV, †Time to intubation, ‡Standard deviation, ⊳Interquartile range, ♂C-MAC™ video laryngoscope, ✶Backward upward rightward pressure, **Laryngeal Mask Airway
first pass failure,[21] restriction of forearm movement and migration of the box. Use of the AB can lead to stress among the anaesthesiologists as evident from the feedback obtained in this study. Participants in one simulated study did not find the AB challenging to use but would not use it in a difficult airway[14] whereas participants in another study were mostly or very unsatisfied as they experienced difficulties with the AB.[12] Nearly 50% of anaesthesiologists reported discomfort while using the AB and 33% reported increased cognitive load from use of the box in simulated intubations.[11]

The skewed distribution of the TTI was not unexpected and the outliers were deliberately not removed as this was not a manikin study and intended to be a real time representation. There are several limitations in this study. It was not a randomised controlled trial (RCT)
of intubation outcomes in patients with and without using an AB, although such a study was not possible in our centre because of ethical concerns. It was subject to multiple confounding factors with regards to the different ABs, patient factors, equipment and operator factors. The association of the TTI with the usage of intubation aids and AB2 should not be over-interpreted as this was an observational study. It is possible that the sample size to identify differences in the intubation outcomes in a difficult airway is much larger given that MP score alone does not predict a difficult airway. We did not examine the protective efficacy of the AB or its use in a critical care or emergency scenario. The strength of our study is that it has objectively captured the performance of the AB in the real world and its relative generalisability in a limited resource setting. An RCT comparing intubation in difficult airways with and without AB is warranted in the future.

**CONCLUSION**

In this single-centre study, we observed a non-significant increasing TTI trend in patients with a higher MP score when compared to a lower score when using the aerosol box. However, this did not translate to a clinically significant difference in the overall intubation outcomes between the two groups.

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**Conflicts of interest**

There are no conflicts of interest.

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### Supplemental Table 1: Factors influencing time to intubation (TTI) after excluding patients with TTI >150 seconds

| Variables                              | n=120 (100%) | Univariate analysis | P  | Multivariate B coefficient (Standard Error) | P  | 95%CI  
|----------------------------------------|--------------|---------------------|----|---------------------------------------------|----|------- |
|                                        |              | Mean TTI* in seconds (SD†) |    |                                             |    |       |
| Mallampati Score                       |              |                     |    |                                             |    |       |
| Group 1                                | 79 (65)      | 56.27 (27.5)        | 0.101 |                                           |    |       |
| Group 2                                | 41 (34.1)    | 65.37 (30.5)        |    |                                             |    |       |
| ULBT Class                              |              |                     |    |                                             |    |       |
| Class I                                | 58 (48.3)    | 60.64 (30.8)        | 0.462 |                                           |    |       |
| Class II-III                           | 55 (45.8)    | 56.6 (26.6)         |    |                                             |    |       |
| BMI‡                                   |              |                     |    |                                             |    |       |
| BMI<30 kg.m⁻²                           | 98 (81.6)    | 61.4 (30.9)         | 0.095 |                                           |    |       |
| BMI≥30 kg.m⁻²                           | 22 (18.3)    | 50.09 (12.8)        |    |                                             |    |       |
| Dentition (Buck teeth/ loose teeth/Dentures) | 28 (23.3)  | 59.7 (27.8)         | 0.932 |                                           |    |       |
| Yes                                    | 92 (76.6)    | 59.25 (29.29)       |    |                                             |    |       |
| No                                      |              |                     |    |                                             |    |       |
| Laryngoscope                           |              |                     |    |                                             |    |       |
| Macintosh                              | 109 (90.8)   | 56.17 (26.5)        | 0.005 | 3.07 (10.70)                                | 0.77 | (-18.13-24.28) |
| CMAC**                                 | 11 (9.1)     | 91.18 (32.8)        |    |                                             |    |       |
| Intubation                              |              |                     |    |                                             |    |       |
| Orotracheal                            | 113 (94.1)   | 57.4 (27.5)         | 0.003 | 6.73 (11.67)                                | 0.56 | (-16.38-29.86) |
| Nasotracheal                           | 7 (5.8)      | 90.8 (33.8)         |    |                                             |    |       |
| Cormack Lehane                          |              |                     |    |                                             |    |       |
| Grade I-II                             | 108 (90)     | 57.2 (28.3)         | 0.015 | -5.30 (7.91)                                | 0.504 | (-20.98-10.38) |
| Grade III-IV                           | 12 (10)      | 78.5 (26.7)         |    |                                             |    |       |
| Intubation Aids                         |              |                     |    |                                             |    |       |
| Yes                                    | 16 (13.3)    | 102.3 (26.36)       | 0.000 | -45.83 (8.45)                               | 0.000 | -62.5- (-29.08) |
| No                                      | 104 (86.6)   | 52.7 (22.9)         |    |                                             |    |       |
| Aerosol box AB††                       |              |                     |    |                                             |    |       |
| AB 1                                   | 42 (35)      | 57.1 (23.8)         | 0.020 |                                           | 1⁺ |       |
| AB 2                                   | 41 (34.1)    | 69.0 (36.9)         |    |                                             | 0.011 | 3.04-22.7 |
| AB 3                                   | 37 (30.8)    | 51.3 (20.26)        | -0.52 (5.12) |                                           | 0.91 | -10.67-9.61 |
| Change in approach                     |              |                     |    |                                             |    |       |
| Yes                                    | 37 (30.8)    | 65.5 (31.6)         | 0.012 | -7.4 (4.4)                                 | 0.096 | -16.11-1.33 |
| No                                      | 83 (69.1)    | 56.6 (27.26)        |    |                                             |    |       |
| Plan modification                      |              |                     |    |                                             |    |       |
| Yes                                    | 117 (97.5)   | 58.1 (28.04)        | 0.003 | 42.02 (12.9)                               | 0.002 | 16.32-67.72 |
| No                                      | 3 (2.5)      | 107.6 (17.21)       |    |                                             |    |       |

*Time to intubation, †Standard deviation, ‡Confidence interval, §Mallampati score: Group 1=MP I-II, Group 2=MP III-IV, ○Upper Lip Bite Test, Class I=Lower incisor can bite upper lips above the vermillion line, Class II=Lower incisor can bite upper lip below the vermillion line, Class III=Lower incisor cannot bite upper lip, ††Analysis of variance (ANOVA) used to compare the time to intubation across the aerosol boxes, ¹Reference standard. Univariate analysis was done using student-t test, Multivariable linear regression model was created.