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Original Article

Effects of a Protective Intubation Box on Success and Duration of Tracheal Intubation in Elective Surgeries: A Randomized Trial

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Abstract

Introduction: The protection of healthcare personnel during airway procedures became a major concern during the COVID-19 pandemic. This study was conducted to examine the effects of intubation box on the duration and success of tracheal intubation in patients undergoing general anesthesia.

Methods: This randomized clinical trial was carried out at Firoozgar Hospital, affiliated with Iran University of Medical Sciences in 2022. A total of 80 adult surgical candidates were allocated to either conventional laryngoscopic intubation or intubation with a barrier box. Demographic variables were recorded, intubation success was confirmed by capnography, and the time required for tube placement was measured by an independent observer.

Results: Gender, age, and BMI distribution showed no significant difference between groups ($P>0.05$). The mean intubation time was markedly shorter using standard technique (8.32 ± 0.62 seconds) than using the box-assisted method (11.48 ± 0.80 seconds). This difference was more pronounced in male patients. The success rate of intubation was 100% with the conventional approach and 92.5% in the box group, although this finding was not statistically significant ($P=0.12$). No post-operative voice changes or vocal cord complications occurred.

Conclusion: While intubation boxes may provide additional protection against aerosol exposure, their use may prolong intubation time, particularly in male patients, without improving success rates. Therefore, their application should balance protective benefits against potential delays in airway management.

Keywords: Tracheal intubation, COVID-19, Barrier device, Intubation box, General anesthesia

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Introduction

The rapid global spread of SARS-CoV-2, causing COVID-19, created unprecedented challenges for healthcare systems worldwide. Protecting frontline medical staff was of great importance in maintaining hospital function and limiting the spread of infection within clinical environments. Because of their direct and repeated exposure to infected individuals, healthcare providers face an elevated risk of acquiring respiratory viruses, a pattern already seen during the outbreak, when a substantial proportion of cases occurred among medical personnel. Early in the pandemic, infections rapidly surpassed one million worldwide, again raising concern for occupational exposure among healthcare workers (1-3).

According to the World Health Organization, infection control strategies rely on the assumption that respiratory droplets are considered the main route of SARS-CoV-2 transmission, either by direct projection onto mucosal surfaces or indirectly through contaminated hands and surfaces. Smaller particles capable of remaining suspended in the air may also contribute to transmission, particularly during aerosol-generating procedures (AGPs). Examples of AGPs include tracheal intubation, airway suctioning, bronchoscopy, nebulization, and positive-pressure ventilation. Therefore, enhanced precautions and appropriate personal protective equipment (PPE) are recommended for clinicians performing these high-risk interventions.

The extent to which SARS-CoV-2 spreads via airborne particles in clinical settings remains under discussion, yet increasing evidence indicates that aerosolized droplets may contribute to transmission, especially in locations where AGPs are conducted. This highlights the need for additional protective approaches during airway manipulation (4-5).

Given that aerosol particles can linger in the air and travel beyond the immediate patient area, various barrier devices have been suggested to offer added protection while performing intubation. A notable example is the transparent "intubation box", originally introduced by a Taiwanese anesthesiologist HY Lai, which is positioned over the patient's head to create a physical barrier during laryngoscopy. Although designed to reduce clinician exposure, the device may limit maneuverability and introduce challenges to airway management, and its protective effectiveness alongside standard PPE is not yet fully established (6-9). In a limited simulation employing fluorescent dye, Canelli et al observed that the use of an intubation box appeared to lessen contamination around the airway. The study included only two trials and the investigators pointed out that their model produced droplets larger than standard aerosol particles (10).

Effective use of PPE remains fundamental during procedures capable of generating aerosols, such as intubation, tracheostomy, bronchoscopy, and suctioning. Therefore, anesthesiologists, who frequently perform these interventions, are at increased occupational risk. The constraints on PPE supplies seen during the pandemic period resulted in the development of additional tools aimed at reducing exposure. Among these innovations was the intubation box, intended to serve as a supplementary barrier during intubation. Given uncertainties about its advantages and potential impact on laryngoscopy, the objective of this research was to examine the effects of the intubation box on intubation time or the success rate of intubation.

Materials and Methods

The present randomized clinical trial took place in 2022 at Firoozgar Hospital, affiliated with Iran University of Medical Sciences. Adult patients undergoing elective procedures with general anesthesia were enrolled in the study.

This study was approved by the Ethics Committee of Iran University of Medical Sciences (IR.IUMS.FMD.REC.1399.780). Additionally, the trial was formally registered beforehand in the Iranian Registry of Clinical Trials (IRCT20140109016151N10).

Participants were randomly assigned to two groups: conventional tracheal intubation and intubation using an intubation box. The randomization sequence was generated using a computer-based balanced block randomization method with a block size of four to ensure equal allocation throughout the study. An independent researcher not involved in patient recruitment prepared sequentially numbered, opaque, and sealed envelopes to maintain allocation concealment. After obtaining written informed consent, the attending anesthesiologist opened the next envelope in sequence to determine the patient's group assignment.

Based on the findings reported by Begley et al (6), and assuming a significance level of $\alpha = 0.05$ with 80% power, the sample size was estimated to be 40 participants per group, yielding a total of 80 subjects for the two study arms. Using the standard sample size estimation formula $n = \left(\frac{Z_{1-\alpha/2} \times \delta}{d}\right)^2$, a total sample size of 80 patients (40 per group) was deemed appropriate to allow meaningful comparison between the two study groups.

Inclusion criteria required adults within the age range of 20–60 years and an ASA physical status designation of I or II, Mallampati class I or II, mouth opening greater than 30 mm, and thyromental distance exceeding 55 mm, BMI less than 30 who were candidates for lower extremity or abdominal surgery under general anesthesia. Individuals with neuromuscular conditions or documented difficult intubation in the past, ischemic heart disease, or hypertension were not included. Exclusion criteria also comprised Cormack-Lehane grade III or IV laryngoscopic view and any failure of equipment during the procedure.

Written consent was obtained from all participants prior to being included in the study. Demographic and clinical baseline data were captured through a pre-defined checklist, including demographic variables, and chronic disorders like diabetes, thyroid disorders, and kidney disorders. All patients received general anesthesia according to a standardized protocol. Routine monitoring and perioperative care were identical in both groups. Induction of anesthesia was carried out with Midazolam 0.02 mg/kg, Fentanyl 3 μg/kg, Propofol 2 mg/kg, and Atracurium 0.5 mg/kg.

For patients in group A, direct laryngoscopy and tracheal intubation were performed using a standard Macintosh laryngoscope. In group B, laryngoscopy was conducted with the patient's head and neck positioned inside an intubation box (Figure 1). The box (measured

Figure 1. Intubation Box over the Head of a Manikin

55 x 60 x 70 cm) was constructed from Plexiglass, allowing for easy cleaning and sterilization. The sides facing the patient's head and legs were open to accelerate the installation of a transparent plastic cover. Built-in holes in the middle of the replaceable cover provided access to the patient's face and airway and could be replaced for each patient. The timing of muscle relaxant administration relative to the start of intubation was kept consistent between the groups. Data collection included collection of demographic data, confirmation of successful intubation by capnography, and measurement of intubation time by an independent observer. The duration of intubation was defined as the period beginning with insertion of the laryngoscope into the oral cavity and ending once the endotracheal tube was seen passing through the vocal cords. All intubations were performed by a third-year anesthesiology resident who had demonstrated sufficient proficiency and experience in the procedure. As soon as the tube was successfully passed through the vocal cords, the observer was informed to stop the timer. Only one attempt was permitted in order to accurately calculate the time taken for intubation. Any complications occurring during intubation were documented.

Data analysis was performed using SPSS version 20 (IBM Corp., Armonk, NY, USA). Descriptive statistics (mean ± standard deviation, frequency, and percentage) were employed to present the data in summary form and presented in tables and figures where appropriate. The Kolmogorov–Smirnov test was used to assess the normal distribution of quantitative data. When data met normality assumptions, the independent samples *t*-test was applied to compare the two groups; for variables that did not follow a normal distribution, comparisons were performed using the Mann–Whitney U test. Discrete variables were evaluated using the Chi-square test or Fisher's exact test when appropriate. A *P*-value of less than 0.05 was considered statistically significant.

Results

The baseline demographic features of the individuals are presented in Table 1. No significant differences were identified when comparing the two study arms in baseline variables (age, BMI, Mallampati) ($P=0.366$).

Table 2 compares intubation duration between the two study arms. Intubation took significantly less time with the routine technique (8.32 ± 0.62 seconds) than with the intubation box (11.48 ± 0.80 seconds; $P=0.002$). When analyzed by gender, men exhibited a marked difference between methods. In other words, the routine approach required 7.95 ± 0.70 seconds, whereas the box-assisted method required 12 ± 1.002 seconds ($P=0.001$). Among women, mean times were 8.77 ± 1.10 seconds in the routine group and 10.94 ± 1.27 seconds in the box group; the finding did not meet the threshold for statistical significance ($P=0.21$).

Success rates did not differ significantly between the two approaches based on the results of Fisher's exact test (92.5% for the box-assisted method vs. 100% for conventional intubation; $P=0.12$). The few unsuccessful attempts (n = 3) in the Box group were attributed to restricted hand motion and patient-related difficulty; in both instances, intubation was successfully completed using the standard method after removing the box. To ensure patients' safety, individuals with Cormack-Lehane grade III or IV were excluded from the study in case of encountering risks and intubation was conducted using the previous standard methods. Fortunately, no patient was excluded from the study for this reason. No hemodynamic changes or desaturation occurred in these patients and no post-operative hoarseness or vocal cord dysfunction occurred in any patient.

Discussion

This randomized clinical trial compared tracheal intubation using an intubation box with conventional intubation. Our findings show that time to achieve intubation was noticeably extended when the device was utilized, although the overall success rates in the two groups were similar. In addition, the prolongation of intubation time appeared more pronounced in male patients, while no significant gender-related difference was observed in success rates.

Following the initial report by Canelli et al (10), who introduced a transparent Plexiglas barrier intended to reduce aerosol dispersion during airway management, several research groups worldwide explored similar protective enclosures. Canelli's simulation demonstrated distinct contamination patterns during coughing events with and without the device, raising questions about potential clinician exposure. Numerous descriptions

Table 2. Relationship between Success Rate, Intubation Time, and Type of Intubation

Variable	Intubation box	Routine intubation	*P*-value
Total success rate	92.5%	100%	0.012
Time in men	12 ± 1.002	7.95 ± 0.70	0.001
Time in women	10.94 ± 1.27	8.77 ± 1.10	0.207
Overall time	11.48 ± 0.80	8.32 ± 0.62	0.002

Table 1. Demographic Data of the Studied Subjects

Variable	Intubation box		Routine intubation	
	Man (n = 20)	Woman (n = 20)	Man (n = 22)	Woman (n = 18)
Age (years)	46.94 ± 3.86	45.52 ± 2.59	41.3 ± 3.08	45.43 ± 4.20
BMI	28.36 ± 1.46	27.96 ± 2.04	27.85 ± 1.94	27.02 ± 2.89
Mallampati Grade 1	15 (75%)	14 (70%)	17 (77.3%)	12 (66.7%)
Mallampati Grade 2	5 (25%)	6 (30%)	5 (22.7%)	6 (33.3%)

of plastic shields and barriers used during procedures such as intubation, supraglottic airway placement, bronchoscopy, and tracheostomy subsequently emerged in the literature. Additional variants, including handmade models, 3D-printed versions, modified incubators, and improvised drapes, were also reported; however, many of them offered limited maneuverability for complex airway interventions (11-14).

Feldman et al supported observations similar to those of Canelli et al (10), showing that simulated airway procedures, including those in pediatric and adult models, can generate aerosolized particles that pose risks to healthcare personnel. They emphasized that individuals performing airway management, especially tracheal intubation, face heightened exposure and therefore require appropriate personal protective equipment (15, 16). Although barrier enclosures may appear beneficial when PPE resources are limited, significant uncertainty persists because many published evaluations involve small sample sizes, variable methodology, and insufficient clinical validation. Hence, expert groups have cautioned that these devices require more rigorous assessment before widespread adaptation.

Similarly, Begley et al observed that intubation boxes substantially prolonged intubation time compared with standard practice (6). Although they reported reductions in airborne contamination, they also noted increased deposition of particles on the box itself and surrounding surfaces. The device limited operator movement and introduced risks such as accidental extubation. These results suggest that while the box may help reduce aerosol dispersion, its practical limitations and potential hazards must be carefully weighed.

Fong et al also reported that intubation boxes resulted in longer intubation times, with the impact being more pronounced in simulated difficult airway scenarios (17). Their findings mirrored earlier observations of greater surface contamination and reduced freedom of movement during the procedure. They concluded that although the device might lower airborne exposure, clinicians must remain aware of its limitations and the additional risks it may introduce.

Additional concerns have been raised about the possibility that such barriers may create a misplaced sense of safety, leading clinicians to inadvertently compromise PPE use or institutions to rely on unvalidated devices during shortages (17–21). Some studies have shown that the rigid edges of these enclosures can damage PPE during use, potentially increasing exposure rather than reducing it. A recent Cochrane review also highlighted inconsistent PPE guidelines and poor adherence in clinical settings. In light of these issues, experts recommend emphasizing correct PPE practices, establishing clear standards for aerosol-generating procedures, and avoiding over-dependence on devices that have not been thoroughly validated.

The present study has several limitations. Given that the nature of the intervention made blinding impossible, operator awareness may have influenced performance. Additionally, the assessment period was limited to the intraoperative phase, preventing evaluation of potential long-term airway complications or postoperative outcomes associated with the use of the intubation device.

Conclusion

In summary, the intubation box may offer an additional barrier that could help reduce viral exposure during airway management; however, using the device led to a marked increase in the time required to secure the airway, particularly among male patients. The success rate of intubation did not differ significantly between the two methods, and no differences were observed in post-operative airway complications or Mallampati classification. These results suggest that while the box may be beneficial in situations where heightened protection is necessary, such as the COVID-19 pandemic, clinicians should carefully consider the potential negative consequences of prolonged intubation time when deciding to use this device.

Authors' Contribution

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Competing Interests

The authors declare that they have no conflict of interests.

Ethical Approval

The present study was approved by the Ethics Committee of Iran University of Medical Sciences (IR.IUMS.FMD.REC.1399.780).

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