Original Article

Evaluation of aerosol box use for ultrasound-guided internal jugular vein cannulation in patients with COVID-19: A short-term randomised study

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ABSTRACT

Background and Aims: During the coronavirus disease 2019 (COVID-19) pandemic, health care workers are at a high risk of infection from aerosols. In this study, we compared the ease of using the aerosol box (AB) with the traditional method during internal jugular vein cannulation attempts (IJVCA). **Methods:** The study included 40 patients with COVID-19 who required central venous catheterisation during treatment in the ward. The patients were randomly allocated to one of the two protective equipment (PPE) groups and then randomly assigned to one of the five anaesthesiologists with at least 5 years of experience. Group P and A had both PPE and AB used, whereas Group P included patients where PPE was used alone. The physicians completed a survey after performing the procedure to evaluate the use of the AB. **Results:** The preparation for the procedure and procedure durations were observed to be statistically longer in Group P and A (P = 0.002 and P = 0.001, respectively). The first attempt in Group P and A was unsuccessful in six patients, whereas the first attempt in Group P was unsuccessful in only two patients (P = 0.235). Anaesthesiologists described difficulty with manipulation during the procedure, discomfort using the box, and resulting cognitive load increase in Group P and A. **Conclusion:** The IJVCA procedures were faster and easier and had greater satisfaction for physicians when the AB was not used. Also, the high complication rate, including carotid artery punctures and disruption of sterility and PPE, albeit not statistically significant, has clinical implications. Therefore, we do not recommend the use of ABs for IJVCA.

Key words: Aerosols, catheterisation, central venous, COVID-19, personal protective equipment, SARS-CoV-2

INTRODUCTION

Transmission of coronavirus disease 2019 (COVID-19) occurs by inhalation of droplets or aerosols carried in the air, which is very common in hospital environments.[1] One of the basic concerns during medical procedures such as intubation and tracheostomy, which require close contact, is to protect health employees from getting infected. The World Health Organization and Centers for Disease Control and Prevention recommend using personal protective equipment (PPE) for all aerosol-generating procedures such as intubation and endoscopy.[2]

In addition to this, worries about transmission have caused physicians to develop new methods. There are very few studies published about the safety or

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efficacy of aerosol boxes, and their use is still not recognised in international PPE guidelines.[3] Despite this, due to the high risk of disease transmission, since the introduction of these devices for tracheal intubation, they have rapidly begun to be used for clinical interventions such as endoscopic procedures, eye surgery and dermatologic examinations.[4,5]

During the pandemic, apart from tracheal intubation, another procedure that might expose anaesthesiologists working in operating rooms to aerosols is the insertion of central venous catheters (CVCs). Apart from the inability to use peripheral venous access, central venous cannulation techniques may be used for patients with COVID-19 due to multiple infusions, haemodynamic monitoring and vasopressor requirements.

For CVC placement, the femoral region is more distant from the patient's oral, nasal and tracheal secretions, which reduces contamination risk to health workers performing the procedure.[6] However, the thrombotic risk is higher for the femoral vein approach, and patients with COVID-19 have an increased tendency for thrombosis.[6] In a study conducted in patients with COVID-19, the lower extremity proximal deep vein thrombosis rate was 34.8%.[7] The subclavian route involves a risk of pneumothorax and may clinically worsen patients with respiratory distress. Anaesthesiologists are well experienced in internal jugular vein cannulation in clinical practice. Considering all this, the internal jugular vein (IJV) is often chosen for cannulation in patients with COVID-19.

The primary objective of this study was to compare the ease of using an aerosol box with the traditional method to prevent droplet contamination of the practitioner during internal jugular vein cannulation attempts (IJVCA), which requires close contact with patients with COVID-19. The secondary objectives were to compare the number of attempts, physician satisfaction, PPE damage, catheter-related infection and time required for the procedure between the two groups.

METHODS

This prospective study was approved by our local ethics committee (2020-287/22.06.2020), Ministry of Health scientific research platform ethics committee, and all patients provided written informed consent [2020-06-11T21_19_35]. In addition, the study was registered at ClinicalTrials.gov (NCT04954118). The study was conducted from March to September 2020 at a training and research hospital affiliated with a university. This study included human participants. All study procedures were abided by organisational and national research committee ethical standards and the 1964 Helsinki Declaration.

The study included 40 patients who were diagnosed as having COVID-19 and had a CVC inserted while being treated in the ward by one of five anaesthetists with at least 5 years of experience in ultrasound (US) guidance. Patients aged under 18 years, those who could not lie in the supine position due to severe respiratory distress and who had thrombus in the right IJV on ultrasound evaluation, were excluded from the study. The patients were divided into two groups according to the use of protective equipment. For Group P, physicians only used PPE, and for Group P and A, an aerosol box was used in addition to PPE. The patients were randomly assigned according to computer-generated simple randomisation into one of the two protective equipment groups and then into one of the five physician groups within each protective equipment group. An independent physician who was blinded to the study performed the patient assignment and preparation of the allocation sequence, and the patients were randomly assigned to one of the two groups. The anaesthesiologists performed the procedure for a total of eight patients, with four patients from each group in 7 months [Figure 1]. Thus, the physicians were aware of the groups to which patients were allocated. This study was single blind, and the anaesthesiologists collecting the data were blinded to the study design.

During the procedures, patients were monitored and received 3–6 L/min oxygen (O_2) treatment through the nasal route. In Group P and A, the head and neck region was covered with the aerosol box. Before using the aerosol box, it was cleaned using Aniosyme DD1 (Laboratoires ANIOS, An Ecolab Company, Lezennes, France), which has high disinfectant properties (0.5% hypochlorite solution). The procedure assistant was an experienced anaesthesiology nurse who was not included in the project design or data collection. The nurse was also evaluated for breaches in sterility and PPE violations during the procedure.

The anaesthetist and nurse wore PPE for both groups. An aerosol box with dimensions of 50 cm × 50 cm × 40 cm was used in Group P and A [Figure 2]. A three-way CVC

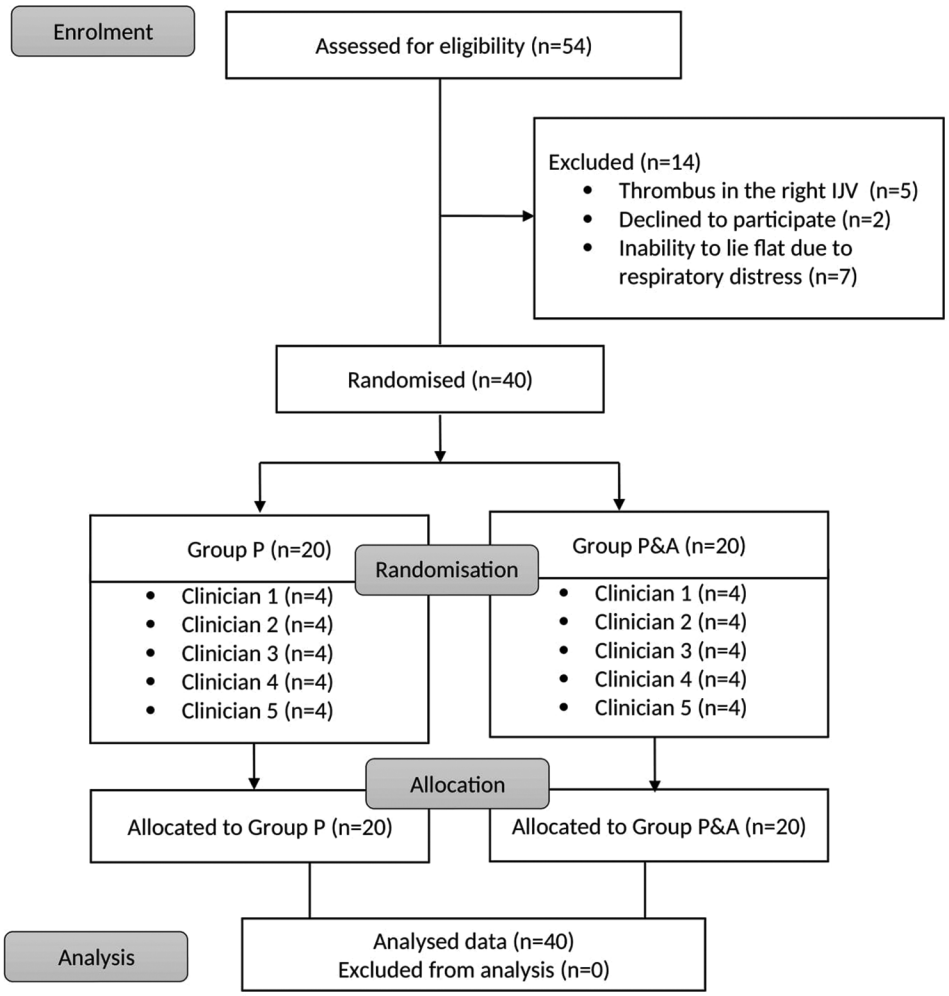

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram, IJV: internal jugular vein

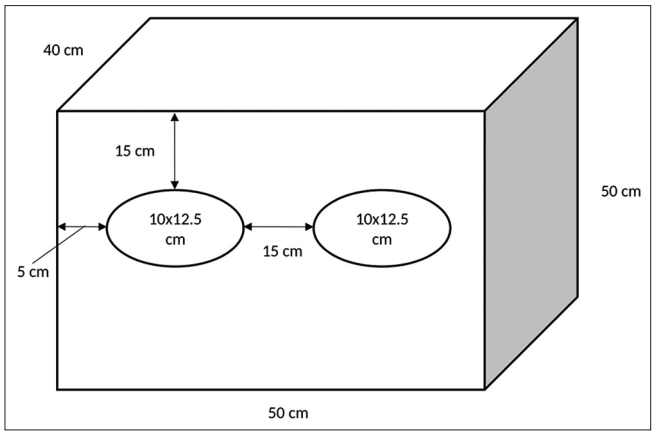

Figure 2: Dimensions of the aerosol box used for an ultrasound-guided central venous catheter procedure

(Certofix Trio V715, B. Braun Melsungen, Germany) and a General Electric (GE) LOGIQ e model (GE Medical Systems, Phoenix, USA) ultrasound device with a linear multifrequency 12 L probe were used in all procedures. Ultrasonography and cannulation were performed by a single anaesthesiologist. During the procedure, assistance was provided through the open end of the aerosol box. The ultrasound probe was given to the anaesthetist via the same route. Due to common habits in the clinic, procedures were completed on the short axis.

After preparation, the area was sterilised using povidone–iodine 10%, the patient's head was slightly turned to the contralateral side, and the IJV was visualised using ultrasound. The needle was inserted into the skin at a 45° angle from the mid-point of the probe and advanced by aspiration towards the IJV. After entering the lumen of the vein, the catheter was placed using the Seldinger technique.

For all patients, saturation values were recorded at 10-min intervals. Data were collected simultaneously by an anaesthetist who was not included in the study. Chest radiography was performed to confirm the CVC

position after the procedure. Patients returned to the wards to continue treatment after the procedure.

Anaesthesiologists completed the physician satisfaction survey after their first procedure using the aerosol box. For repeated box use, they were requested to complete the survey form again. Thus, the opinions of anaesthesiologists were clearly determined. There is no scale developed to determine satisfaction with the use of PPE. For this reason, the survey was conducted based on interviews with the five physicians included in the study and the relevant literature. Validity and reliability analyses of the questions asked were made, and a satisfaction survey consisting of six questions was developed. The survey consisted of two answers as '1—yes' and '2—no'. The survey's Rasch reliability coefficient was determined as 0.78, and the discrimination index value was determined as 1.89.

The G*Power 3.1.9.2 programme was used to calculate the sample size of the study. A pilot study was conducted with 10 patients from each group to determine the minimum sample size for the primary outcome. The mean duration of the procedures was 24.6 ± 8.5 min in Group P and 32.7 ± 12.2 min in Group P and A. An α error of 0.05 with a power of 80% was assumed so that each group had at least nine participants. We included 20 patients in each group due to the possibility of dropouts. Patient data from the pilot study were not included in the main study. The pilot study included primary and secondary outcomes, and the outcomes were similar to the study results.

The demographic characteristics and collected data were entered into the International Business Machines® Statistical Package for the Social Sciences® version 23. Variables were characterised using mean, maximum and minimum values, and percentage values were used for qualitative variables. When histogram plot analysis and the skewness and kurtosis normality analysis were performed, the distribution of measurements was nonparametric. The data which follow the normal distribution were reported as mean ± standard deviation, and comparisons between the groups were made using the Student's *t* test. In addition, Fisher's exact test was used for groups with less sample size and fewer categorical options. Also, the Pearson's Chi-square test was used to compare categorical data. Nonparametric continuous variables were recorded as median and interval distributions. The Mann–Whitney U test was used for comparisons. A value of $P < 0.05$ was accepted as statistically significant.

RESULTS

Initially, 54 patients were enroled. Fourteen patients were excluded from the study due to the presence of thrombus in the IJV, inability to lie flat due to respiratory distress, and refusal to participate in the study. Data analysis was performed for 20 patients for each group [Figure 1].

The mean age was 64.0 ± 11.7 years (the interval age of 39–88 years) for 40 patients, comprising 23 men (57.5%) and 17 women (42.5%). Hospitalisation of the patients occurred 9.4 ± 5.8 days after symptom onset. CVCs were inserted at a mean of 6.7 ± 4.6 days after the patients were admitted to the hospital. The age, peripheral oxygen saturation (SpO_2), duration of preparation and procedure, and ward and intensive care unit (ICU) length of stay were recorded as nonparametric data [Table 1]. The Mann–Whitney test was used for comparing these parameters.

There was no difference between the groups regarding age, sex, comorbidity and initial SpO_2. The procedure preparation and procedure duration were observed to be longer in Group P and A, with statistical differences ($P = 0.002$ and $P = 0.001$, respectively) [Table 1]. In Group P, the first attempt success rate was 90.0%, whereas this rate was 70.0% in Group P and A; however, the difference was not statistically significant ($P = 0.235$). The arterial puncture rate was less in Group P than in Group P and A. Similarly, sterilisation violation was more frequent in Group P and A [Table 2].

Seven patients with central catheters inserted continued treatment in the ward and were discharged when fully healed. Thirty-three other patients with CVCs placed (82% of patients) were intubated due to respiratory failure in the later days and were admitted to the ICU. Patient admission to intensive care occurred at a mean of 3.5 ± 2.4 days after catheter insertion.

In the survey completed after the procedure, all physicians described difficulty in manipulation [Table 3]. Other frequently encountered problems were discomfort felt while using the box and increased cognitive load linked to this. Only one anaesthesiologist experienced excessive fogging of glasses and wanted to remove them due to vision problems. The procedure

Table 1: Comparison of demographic characteristics for patients, procedure preparation duration and procedure duration between the groups

	Total (*n*=40)	Group P (*n*=20)	Group P&A (*n*=20)	*P*
Age	64.0±11.7	64.0±8.4	64.0±14.5	0.904
Sex				0.749
Female	17 (42.5%)	8 (40.0%)	9 (45.0%)	
Male	23 (57.5%)	12 (60.0%)	11 (55.0%)	
Comorbidity	34 (85.0%)	18 (90.0%)	16 (80.0%)	0.661
SpO_2	86.8±5.1	85.9±5.4	87.7±4.8	0.277
Procedure preparation duration (min)	35.4±7.2	32.0±6.0	38.9±6.7	0.002
Procedure duration (min)	37.5±14.7	29.9±7.5	45.1±15.4	0.001
Ward (days)	12.6±8.43	10.6±5.1	14.5±10.5	0.512
ICU (days)	15.8±9.6	16.7±8.1	14.9±11.0	0,641
Hospital LOS	28.4±11.23	27.3±10.4	29.4±12.1	0.620
Mortality	23 (57.5%)	11 (55.0%)	12 (60.0%)	0.749

Data are presented as mean±standard deviation or number (*n*—%). SpO_2: peripheral oxygen saturation, ICU: intensive care unit, LOS: length of stay

Table 2: Comparison of intervention attempts and quality between the groups

	Group P (*n*=20)	Group P&A (*n*=20)	Odds Ratio	95% CI	*P*
First-attempt success	18 (90.0%)	14 (70.0%)	0.259	0.045-1.486	0.235
Number of attempts	-	-	NA	NA	
Artery puncture	1 (5.0%)	4 (20.0%)	4.750	0.481-46.906	0.342
Disruption of sterilisation	1 (5.0%)	4 (20.0%)	4.750	0.481-46.906	0.342
Violation of PPE	0 (0.0%)	3 (15.0%)	NA	NA	0.231
Catheter infection	5 (25.0%)	6 (30.0%)	1.286	0.319-5.175	0.723

Data are presented as number (*n*—%). CI: confidence interval, NA: not applicable, PPE: personal protective equipment

Table 3: Survey answers reported by anaesthesiologists performing catheterisation with aerosol box

Evaluation of comfort with aerosol box (survey content)	Participants (*n*=5)	
	Yes	No
Discomfort using box	4	1
Difficulty in manipulation during the performance	5	0
Difficulty in use of US device restricted by box	2	3
Increased cognitive load from the use of box	2	3
Increased physical load from the use of box	1	4
User satisfaction	1	4

Data are expressed as number, US: ultrasound

was continued with a facial shield after the PPE violation. Anaesthesiologists underwent real-time polymerase chain reaction tests on the 7th day after the procedures, and none had positive results in either group.

A comparison of patients with and without identified catheter infections was made [Table 4]. The patients with catheter infections had longer procedure preparation and procedure durations; however, the differences were not statistically significant ($P = 0.196$ and $P = 0.280$, respectively). In addition, the number of attempts, arterial punctures, breaches in the sterility and PPE violations were higher for patients with catheter infections; however, these differences were not statistically significant.

DISCUSSION

This study is probably the first to compare the ease of IJVCA when using aerosol boxes. It has been shown that the procedure is much more difficult when an aerosol box is used to prevent contamination of the practitioner by droplets during IJVCA, which requires close contact with patients with COVID-19. There was no difference between the two groups regarding the number of attempts, first-attempt success and artery punctures. However, preparation and procedure duration were found to be significantly longer in the Group P and A.

The COVID-19 transmission risk from CVC insertion procedures is theoretical; however, the transmission risk cannot be ignored considering the oral, nasal and ocular exposure. The use of an aerosol box and PPE during the procedure should aid in reducing the transmission risk.

The criticisms of studies evaluating intubation are that the aerosol box size may not be appropriate

Table 4: Correlations between catheter infection and variables examined in the study

	Catheter infection (-) (*n*=29)	Catheter infection (+) (*n*=11)	*P*
Age	63.5±10.5	65.4±14.9	0.676
Sex	12 (41.4%)	5 (45.5%)	0.816
Male	17 (58.6%)	6 (54.5%)	
Female			
Comorbidity	25 (86.2%)	9 (81.8%)	0.882
Entry SpO_2	87.6±4.9	84.8±5.2	0.090
Duration of preparation (min)	34.7±7.5	37.2±6.0	0.196
Duration of procedure (min)	36.0±13.8	41.3±15.4	0.280
First-attempt success	25 (86.2%)	7 (63.6%)	0.182
Number of attempts	1.2±0.6	1.7±1.1	0.267
Artery puncture	2 (6.9%)	3 (27.3%)	0.117
Disruption of sterilisation	2 (6.9%)	3 (27.3%)	0.117
Violation of PPE	2 (6.9%)	1 (9.1%)	0.161
ICU (days)	15.1±9.3	17.5±10.5	0.530
Hospital LOS (days)	26.2±10.5	34.0±11.5	0.048
Mortality	18 (62.1%)	5 (45.5%)	0.343

Data are presented as mean±standard deviation or number (*n*—%). SpO_2: peripheral oxygen saturation, PPE: personal protective equipment, ICU: intensive care unit, LOS: length of stay

for all patients and the narrow area inside the box may prevent the full manipulation required for the procedure.[8] In the present study, there was a high probability that sterilisation violations that occurred during manipulations related to the J-wire and catheter were due to the insufficient width and height of the box. Although no statistically significant results were obtained, Group P and A had lower first-attempt success rates, higher sterilisation disruption rates and more complications such as arterial puncture than Group P, which could have been due to the difficulty in using the aerosol box with PPE.

Difficulties encountered while using these boxes and the linked physical and cognitive load might have caused the procedure duration to lengthen and increased the duration of contact with the patient and the incidence of complications. Similarly, some studies related to intubation duration stated that the use of aerosol boxes extended the intubation time.[9-11]

Although the physicians using the aerosol boxes did not develop an infection, it is uncertain whether the lengthened procedure duration due to the use of the aerosol box increased the risk of disease. However, a narrative review stated that the aerosol boxes might increase exposure to the high concentration of viral aerosols.[12] A recent study measured particulate amounts in the air during intubation using a variety of aerosol capture devices. The authors determined that the aerosol boxes significantly increased particulate contamination in the air.[13] Though preliminary studies were published about this topic in the literature, some publications recommended removing aerosol boxes when difficulties were encountered.[14,15]

In the satisfaction survey performed in this study, physicians stated that using the box was uncomfortable, and they experienced difficulties with manipulation and vision during the procedure.

The development of these negative aspects during the procedure increased cognitive load and made the anaesthesiologist's task more difficult.[16] Additionally, having patients with respiratory distress who are conscious and remain in the supine position for an extended period, along with unsuccessful attempts, creates additional stress factors for physicians, which may increase the possibility of errors.[17] A study reported that complications related to CVC insertion were linked to stress.[18]

One of the most unwanted complications during IJVCA procedures is carotid artery puncture.[19] A study that did not use ultrasound identified that IJVCA in patients without anaesthesia increased carotid artery puncture fifteen times and attempt numbers four times. It reported 24% puncture rates and the number of attempts are consistent with the rates in our study.[20]

The limitations of this study are that it was based on the experience in a single centre and the sample size was small; this situation restricts the inferences that can be made from the outcomes. Studies with more significant sample numbers may bring parameters such as arterial puncture, sterilisation violations and

catheter infections to statistical significance. The validity of the study is limited to the design of the aerosol box used. In addition, physicians do not yet have sufficient experience in using aerosol boxes. The knowledge gained after long-term use of aerosol boxes may change the results of the study. Nevertheless, nowadays ultrasonography-guided central venous cannulation is the standard of care and the application of ultrasonography inside the box is not easy.

CONCLUSION

Aerosol box use resulted in more difficult CVC procedures compared with directly administered IJVCA. Also, in the study, the high complication rate of carotid artery punctures and disruption of sterility and PPE, albeit not statistically significant, have clinical implications. Therefore, we do not recommend the use of aerosol boxes for IJVCA.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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