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Date: 2020

Type: Article de revue / Article

Référence: Idei, M., Nomura, T., Jouvet, P., Aubin, C.-É., Kawaguchi, A., & Nakagawa, M. (2020). Video Laryngoscope Intubation With an Aerosol Barrier Device: A Randomized Sequential Crossover Pilot Study. *Critical care explorations*, 2(10), e0234 (4 pages). <https://doi.org/10.1097/cce.0000000000000234>

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Document publié chez l'éditeur officiel

Document issued by the official publisher

Titre de la revue: Critical care explorations (vol. 2, no. 10)
Journal Title:

Maison d'édition: Wolters Kluwer
Publisher:

URL officiel: <https://doi.org/10.1097/cce.0000000000000234>
Official URL:

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Video Laryngoscope Intubation With an Aerosol Barrier Device: A Randomized Sequential Crossover Pilot Study

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Objectives: To assess the impact of the use of aerosol barrier device, Splashguard-CG, on the endotracheal intubation with different types of laryngoscope.

Design: A pilot randomized sequential crossover simulation study.

Setting: A single academic center in Japan.

Subjects: Physicians in a single academic university hospital in Japan.

Interventions: Use of Splashguard-CG.

Measurements and Main Results: All participants were asked to perform endotracheal intubation to a manikin simulator using three different devices (Macintosh laryngoscope; Airway Scope [Nihon Kohden, Tokyo, Japan]; and McGrath MAC [Aircraft Medical, Edinburgh, United Kingdom]) with and without Splashguard-CG in place, which required a total of six attempts and measured the intubation time as the primary outcome. Thirty physicians (15 experienced physicians and 15 less-experienced physicians) were included. Intubation time using Macintosh laryngoscope was significantly longer in the group with Macintosh laryngoscope and Splashguard-CG compared with the group without Splashguard-CG by the median difference of 4.3 seconds (interquartile range, 2.6–7.4 s; $p < 0.001$). There was no significant increase in the intubation time with or without Splashguard-CG for the Airway Scope (0.6 s; interquartile range, −3.7 to 3.2 s; $p = 0.97$) and the McGrath MAC (0.5 s; interquartile range, −1.4 to 4.6 s; $p = 0.09$). This trend was found in both the

experienced and less-experienced groups. We observed significant increases of subjective difficulty of the endotracheal intubation evaluated by using a Visual Analog Scale in the Splashguard-CG groups for all three types of devices.

Conclusions: The use of a video laryngoscope with an aerosol barrier device does not impact the time required endotracheal intubation in a simulation environment. This method can be considered as airway management for coronavirus disease 2019.

Key Words: aerosol; barrier device; coronavirus disease 2019; endotracheal intubation

Frontline healthcare workers are practicing next to the risk of their infection in the novel coronavirus disease 2019 (COVID-19) pandemic. Aerosol-generating procedures (AGPs) such as endotracheal intubation particularly can increase the risk of aerosol exposure and the viral infection, which should be minimized through various measures (1–3). Several reports state that aerosol barrier boxes (ABBs) can reduce the risk of exposure of healthcare workers to the virus, particularly for AGPs as endotracheal intubation in operating room setting (4, 5). Nonetheless, potential drawbacks of the use of the ABBs have been described such as technical difficulties in endotracheal intubations due to the limited space, insufficient captures of generated aerosols due to the potential air leaks from the box (6). The Splashguard-CG (SGCG) has been proposed as a redesigned “aerosol box,” which was originally invented by a Taiwanese anesthesiologist (7), aiming to overcome those potential disadvantages, and was made openly available on (8). SGCG can allow more than one provider to access the patient simultaneously and to create a negative pressure circumstance by applying continuous suctioning, which may further decrease the risk of dispersion of the aerosol (Fig. 1). The SGCG also has many novel features such as various openings (ports) for procedures and passage tubes (ventilation systems, probes, etc.), safety anchors, and dimensions allowing a variety of procedures.

However, when using this type of system to perform ventilation with a bag valve mask and endotracheal intubation, one could question if the range of motion of arms and hands could be limited which could make it ergonomically difficult to manipulate

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Crit Care Expl 2020; 2:e0234

DOI: 10.1097/CCE.0000000000000234

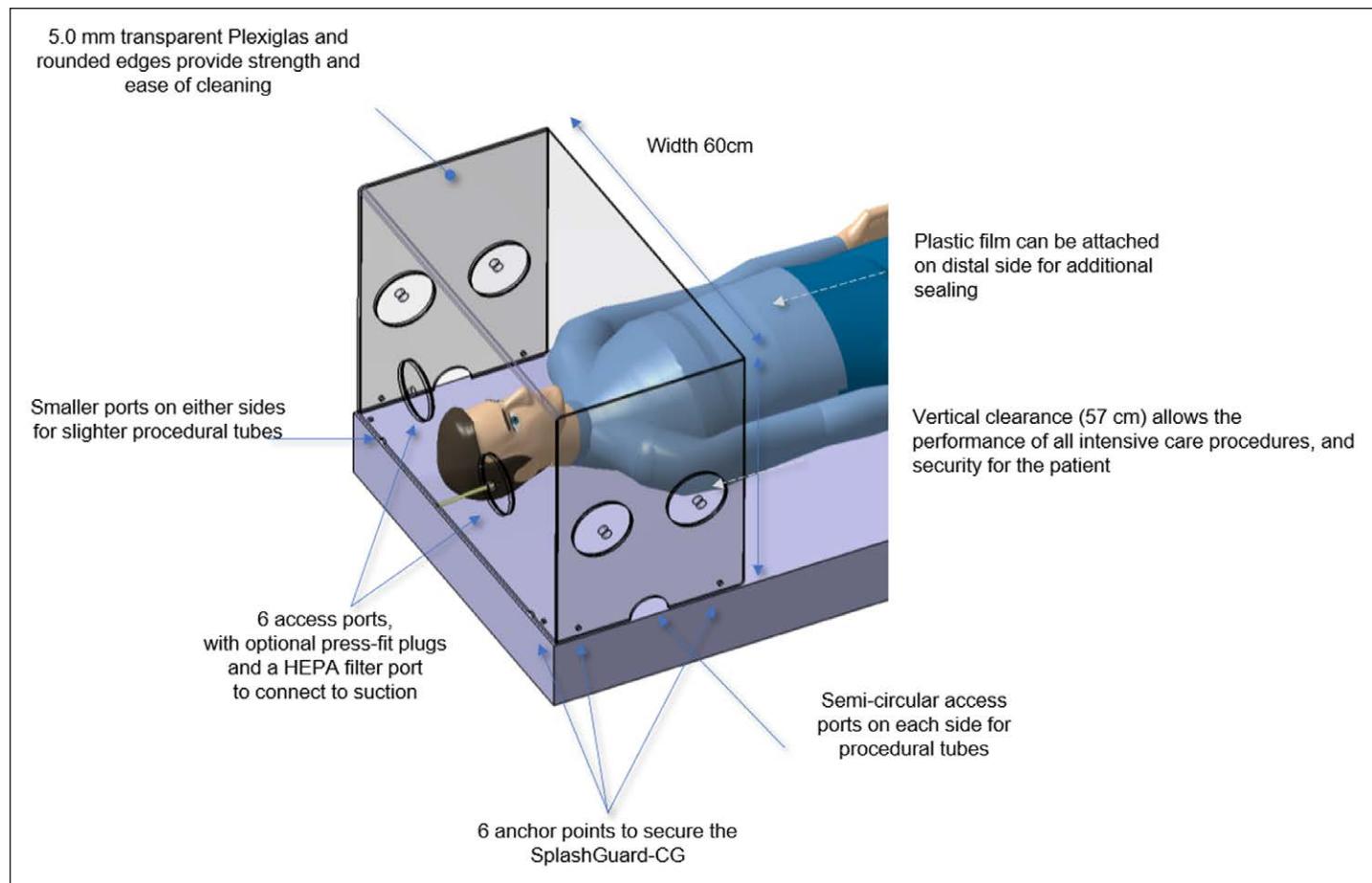


Figure 1. The overview of SplashGuard-CG. HEPA = high-efficiency particulate air.

airway equipment in the small box in place. There are only a few brief reports regarding the use of these types of the ABBs for airway management, and the best-recommended practice for endotracheal intubations with ABBs are unknown (9–11). In this pilot study, we aimed to assess the impact of the use of SGCG on the endotracheal intubation with different types of laryngoscope including monitor-integrated video laryngoscopes providing real-time visibility.

MATERIALS AND METHODS

Study Design and Population

This was a randomized sequential crossover pilot study performed in a single academic center in Japan approved by the Tokyo Women's Medical University Ethics Committee (5582) and registered in the University Hospital Medical Information Network (000040289; May 1, 2020). We randomly invited physicians (experienced physicians of airway management: anesthesiologists and an emergency physician and less-experienced physicians: physicians with another specialty background[s]) and enrolled from those who agreed to participate with a written consent. We asked the participants to perform the endotracheal intubation using three different airway devices: 1) size 3 blade of Macintosh laryngoscope (ML); 2) Airway Scope (AWS) S-100 (Nihon Kohden, Tokyo, Japan); and 3) size 3 blade of McGrath MAC (MAC)

(Aircraft Medical, Edinburgh, United Kingdom), with and without SGCG. There were a total of six experiments per participant. The order of the procedures was randomized using a lottery method.

Intervention Procedures and Outcomes

We used a simulation manikin Laerdal Airway Management Trainer (Laerdal Medical Japan, Tokyo, Japan) and an internal diameter 7.0 mm cuffed tracheal tube for all the procedures with a stylet for ML and MAC. The participants could manipulate the height of the bed and the pillow, and the position of the manikin as needed. They could ask for assistance such as removing a stylet and providing a backward, upward, and rightward pressure (BURP) maneuver through the side holes of SGCG, which was done by a staff anesthesiologist. Because this study focused on the endotracheal intubation technique, a plastic drape which supposes to be attached on the far side of the box to create a closed space was not placed. We defined the intubation time as the time taken for the participants to hold the intubation device until the ventilation with a bag valve mask via the successfully placed endotracheal tube was confirmed. We also examined the subjective difficulty for each procedure by using a Visual Analog Scale (VAS) 0 to 100 (easy to very difficult). We calculated the required sample size assuming that the expected difference in intubation time was 5 seconds (SD of 5 s) with and without SGCG, with the alpha of 0.05 and beta error to 0.20, which gave 26 required samples in total.

TABLE 1. Intubation Time and Subjective Difficulty of the Intubation by Three Devices

Intubation Time	SGCG, Medians (IQRs)	Without SGCG, Medians (IQRs)	Median Differences (IQRs)	p
Entire participants				
ML	23.2 (18.1–25.7)	17.5 (15.9–21.8)	4.3 (2.6–7.4)	< 0.001
AWS	19 (15.1–22.6)	18.3 (15.2–21.7)	0.6 (–3.7 to 3.2)	0.97
MAC	20.4 (17.0–25.1)	18.4 (15.6–21.8)	0.5 (–1.4 to 4.6)	0.09
Experienced group				
ML	20.6 (17.1–23.2)	16.4 (14.9–17.8)	4.3 (2.6–5.7)	< 0.001
AWS	15.3 (13.8–18.7)	15.3 (12.3–17.0)	0.7 (–1.7 to 3.2)	0.42
MAC	17.0 (15.0–19.0)	15.7 (14.4–17.7)	0.1 (–1.1 to 3.4)	0.24
Inexperienced group				
ML	25.4 (22–28.7)	20.8 (17.2–23.2)	4.3 (1.7–7.6)	0.001
AWS	22.1 (20.4–23.6)	21.9 (19.7–25.7)	–1.8 (–5.4 to 2.2)	0.46
MAC	23.3 (20.6–25.6)	21.6 (19.0–24.8)	0.7 (–1.7 to 5.3)	0.17
Visual Analog Scale (subjective difficulty of intubation)				
ML	50 (50–67.5)	50 (25–50)	20 (5–20)	< 0.001
AWS	40 (30–50)	30 (15–47.5)	10 (0–20)	< 0.001
MAC	40 (40–50)	30 (20–42.5)	10 (5–20)	< 0.001

AWS = Airway Scope, IQR = interquartile range, MAC = McGRAH MAC, ML = Macintosh laryngoscope, SGCG = Splashguard-CG.

Statistical Analyses

All the data were described with medians and the interquartile ranges (IQRs), and Wilcoxon signed-rank tests were applied for the comparisons of each pair. We have also performed a simple regression to explore the linear association between the intubation time and each participant's intubation experience. Statistical analyses were performed using JMP Pro14 (SAS Institute, Cary, NC).

RESULTS

In total, 30 physicians (15 experienced physicians: anesthesiologists [14], emergency physician [1] and 15 less-experienced physicians: cardiovascular surgeons [6], orthopedic surgeons [2], urologist [1], general medicine physicians [5], and ICU rotated resident [1]) were included. All endotracheal intubation procedures were successfully done for all the participants. Two less-experienced physicians requested a BURP maneuver for the endotracheal intubation when using ML with SGCG, which was provided by the staff anesthesiologist. Intubation time was significantly longer in the ML with SGCG (ML-S) compared with the ML without SGCG (ML) by the median difference of 4.3 seconds (IQR, 2.6–7.4 s; $p < 0.001$). There was no significant increase in the endotracheal intubation time with or without SGCG for the AWS and the MAC (Table 1). We observed the significant increases of VAS in the SGCG groups for all the three types of airway devices. When stratifying the groups into the experienced and less-experienced physicians, a significant prolongation in the intubation time was observed in the ML and ML-S for both groups, while there were no differences in either group for the AWS and MAC

(Table 1). Linear associations were observed between intubation time and intubation experience, decreasing respectively by 0.3 seconds for each 100 intubations experience (95% CI, 0.1–0.4; $p = 0.001$ in the ML-S, 0.3 s for each 10 intubations experience [95% CI, 0.1–0.6; $p = 0.02$] in the AWS-S, and 0.2 s for each 10 intubations experience [95% CI, 0.0–0.4; $p = 0.03$] in the MAC-S).

DISCUSSION

This is the first report presenting the impact of the SGCG on endotracheal intubation with a video laryngoscope. This study suggests that SGCG could make an extra challenge to the endotracheal intubation when it is applied to ML, but not to the AWS or MAC. SGCG could affect the range of motion of the arm more significantly when applying ML than the video laryngoscopes. The use of a video laryngoscope is recommended for the endotracheal intubation for the COVID-19 aiming to minimize the exposure to the aerosol (12). We believe the combination of using the video laryngoscope and SGCG can further decrease the risk of health-care workers in AGPs.

It is also recommended that the endotracheal intubation for the COVID-19 should be performed by the most experienced physician with the least number of persons when it is possible (11). However, particularly with an excessive surge of the cases observed, it may need to be done by a physician without an expertise in emergency situations. We found that SGCG at least impacts on the intubation time with an analogous trend when using AWS and MAC for both experienced and less-experienced physicians. We could say that endotracheal intubation via SGCG with video

laryngoscope is a safe and feasible procedure, even for less-experienced physicians, as it has minimal impact on intubation time and subjective difficulty of endotracheal intubation. However, at the same time, our study suggests that the experience could affect the intubation time itself which should support the existing recommendations.

Limitations of this study were that it was a simulation-based study without considering various aspects of the real endotracheal intubations, which may include a potential component of the difficult airway such as short neck or excessive oral secretions and hemodynamic instability. Also, we did not apply for suctioning by providing gas flow on SGCG in this study, which might possibly compromise the intubation procedures. This study mainly focused on the effect of endotracheal intubation devices. We are currently conducting a simulation study examining the roles and effects of SGCG in endotracheal intubation with video laryngoscopy on the aerosol generation and its exposure to the healthcare workers.

In conclusion, endotracheal intubations using a video laryngoscope with SGCG could be feasible with minimal impacts on intubation time when using video laryngoscope. Further studies should be warranted to determine the impacts of this procedure in a real clinical setting. The findings of this pilot study can be applied to future studies of airway management for COVID-19 patients.

ACKNOWLEDGMENTS

We thank the recent invention from Taiwanese anesthesiologist Dr. Hsien Yung Lai created for intubation in the context of coronavirus disease 2019: <https://sites.google.com/view/aerosolbox/> design.

This work was performed at Tokyo Women's Medical University Hospital.

Drs. Jouvet and Aubin invented the Splashguard-CG system and provided the procedural manual. Drs. Jouvet and Aubin made an advice on and Drs. Idei, Nomura, Kawaguchi, and Nakagawa designed the study. Drs. Idei and Kawaguchi analyzed the data and wrote the draft article. Drs. Nomura, Jouvet, Aubin, Kawaguchi, and Nakagawa reviewed and revised the article. All authors approved the final article as submitted and agree to be accountable for all aspects of the work.

The authors have disclosed that they do not have any potential conflicts of interest.

University Hospital Medical Information Network (UMIN000040289 registered on May 1, 2020).

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