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Time to intubation with McGrath™ videolaryngoscope versus direct laryngoscope in powered air-purifying respirator: a randomised controlled trial

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ABSTRACT

Introduction: During the COVID-19 pandemic, multiple guidelines have recommended the videolaryngoscope for tracheal intubation. However, there is no evidence that videolaryngoscope reduces time to tracheal intubation, which is important for COVID-19 patients with respiratory failure.

Methods: To simulate intubation of COVID-19 patients, we randomised 28 elective surgical patients to be intubated with either the McGrath™ MAC videolaryngoscope or the direct laryngoscope by specialist anaesthetists donning 3M™ Jupiter™ powered air-purifying respirators (PAPR) and N95 masks. Primary outcome was time to intubation.

Results: The median (IQR) times to intubation were 61s (37–63 s) and 41.5s (37–56 s) in the videolaryngoscope and direct laryngoscope groups respectively ($p = 0.35$). The closest mean (SD) distances between the anaesthetist and the patient during intubation were 21.6 cm (4.8 cm) and 17.6 cm (5.3 cm) in the videolaryngoscope and direct laryngoscope groups, respectively ($p = 0.045$). There were no significant differences in the median intubation difficulty scale scores, proportion of successful intubation at first laryngoscopic attempt and proportion of intubations requiring adjuncts. Intubations for all the patients were successful with no adverse event.

Conclusion: There was no significant difference in the time to intubation by specialist anaesthetists who were donned in PAPR and N95 masks on elective surgical patients with either the McGrath™ videolaryngoscope or direct laryngoscope. The distance between the anaesthetist and patient was significantly further with the videolaryngoscope. The direct laryngoscope could be an equal alternative to videolaryngoscope for specialist anaesthetists when resources are limited or disrupted due to the pandemic.

Keywords: coronavirus disease 2019, intubation, personal protective equipment, powered air-purifying respirator, videolaryngoscope

INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has led to more than 80 million infections and 1.7 million deaths.⁽¹⁾ As a significant proportion of patients with COVID-19 may require tracheal intubation for mechanical ventilation due to respiratory failure,⁽²⁾ various airway societies have devised airway management guidelines. These guidelines advocate videolaryngoscope (VL) over direct laryngoscope (DL) for intubation of COVID-19 patients⁽³⁻⁷⁾ due to the proposed benefits of VL in improving first pass intubation success thereby decreasing duration of aerosol exposure to healthcare workers, and increasing the distance between the laryngoscopist and patient during intubation. Based on current knowledge, VL may reduce the number of failed intubations, particularly in patients with difficult airways.⁽⁸⁾ However, there is no consistent evidence that VL reduces the time to intubation.⁽⁸⁾ Longer time to intubation can increase the risk of hypoxia for COVID-19 patients⁽⁹⁾ and the duration of aerosol exposure to healthcare workers. It is essential to assess if VL can truly decrease the time to intubation compared to DL because of shortages in VL supplies.⁽¹⁰⁾

The guidelines also recommend the use of personal protective equipment (PPE) with N95 masks or powered air-purifying respirator (PAPR) to protect healthcare workers performing tracheal intubations. PAPRs, especially hooded ones, may affect intubation performance due to the face shields causing glare, reflection, visual field limitation and noisy motor affecting communication.⁽¹¹⁾ There is conflicting evidence whether PAPR degrades intubation performance because available studies are largely performed on manikins,⁽¹¹⁻¹³⁾ with different protective gears ranging from anti-chemical protective gear^(12,14) to hooded PAPRs,^(11,13) and have different definitions for time to intubation with varying operator experiences.

In this study to simulate the intubation conditions of COVID-19 patients in an operating theatre, we compared the time to intubation by using McGrath™ MAC videolaryngoscope (Medtronic, Minneapolis, MN, USA) versus DL on elective surgical patients under general anaesthesia. Specialist anaesthetists who were donned in PPE and hooded PAPR performed the intubations. We hypothesise that there will be a difference in *time to intubation* with the use of McGrath™ MAC videolaryngoscope compared to *direct laryngoscope* under such operating theatre conditions (TIVIDI).

METHODS

This study is a non-blinded, randomised clinical trial conducted in Singapore General Hospital, a tertiary acute care academic hospital, from June to July 2020. The SingHealth Centralised Institutional Review Board granted ethical approval (IRB Ref.: 2020/2329) for this study on 30th April 2020. This trial was registered with ClinicalTrials.gov (identifier: NCT04424953). Study team members obtained signed written informed consent from participants during their assessment in the Preanaesthesia Assessment Clinic. The attending anaesthetists provided signed written consent prior to induction of anaesthesia. All authors have declared no conflict of interest and vouch for the accuracy and completeness of the reported data and for adherence to trial protocol.

Patients were eligible if they were adults (≥ 21 years of age) planned for elective surgery requiring general anaesthesia and orotracheal intubation, not pregnant, of ASA status I to III, with Body Mass Index (BMI) $< 35\text{kg m}^{-2}$ and able to give consent. Exclusion criteria included the presence of any features of difficult airway which are Class III and IV on the Modified Mallampati Classification, thyromental distance < 6.5 cm, mouth opening < 3.5 cm, sterno-mental distance < 12.5 cm, history of difficult intubation and/or unstable cervical spine.^(15,16) For safety reasons, we

excluded patients with signs of difficult airway as the PAPR and the random allocation of laryngoscope may make intubation more difficult.

All intubations were performed by experienced specialist anaesthetists who had performed more than 20 successful intubations with the devices being tested.

A research coordinator randomised the patients, using block sizes of 4, to either McGrath^(TM) VL or DL using Research Randomizer (www.randomizer.org) and concealed the study-group assignments. On the day of surgery, the group allocation was revealed to a study team member who was facilitating the study and the attending anaesthetist.

We chose the McGrath^(TM) VL over other VLs because the McGrath^(TM) VL is more portable, compact and has a smaller exposed surface for decontamination. Its laryngeal blades are disposable. In our institution, it is more readily available than other screen-mounted VLs.

In our institution, staff participating in aerosol-generating procedures for COVID-19 patients can don a PAPR in addition to a N95 mask.⁽¹⁷⁾ This is because N95 masks alone may not fully protect staff during intubation^(18,19) and N95 masks can increase the PAPR protection factor.⁽²⁰⁾ To simulate intubation of COVID-19 patients, the anaesthetist donned a PAPR (3M^(TM) Jupiter^(TM) Powered Air Turbo Unit, Saint Paul, Minnesota, United States) with a N95 mask, fluid resistant gown and gloves. A video camera was set up to record the intubation process with a calibration ruler so that the video record could be played back for measurement of the intubation duration and the closest distance between the patient's and anaesthetist's mouths (Fig. 1). The video-recording set-up was similar to a previous study.⁽²¹⁾ Orotracheal intubation was performed in both groups according to the following protocol:

1. The anaesthetist pre-oxygenated the patient until end-tidal oxygen concentration reached at least 85% or more.⁽⁴⁾

2. The anaesthetist performed rapid sequence induction to avoid the need for bag-mask ventilation⁽⁵⁾ and resultant aerosolisation.⁽²²⁾ The anaesthetist decided on the choice and dose of induction agents. We standardised the dose of intravenous succinylcholine at 1.5mg/kg of the patient's total body weight.
3. The anaesthetist performed laryngoscopy using the randomly-allocated device after disappearance of muscle fasciculations. The anaesthetist could choose the blade size (Macintosh blade 3 or 4) according to personal judgement. We informed the anaesthetist to avoid the use of adjuncts (bougie, stylet, external laryngeal pressure) and hyperangulated blades at the first intubation attempt if possible, as we were assessing the actual difficulty of intubation using the randomly-allocated laryngoscope. Using these adjuncts at the first attempt may mask the intubation difficulty. We recorded the use of these adjuncts as secondary outcomes to indicate intubation difficulty.
4. After tracheal intubation, the tracheal tube cuff was inflated by the anaesthetic assistant and the anaesthetist ventilated the patient manually. Tracheal tube position was confirmed by visualisation of square end-tidal carbon dioxide waveforms.
5. In the event of intubation failure, the anaesthetist chose his/her own method to re-attempt intubation.

The study team member who facilitated the set-up in the operating theatre interviewed the attending anaesthetist to find out the required lifting force on the laryngoscope, glottic view on first attempt and position of the vocal cords during laryngoscopy. Three study team members reviewed the recorded video of the intubation process to determine the number of laryngoscopic attempts (defined as one insertion of the laryngoscope into the oral cavity), number of supplementary attempts (defined as one advancement of the tube in the direction of the glottis),

number of supplementary operators, use of alternative techniques and the closest distance between the anaesthetist's and patient's mouths during intubation. The three study team members resolved any disagreement by reviewing the video clips together to arrive at a consensus.

The primary outcome was time to successful tracheal intubation, which was measured from the time the anaesthetist took over the laryngoscope from the assistant to the time a capnography waveform first appeared.

The secondary outcomes were the closest distance between the anaesthetist and the patient, intubation difficulty scale (IDS) scores,⁽²³⁾ proportion of successful intubation at first laryngoscopic attempt, use of adjuncts (bougie, stylet and/or external laryngeal pressure), proportion of adverse events (oxygen desaturation to less than 88% and/or oro-dental injuries), and inability to intubate (unable to pass the tracheal tube between the vocal cords). The IDS score is the sum of 7 variables which are numbers of supplementary attempts, supplementary operators, alternative techniques, glottic exposure, lifting force during laryngoscopy, necessity of applied external laryngeal pressure and position of vocal cords. The difficulty of intubation increases from a score of 0 (easy intubation) to infinity (impossible intubation).

An a priori power analysis to determine sample size was based on a previous simulation study which showed that the median (interquartile range, IQR) time to complete tracheal intubation on a manikin while wearing a hooded PPE was 18.2 (15.1-22.1) seconds with videolaryngoscope, compared to 26.4 (23.1-35.2) seconds for DL.⁽²⁴⁾ For a normal distribution, the IQR which covers the middle 50% of the whole distribution is approximately equal to mean \pm 0.6 standard deviation (SD), or equivalently 1.2 SD. If time to complete intubation is normally distributed, the SD for suited VL and suited DL are approximately 5.8 and 10.1 seconds, respectively. To be conservative, the larger SD of 10.1 seconds for suited DL is used. Moreover, the distribution of time to complete

intubation is unlikely normal but skewed, an inflated SD is assumed to compensate for the violation of normal distribution. Hence, a SD of 18 seconds is used.

The minimal clinically important difference (MCID) for time to complete intubation in comparing different laryngoscopes is not defined in the literature.⁽²⁵⁾ MCIDs ranging between 10⁽²⁶⁾ and 20^(27,28) seconds to compare intubation times using different laryngoscopes have been used. In our study, we assumed a MCID of 20 seconds because we were simulating tracheal intubations of severely-ill COVID-19 patients. These patients would have failed non-invasive ventilatory support with oxygen saturations $< 94\%$ ⁽²⁹⁾ and are at high risk of oxygen desaturation during intubation.⁽⁹⁾ A difference of 20 seconds in the time to intubation will have a significant impact on their oxygen saturations and potentially clinical outcomes.

Therefore, to detect a difference of at least 20 seconds between the suited DL and suited VL groups, targeting a power of 80% and a 2-sided type I error of 5%, a sample size of 14 patients was required for each group (i.e. a total of 28 patients for the study).

Median values with IQRs and mean values with SDs were reported for continuous variables. Frequencies together with proportions were reported for categorical data. Mann-Whitney U test was performed to compare the time to intubation and IDS scores. Student T-test was used to compare the closest distance between the patient and anaesthetist. Fisher's exact test was performed to compare the proportions of successful intubation at first laryngoscopic attempt and the use of adjuncts between the two groups. Univariable linear regression (mixed model) was carried out to evaluate the effects of potential factors (BMI, years of experience as specialist anaesthetists and prior intubations in PAPR) on time to intubation. All analyses were done by StataCorp. 2019 (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC).

RESULTS

We assessed 40 patients for eligibility and 28 patients were randomised (Fig. 2). Baseline characteristics of the 28 patients are shown in Table I. Follow-up and analysis were completed for all 28 patients. 17 anaesthetists were recruited for the study.

There was no statistically significant difference in the median [IQR] time to intubation (VL: 61 [37-63] s; DL 41.5 [37-56] s, $p=0.35$). There was an attempt with DL that took 160s because of 2 oesophageal intubations before an eventual successful tracheal intubation. The closest mean [SD] distance between the anaesthetist and the patient during intubation was significantly further for McGrath^(TM) VL compared to DL (VL: 21.6 [4.8] cm; DL: 17.6 [5.3] cm, $p=0.045$). There were no significant differences in the median [IQR] IDS scores (VL: 4 [2-6]; DL: 2.5 [1-3], $p=0.13$), proportion of successful intubation at first laryngoscopic attempt (VL: 14/14 [100%]; DL: 13/14 [92.9%], $p=1.00$) and proportion of intubations requiring adjuncts (VL: 9/14 [64.3%]; DL: 10/14 [71.4%], $p=1.00$) between McGrath^(TM) VL and DL (Table II). All patients were successfully intubated with the initial laryngoscopes that they were assigned to. Only Macintosh blades were used. There was no adverse event (oxygen desaturation to less than 88% and/or orodental injuries).

Univariable mixed model regression did not show any significant effect of BMI (coefficient 2.08, 95% CI -0.44 to 4.6, $p=0.14$), number of years of experience as specialist anaesthetist (coefficient -0.47, 95% CI -1.46 to 0.52, $p=0.37$) or number of prior intubations performed in PAPR (coefficient 1.23, 95% CI -0.27 to 2.72, $p=0.14$) on the time to intubation.

DISCUSSION

Our trial showed that there was no significant difference in the time to tracheal intubation between McGrath(™) VL and DL when attempted by specialist anaesthetists, who were donned in hooded PAPR and N95 masks, on elective surgical patients with no sign of difficult airway.

This finding is similar to a Cochrane systematic review which compared VL against DL, inclusive of difficult airways, and stated that there is no evidence that VL affects time required for intubation under normal non-PAPR intubating conditions.⁽⁸⁾ Our study simulated intubating conditions similar to that for COVID-19 patients by requiring our anaesthetists to don PAPR and N95 masks during intubation. While we did not find a statistically significant difference with the set MCID at 20 seconds, there is a signal that direct laryngoscope may indeed be a quicker way to achieve tracheal intubation in the studied setting. This may be an important consideration in the clinical setting of critically COVID-19 patients in severe respiratory failure.

The median times to intubation in our study were longer than other studies on intubation performance in PAPRs and this may be due to the different definitions for intubation duration. For example, we defined the time to intubation from the time the operator grasped the laryngoscope to the first appearance of capnography waveform but the study by Shin et al⁽²⁴⁾ defined it as from the time the operator grasped the laryngoscope to visible chest rise on a manikin. Furthermore, our study was conducted on real elective surgical patients, instead of manikins, and thus our operators might have taken more care and time during the intubation. In addition, the PAPR was bulky which could have impeded the operator's movement and positioning. The protective plastic hood was also reflective and could have made it harder for the operator to visualise the larynx.

It is controversial whether distance protects the anaesthetist during intubation. An observational study on patients scheduled for elective surgery showed that aerosols were generated

during tracheal intubation and spread throughout the operating theatre⁽²²⁾ but another similar observational study did not show significant aerosol generation.⁽³⁰⁾ In our study, the mean closest distance between the anaesthetist and the patient during intubation was further for VL compared to DL. This statistically significant finding is similar to a manikin study which reported that the mean distance during intubation with VL on manikin was significantly further than with DL (35.6 vs 15.4 cm, $p < 0.0001$).⁽²¹⁾ The mean distance for intubation using VL in our study was shorter than that in the manikin study. This could be due to the anaesthetist being more careful with intubation of a patient, compared to a manikin, to minimise oro-dental injury. Another reason could be that the McGrath VL has a small (2.5 inch) low-resolution (240 x 320 pixels) integrated screen as compared to the APA™ Venner VL (Venner Medical, Jersey, UK) that was used in the manikin study which has a slightly larger (3.5 inch) with similar resolution (240 x 320 pixels). This might have resulted in the anaesthetists having to go closer to the screen for the McGrath VL compared to the APA Venner VL. The difference in mouth-to-mouth distances may have been greater if VLs with larger and higher resolution screens on separately-mounted stands, such as the C-MAC® (Karl Storz, Tuttlingen, Germany) (7 inch monitor with 1280 x 800 pixels) and Glidescope® (Verathon Inc, Bothell, USA) (6.4 inch monitor with 640 x 480 pixels), or VLs with integrated screens that have the option of cable connection to project the images onto separately-mounted stand, such as the APA Venner VL, were used.

VL has a higher median and wide IQR for IDS compared to DL. This could be explained by the fact that a higher proportion of intubations (7 out of 14 intubations) with VL required 3 or more supplemental attempts as compared to DL (2 out of 14 intubations). However, there was no statistically significant difference in the IDS scores. While this could imply that the specialist anaesthetists did not find any difference in the overall intubation difficulty between VL and DL

for patients with no sign of difficult airway, the statistical insignificance could also be due to small sample size as the study was not powered to detect IDS differences as the primary outcome.

Our findings suggest that even though current guidelines recommend VL for tracheal intubation of COVID-19 patients, this needs to be balanced against local constraints. VL may not be required if the patient does not have any sign of difficult airway and will be intubated by a specialist anaesthetist. In settings where resource is limited or where the global medical supply chain has been disrupted due to the pandemic,⁽³¹⁾ it may not be compulsory to attempt all intubations with VLs. Instead, clinicians should use the laryngoscopes which they are most comfortable with and are readily available.

Our univariate mixed model analysis showed that BMI, the number of years of experience as a specialist anaesthetist and number of prior intubations in PAPR have no significant effect on the time to intubation. A possible explanation could be that we restricted our patient selection to BMI <35 kg m⁻² to decrease the risk of having a difficult airway. We restricted our anaesthetists to specialist anaesthetists, which follows the recommended guidelines that intubations should be performed by the most experienced medical personnel.

To our knowledge, this is the only study on real patients comparing the time to intubation between VL and DL, performed by specialist anaesthetists who were donned in hooded PAPR. The use of video-recording allowed for repeated playback of the video clips for the accurate measurements of outcomes, especially for the time to intubation and the closest distance between the anaesthetist and the patient.

This study was not without limitations. Firstly, we were unable to blind the anaesthetists to the airway device being tested. Secondly, we would have preferred to limit the number of anaesthetists involved in the study to obtain a consistent perspective since some of our endpoints,

like lifting force required and quality of view obtained, are subjective. However, we were limited by our human resource and logistical arrangements during the current pandemic. Thirdly, we excluded patients with predictors of difficult airway for safety reasons mentioned earlier. Therefore, we were unable to determine if VL led to shorter intubation duration compared to DL for intubation in this group of patients. We were also unable to determine any difference in failed intubations between VL and DL as all our patients were successfully intubated with the laryngoscopes that they were randomized to. Differences in the percentages of failed intubations would be important because failed intubations would have compromised the patients' conditions and increased the risk of healthcare workers' exposure to infection. We chose not to conduct the study in confirmed COVID-19 patients because of perceived increased risk of hypoxia to critically-ill COVID-19 patients requiring intubation and mechanical ventilation, and risk of infection to study team members. Lastly, the intubations in our study were performed by specialist anaesthetists and thus the results may not be generalisable to less experienced operators.

As there was a lack of studies done on actual patients under similar settings comparing VL to DL with the operators donned in PAPR, we obtained our sample size calculation based on intubation timings from manikin studies. These timings had a smaller variance compared to what was observed in our study. Our study can therefore be used for sample size and power calculations for similar studies on patients in the future. We propose more randomised controlled trials comparing different types of VLs and DL for intubation by clinicians of varying levels of experience and in various clinical settings with varied resource availability. We also propose using different forms of PAPRs (hooded vs non-hooded), with and without N95 masks. As simulations for tracheal intubations in PAPR have been encouraged to promote operator familiarity,⁽³²⁾ we

could also conduct studies to determine the optimal amount of simulation exercises that are required to improve intubation performance.

This will allow future recommendations to be made about which laryngoscope to be used, taking into account the patient's condition, experience of the operator, and resource availability, should we be faced with another high-risk respiratory viral pandemic.

In conclusion, while VL is currently being advocated for intubation of COVID-19 patients, especially to decrease the risk of hypoxia during failed intubations, our study showed that there was no difference in the time to intubation between the McGrath^(TM) VL and DL. The intubations in our study were carried out by specialist anaesthetists and thus results may vary with less experienced operators. Although the McGrath^(TM) VL increased the distance of the anaesthetist from the patient during intubation, it is controversial whether significant aerosols are generated and whether being further away protects the anaesthetist during intubation. Even though we should adhere to guidelines wherever possible, it may not be feasible due to lack of access and supply chain disruptions. Under such circumstances, we should strive to validate equally efficacious and safe alternatives, such as considering DL as a comparable alternative to VL.

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Table 1. Patients and baseline characteristics of the 2 different groups.

| | Mean (SD)/Median (IQR)/Frequency (Proportion) | |
|---|---|----------------------------|
| | Videolaryngoscope (n=14) | Direct laryngoscope (n=14) |
| Age; years | 66(10.5) | 57.6(14.8) |
| Gender | | |
| Male | 9 (64.3%) | 9 (64.3%) |
| Female | 5 (35.7%) | 5 (35.7%) |
| Weight; kg | 65.2(12.5) | 64.6(16.2) |
| Height; m | 1.6(0.1) | 1.6(0.1) |
| BMI; kg m ⁻² | 24.5(4.2) | 23.4(3.7) |
| ASA status | | |
| I | 0 (0%) | 2 (14.3%) |
| II | 14 (100%) | 11 (78.6%) |
| III | 0 (0%) | 1 (7.10%) |
| Type of surgery | | |
| Gallbladder; appendix; adrenal; spleen | 3 (21.4%) | 2 (14.3%) |
| Intestinal | 6 (42.9%) | 5 (35.7%) |
| Obstetric; gynaecological | 1 (7.10%) | 0 (0%) |
| Urology | 0 (0%) | 2 (14.3%) |
| Orthopaedic and non-vascular extremity | 2 (14.3%) | 1 (7.10%) |
| Spine | 1 (7.10%) | 3 (21.4%) |
| Upper gastrointestinal; hepatopancreatobiliary | 0 (0%) | 1 (7.10%) |
| Complex | 1 (7.10%) | 0 (0%) |
| Experience of anaesthetist as specialist; years | 3.5 (3, 5) | 3 (2, 20) |
| Prior intubations in PAPR by anaesthetist | 2 (1, 15) | 1.5 (0, 3) |

Student's t-test was used for comparing age, weight, height and body mass index; Mann-Whitney test was used for comparing experience of anaesthetist as a specialist and prior intubations in powered air-purifying respirator; and Fisher's exact test was used for comparing gender, American Society of Anaesthesiologist status and type of surgery

Abbreviations: BMI: body mass index; ASA: American Society of Anaesthesiologists; PAPR: powered air purifying respirator

Table 2. Outcomes of patients in the videolaryngoscope and direct laryngoscope groups.

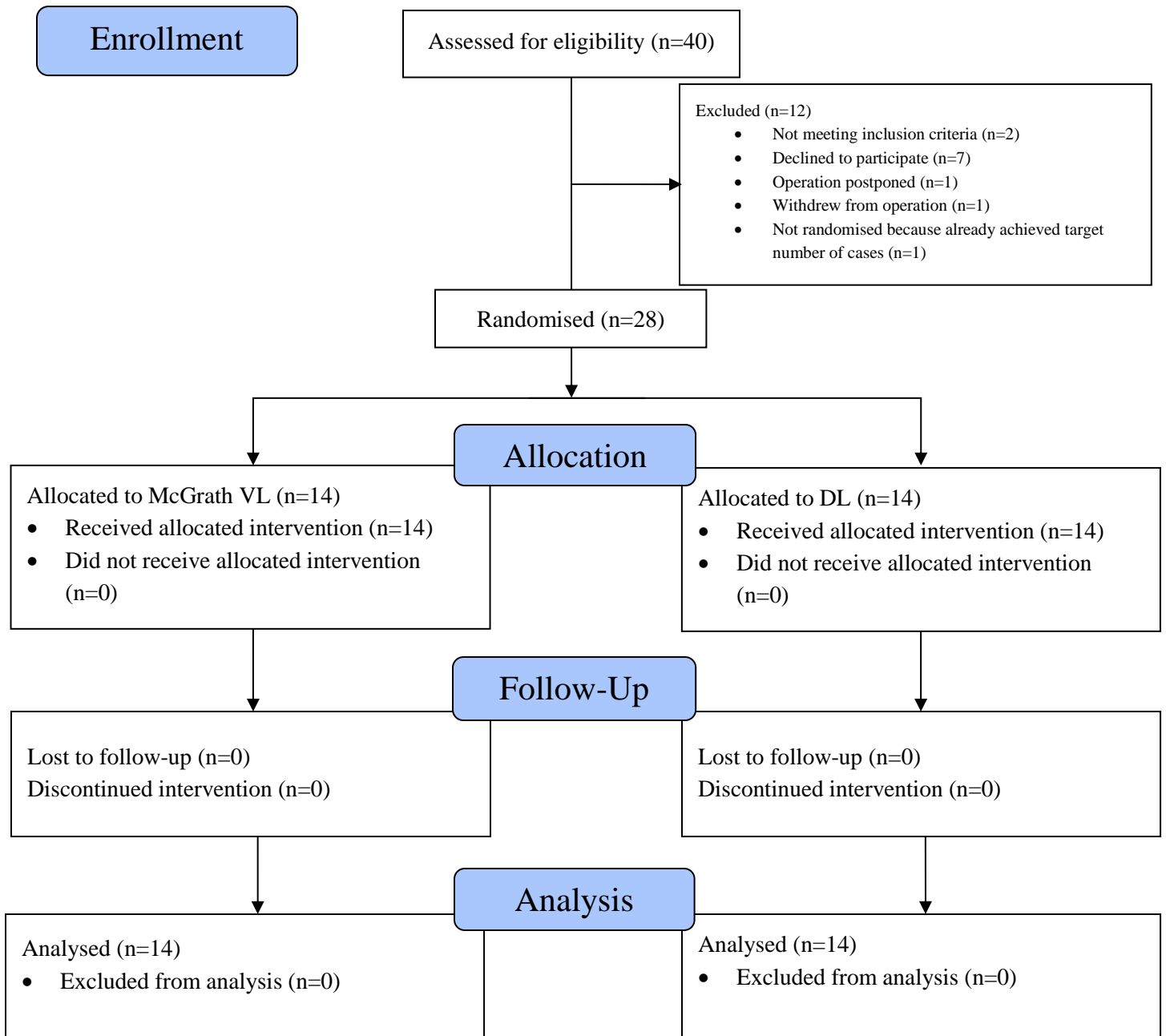
| | Mean (SD)/Median (IQR)/Frequency (Proportion) | | |
|---|--|-------------------------------|---------|
| | Videolaryngoscope (n=14) | Direct laryngoscope (n=14) | p value |
| Time to intubation; s | 61 (37-63) | 41.5 (37-56) | 0.35 |
| Distance; cm | 21.6 (SD 4.8) | 17.6 (SD 5.3) | 0.045 |
| IDS score | 4 (2-6) | 2.5 (1-3) | 0.13 |
| Intubation outcome at first laryngoscopic attempt | | | 1.00 |
| Success | 13 (92.9%) | 14 (100%) | |
| Fail | 1 (7.10%) | 0 (0%) | |
| Use of adjuncts (bougie, stylet and/or external laryngeal pressure) | | | 1.00 |
| Yes | 10 (71.4%) | 9 (64.3%) | |
| No | 4 (28.6%) | 5 (35.7%) | |

The Mann-Whitney U test was carried out to compare time to intubation and IDS scores. Student T-test was used to compare the closest distance between the patient and anaesthetist. Fisher's exact test was performed to compare the proportions of successful intubation at first laryngoscopic attempt and the use of adjuncts between the two groups.

Abbreviations: IDS: intubation difficulty scale



Fig. 1. Set-up of video-recording in the operating theatre showing the anaesthetist intubating a patient in a powered air-purifying respirator (PAPR).



VL: videolaryngoscope; DL: direct laryngoscope

Fig. 2. CONSORT diagram of patient recruitment.