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Comparison of direct and indirect images and hemodynamic response of two different video laryngoscopes to tracheal intubation

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Abstract

Aims The aim of this study was to compare the effects of two different videolaryngoscopes (VLs) on direct (through the mouth) and indirect (screen images) laryngoscopy and to evaluate their effects on hemodynamic response.

Settings and design A total of 70 patients between the ages of 18 and 65 years with ASA I-III physical status, planned for general anesthesia, with an expected difficult airway, were included in the study. Patients were enrolled in the study between 02/ 2022 and 06/ 2022. Patients were randomly divided into two groups. McGrath video laryngoscope was used in Group MC and Hugemed video laryngoscope was used in Group H. Modified Cormack Lehane and POGO scores (Percentage of glottic opening) of all patients on direct and indirect laryngoscopy were evaluated and recorded and then orotracheal intubation was performed. Demographic data, ASA status, Mallampati classification, thyromental distances and mouth opening were recorded. Standard monitoring was applied to all patients. During intubation, endotracheal intubation time, number of attempts, intubation-related complications and sore throat were recorded. Hemodynamic parameters (mean arterial pressure, peripheral oxygen saturation values) were recorded before, after induction and after intubation.

Results There was no difference between the groups in terms of descriptive characteristics ($p > 0.05$). When direct and indirect POGO scores were compared in group MC, no difference was found between the patients ($p > 0.05$). When direct and indirect POGO scores were compared, no difference was found between patients in Group H ($p > 0.05$). The mean POGO VL indirect score of Group H patients was found to be significantly higher than that of Group MC ($p < 0.035$). Both VLs showed similar results in terms of intubation time, number of attempts and hemodynamic findings.

Conclusions McGrath and Hugemed videolaryngoscopes provide a good laryngeal view with similar Cormack Lehane scores during non-difficult endotracheal intubation and facilitate successful intubation by maintaining hemodynamic stability. It was observed that the Hugemed VL had a better indirect POGO score, but the images provided by the blades of both VLs on direct laryngoscopy allowed intubation.

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Keywords Airway management, Video laryngoscopy, Intubation

Introduction

Videolaryngoscopy (VL) is a frequently employed method in the field of airway management, with the objective of enhancing the efficacy of tracheal intubation. Video laryngoscopes are equipped with a miniature video camera at the tip of the blades, which enables indirect visualization of the glottis [1–3].

The American Society of Anaesthesiologists (ASA) recommends the availability and utilization of a VL for all patients presenting with a particularly challenging airway, for whom tracheal intubation is planned [4].

In their guidelines for difficult airway management, the Spanish Society of Anesthesiology, Reanimation and Pain Management (SEDAR), the Spanish Society of Emergency and Emergency Medicine (SEMES) and the Spanish Society of Otolaryngology, Head and Neck Surgery (SEORL-CCC) recommend the use of VL as first choice instead of direct laryngoscopy (DL) [5].

Most meta-analyses, despite their heterogeneity, suggest the superiority of VL over DL [6, 7]. Overall, VL compared to DL increases first-attempt success, improves glottis visualization, and reduces the incidence of complications mainly trauma and esophageal intubation by up to 50% [8–11]. VL has been shown to be superior to DL for glottic visualization, especially in difficult airway cases [12–14].

Notwithstanding the aforementioned advantages, the most significant criticism levied against VLs pertains to the issue of fogging. Furthermore, contact between the video camera and secretions within the oral cavity during intubation may result in image distortion, particularly in instances of repeated attempts. Poor visualization can lead to an increase in the number and duration of procedures and in some cases direct laryngoscopy may be required. In this case, the VL can also be used as a direct laryngoscope.

Standard Macintosh blade devices (allowing both direct and indirect laryngoscopy) are appropriate for managing the airway without predictors of difficulty, while hyper angulated blade devices (with or without a guiding channel) are indicated for known or anticipated difficult airway [5].

Although there are many studies comparing VLs, there are not enough studies comparing direct laryngoscopic images of VLs.

McGrath videolaryngoscopes comprise a direct video laryngoscope, a battery-contained handle, and a disposable plastic blade in a single device, and anesthesiologists can perform intubation using a McGrath

videolaryngoscope in patients with either normal or difficult airways [15]. The Hugemed videolaryngoscope is equipped with a reusable Macintosh blade [16].

The aim of this study was to compare the images of two different VLs with Macintosh blades (McGrath videolaryngoscope and Hugemed videolaryngoscope) in both indirect and direct laryngoscopy and their effects on the hemodynamic response.

The main aim of this study was to compare two different VLs during direct and indirect laryngoscopy in patients without a difficult airway. The secondary aim is to compare their effects on hemodynamic response.

Subjects and methods

This prospective, randomized study was conducted in the University of Health Sciences, Kartal Dr Lütfi Kırdar City hospital from after approval from the Institutional Ethics Committee (2018/ 514/124/9). Patients were enrolled in the study between 02/ 2022 and 06/ 2022.

After written informed consent was obtained from each patient, 70 American Society of Anesthesiologists (ASA) physical status class I-III patients aged 18 to 65 years who were scheduled for endotracheal intubation for elective surgery and who were not expected to have difficult airway were included in the study.

The patients were one-to-one randomized into two groups: the MC and H group, using the method of drawing lots from an envelope with an equal number of papers on which the group is indicated.

The following patients were excluded from the study: those for whom consent was not obtained, those with an American Society of Anesthesiologists (ASA) classification of IV or above, those with severe cardiac or respiratory problems, and those with an anticipated difficult airway.

All patients were premedicated intravenously with 0.03 mg/kg midazolam approximately 30 min prior to the induction of anesthesia. Prior to the surgical procedure, the standard monitoring protocol included a three-lead electrocardiogram (ECG) with continuous ST-segment analysis, as well as the evaluation of peripheral oxygen saturation (SpO₂) and intermittent non-invasive blood pressure.

Following three minutes of preoxygenation with 100% oxygen, general anesthesia was induced with propofol (3 mg/kg) a few minutes after a fentanyl (2 µg/kg) injection. Neuromuscular paralysis was achieved in all patients through the administration of rocuronium (0.6 mg/kg).



Fig. 1 McGrath video laryngoscope



Fig. 2 Hugemed video laryngoscope

Following the administration of general anesthesia, the McGrath video laryngoscope (MC) was utilized in patients belonging to Group MC. The McGrath videolaryngoscope exhibits comparable characteristics to the Macintosh laryngoscope (ML). McGrath video

laryngoscope is more lightweight than the Macintosh laryngoscope, free from condensation, constructed from optical polymer, equipped with a disposable transparent blade, and features an LCD screen mounted on the handle [15] (Fig. 1). The Modified Cormack Lehane score and Percentage of glottic opening (POGO) score on direct laryngoscopic images, as well as the Modified Cormack Lehane score and POGO score on indirect laryngoscopic images, were evaluated and documented. Subsequently, orotracheal intubation was conducted.

In Group H, a Hugemed videolaryngoscope (HG) was employed for orotracheal intubation, with the Modified Cormack Lehane and POGO scores documented from direct and indirect laryngoscopic images of the patients, respectively. Hugemed videolaryngoscope is equipped with a 3.5-inch high-definition screen situated on the upper portion of the handle. The screen is capable of rotation in multiple axes, including rightward, leftward, upward, and downward. The field of view of the camera at the tip of the blade is 60 degrees [16] (Fig. 2).

Modified cormack-lehane scoring system

- 1: The entire glottis is visible.
- 2 A: The glottis is partially visible.
- 2B: Only the arytenoids are visible.
- 3: Only the epiglottis is visible.
- 4: The epiglottis is also not visible [17].

POGO classification

A POGO grading of 100% was indicative of complete patency of the glottis, extending from the anterior commissure to the posterior cartilage. The absence of glottic patency was assigned a value of zero [18].

Data collection

Age, gender, body weight, Mallampati score, mouth opening, thyromental distance, American Society of Anaesthesiologists (ASA) physical status classification and the duration intubation were recorded. The intubation time was defined as the period from the initiation of laryngoscopy to the administration of endotracheal intubation and the detection of end-tidal carbon dioxide (EtCO₂).

Furthermore, the following parameters were recorded before and after the induction of anaesthesia and after intubation: systolic arterial pressure (SAP), diastolic arterial pressure (DAP), mean arterial pressure (MAP), heart rate (HR), peripheral oxygen saturation (SpO₂) and end-tidal carbon dioxide (EtCO₂) concentration.

In all patients, both modified Cormack-Lehane scores and POGO scores were recorded, using both indirect (screen images) and direct (through the mouth) laryngoscopy.

Table 1 A comparison of the groups in terms of their descriptive characteristics

| | | Group H(n=35) | Group MC (n=35) | t | p |
|----------------------|--------|------------------|--------------------|----------------|-------|
| Age (Mean ± SD) | | 45,51 ± 13,16 | 44,14 ± 14,23 | 0,422 | 0,674 |
| | | % (n) | % (n) | X ² | P |
| Gender | Female | 71,4 (25) | 58,3 (20) | 1,334 | 0,248 |
| | Male | 28,6 (10) | 41,7 (15) | | |
| ASA | 1 | 25,7 (9) | 25 (9) | 0,006 | 0,997 |
| | 2 | 71,4 (25) | 72,2(25) | | |
| | 3 | 2,9 (1) | 2,8 (1) | | |
| Mallampati score | 1 | 45,7 (16) | 55,6 (20) | 1,463 | 0,481 |
| | 2 | 45,7 (16) | 41,7 (14) | | |
| | 3 | 8,6 (3) | 2,8 (1) | | |
| Thyromental distance | 5 | 2,9 (1) | 2,8 (1) | 0,595 | 0,897 |
| | 6 | 22,9 (8) | 22,2 (8) | | |
| | 7 | 57,1 (20) | 63,9 (22) | | |
| Mouth opening | 8 | 17,1 (6) | 11,1 (4) | 6,187 | 0,103 |
| | 4 | 0 (0) | 11,1 (4) | | |
| | 4,5 | 5,7 (2) | 5,6 (2) | | |
| | 5 | 60 (21) | 66,7 (23) | | |
| Body mass index | 6 | 34,3 (12) | 16,7 (6) | -0,309 | 0,758 |
| | | 27,17 ± 5,14 | 27,56 ± 5,33 | | |

The number of intubation attempts, the incidence of intubation-related complications and the prevalence of sore throat were documented in both groups.

Statistical analysis

The statistical analyses were conducted using the SPSS version 25 statistical software package. Descriptive statistical methods, including the calculation of mean, frequency, percentage, minimum, and maximum, were employed to summarize the data. The Shapiro-Wilk test was employed for the purpose of conducting normality tests on continuous variables. In the investigation of the differences between two groups, a t-test was employed for continuous variables exhibiting normal distribution, whereas a Mann-Whitney U Test was utilized for the comparison of non-normally distributed data. In the event that the variables obtained from the same subjects exhibited normality, the dependent sample was subjected to a paired test. Conversely, if normality was not provided, the Wilcoxon signed-rank test was employed.

Sample size: The significance level was 0.05 in the GPower program; when 80% power and effect size d0.8 were taken, it was calculated that there should be 54 patients out of 27. A total of 70 patients were included and the power was close to 90%.

Table 2 Comparison of Direct and Indirect Modified Cormack Lehane scores between groups

| | | Group H (n=35) | Group MC (n=35) | X ² | P |
|----------------------------------|--|----------------------|-----------------------|----------------|-------|
| | | % (n) | % (n) | | |
| Modified Cormack Lehane indirect | The entire glottis is visible (1) | 57,1 (20) | 80,6 (28) | 5,111 | 0,164 |
| | The glottis is partially visible (2a) | 31,4 (12) | 16,7 (6) | | |
| | Only the arytenoids are visible (2b) | 8,6 (3) | 2,8 (1) | | |
| | Only the epiglottis is visible (3) | 0 | 0 | | |
| Modified Cormack Lehane direct | The epiglottis is also not visible (4) | 0 (0) | 0 (0) | 4,948 | 0,293 |
| | The entire glottis is visible (1) | 2,9 (1) | 2,8 (1) | | |
| | The glottis is partially visible (2a) | 5,7 (2) | 16,7 (6) | | |
| | Only the arytenoids are visible (2b) | 37,1 (13) | 16,7 (6) | | |
| | Only the epiglottis is visible (3) | 25,7 (9) | 30,6 (10) | | |
| | The epiglottis is also not visible (4) | 28,6 (10) | 54,5 (12) | | |

Results

A total of 70 patients were included in the study, of whom 25 were male and 45 were female. McGrath VL (MC) was performed in 35 patients, while Hugemed VL (H) was performed in 35 patients.

All patients completed the study, and the data were comparable across all variables, including age, gender, body mass index, ASA classification, Mallampati score, thyromental distance, and mouth opening. No statistically significant differences were observed between the groups with regard to the descriptive data ($p > 0.05$) (Table 1).

A direct and indirect comparison of Modified Cormack-Lehane scores in Group MC, utilizing the McGrath videolaryngoscope, and in Group H, employing the Hugemed videolaryngoscope, revealed no statistically significant difference between the two groups ($p > 0.05$) (Table 2).

When direct and indirect POGO scores were compared in group MC, no difference was found between the patients ($p > 0.05$).

When direct and indirect POGO scores were compared, no difference was found between patients in Group H ($p > 0.05$).

In the intergroup comparison, the mean POGO VL indirect score of Group H patients was found to be significantly higher than that of Group MC ($p < 0.05$) (Table 3).

Table 3 A comparison of POGO scores between groups

| | Group H | Group MC | t | P |
|---------------|-------------------|------------------|--------|-------|
| | Mean \pm SD | Mean \pm SD | | |
| POGO indirect | 97,78 \pm 6,8 | 89,43 \pm 24 | -2,006 | 0,049 |
| POGO direct | 30,83 \pm 33,58 | 32,57 \pm 33,6 | 0,218 | 0,828 |

Table 4 A comparison of hemodynamic parameters within groups

| Group MC | | Difference of means | Pvalue |
|-----------------------|-----------------------|---------------------|--------------------|
| After induction SAP | Before induction SAP | 9,000 | 0,000 ² |
| After induction DAP | Before induction DAP | -6,143 | 0,006 ² |
| After induction MAP | Before induction MAP | -13,543 | 0,000 ¹ |
| After induction HR | Before induction HR | -0,371 | 0,897 ¹ |
| After induction SpO2 | Before induction SpO2 | 0,514 | 0,085 ² |
| After intubation SAP | Before induction SAP | 52,229 | 0,007 ² |
| After intubation SAP | After induction SAP | -14,314 | 0,001 ² |
| After intubation DAP | Before induction DAP | 4,914 | 0,048 ¹ |
| After intubation DAP | After induction DAP | 11,057 | 0,000 ¹ |
| After intubation MAP | Before induction MAP | -2,457 | 0,409 ¹ |
| After intubation MAP | After induction MAP | 11,086 | 0,001 ¹ |
| After intubation HR | Before induction HR | 5,857 | 0,006 ¹ |
| After intubation HR | After induction HR | 6,229 | 0,008 ¹ |
| After intubation SpO2 | Before inductionSpO2 | 0,486 | 0,187 ² |
| After intubation SpO2 | After induction SpO2 | -0,029 | 0,739 ² |
| Group H | | Difference of means | P value |
| After induction SAP | Before induction SAP | -17,33 | 0,000 ¹ |
| After induction DAP | Before induction DAP | -7,17 | 0,003 ¹ |
| After induction MAP | Before induction MAP | -12,97 | 0,001 ² |
| After induction HR | Before induction HR | 6,61 | 0,004 ¹ |
| After induction SpO2 | Before induction SpO2 | -23,83 | 0,006 ² |
| After intubation SAP | Before induction SAP | 1,750 | 0,560 ¹ |
| After intubation SAP | After induction SAP | 19,083 | 0,000 ¹ |
| After intubation DAP | Before induction DAP | 6,389 | 0,010 ¹ |
| After intubation DAP | After induction DAP | 13,556 | 0,000 ¹ |
| After intubation MAP | Before induction MAP | 2,222 | 0,203 ² |
| After intubation MAP | After induction MAP | 15,194 | 0,000 ² |
| After intubation HR | Before induction HR | 11,222 | 0,000 ¹ |
| After intubation HR | After induction HR | 4,611 | 0,036 ¹ |
| After intubation SpO2 | Before inductionSpO2 | -23,694 | 0,025 ² |
| After intubation SpO2 | After induction SpO2 | 0,139 | 0,132 ² |

1 Paired t-test 2 Wilcoxon Signed Ranks

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Table 4 presents the results of the significance test between the pre-induction SAP, DAP, MAP, HR and SpO2 values obtained in Group MC and Group H and the corresponding post-induction values. The difference between SAP, DAP, MAP, HR, SPO2 values before induction and SAP, DAP, MAP, HR, SPO2 values after induction in both group MC and group H was statistically significant ($p < 0.05$). When SAP, DAP, MAP, HR, SPO2 values obtained after intubation in Group MC were compared with SAP, DAP, MAP, HR and SPO2

Table 5 Comparison of hemodynamic data between groups

| | Group H | Group MC | P |
|------------------------|---------|----------|--------|
| Before induction SAP | 140,83 | 134,33 | 0,015* |
| After induction SAP | 149,83 | 117,00 | 0,016* |
| After intubation SAP | 135,51 | 136,08 | 0,822 |
| Before induction DAP | 83,29 | 82,19 | 0,641 |
| After induction DAP | 77,14 | 75,03 | 0,515 |
| After intubation DAP | 88,20 | 88,58 | 0,912 |
| Before induction MAP | 104,83 | 101,78 | 0,083 |
| After induction MAP | 91,29 | 88,81 | 0,461 |
| After intubation MAP | 102,37 | 104,00 | 0,605 |
| Before induction HR | 83,43 | 80,19 | 0,367 |
| After induction HR | 83,06 | 86,81 | 0,284 |
| After intubation HR | 89,29 | 91,42 | 0,540 |
| Before induction SpO2 | 99,23 | 123,14 | 0,174 |
| After induction SpO2 | 99,74 | 99,31 | 0,070 |
| After intubation SpO2 | 99,71 | 99,44 | 0,080 |
| After intubation ETCO2 | 36,14 | 38,28 | 0,750 |

values obtained before and after induction, the difference between them was statistically significant ($p < 0.05$).

In Group H, when SAP, DAP, MAP, HR, SPO2 values obtained after intubation were compared with SAP, DAP, MAP, HR and SPO2 values obtained before and after induction, the difference between them was found statistically significant ($p < 0.05$).

Comparison of hemodynamic parameters between the groups is presented in Table 5. Figure 3.

When a comparison was made between the groups, the difference between pre-induction SAP and post-induction SAP values was statistically significant ($p < 0.05$).

The intubation times for Group MC were 41.11 ± 31.99 s, while those for Group H were 58.67 ± 47.26 s. No significant difference was observed between the two groups ($p > 0.05$). The mean number of intubation attempts was 1.14 ± 0.3 in Group MC and 1.11 ± 0.3 in Group H, with no significant difference ($p > 0.05$). Upon questioning, two patients in Group MC and four patients in Group H reported experiencing a sore throat. Nevertheless, no significant difference was observed between the two groups in terms of the incidence of sore throat ($p > 0.05$).

Discussion

Tracheal intubation is a frequently employed procedure for the purpose of securing the airway in children and adults undergoing surgical procedures. In recent years, a number of videolaryngoscopes have been introduced, resulting in an increased success rate for intubation due to their enhanced glottic view. Many studies have been conducted to know the laryngoscopic view, ease of intubation, hemodynamic changes during laryngoscopy and intubation, and associated complications with the evolution of the various type of laryngoscope.

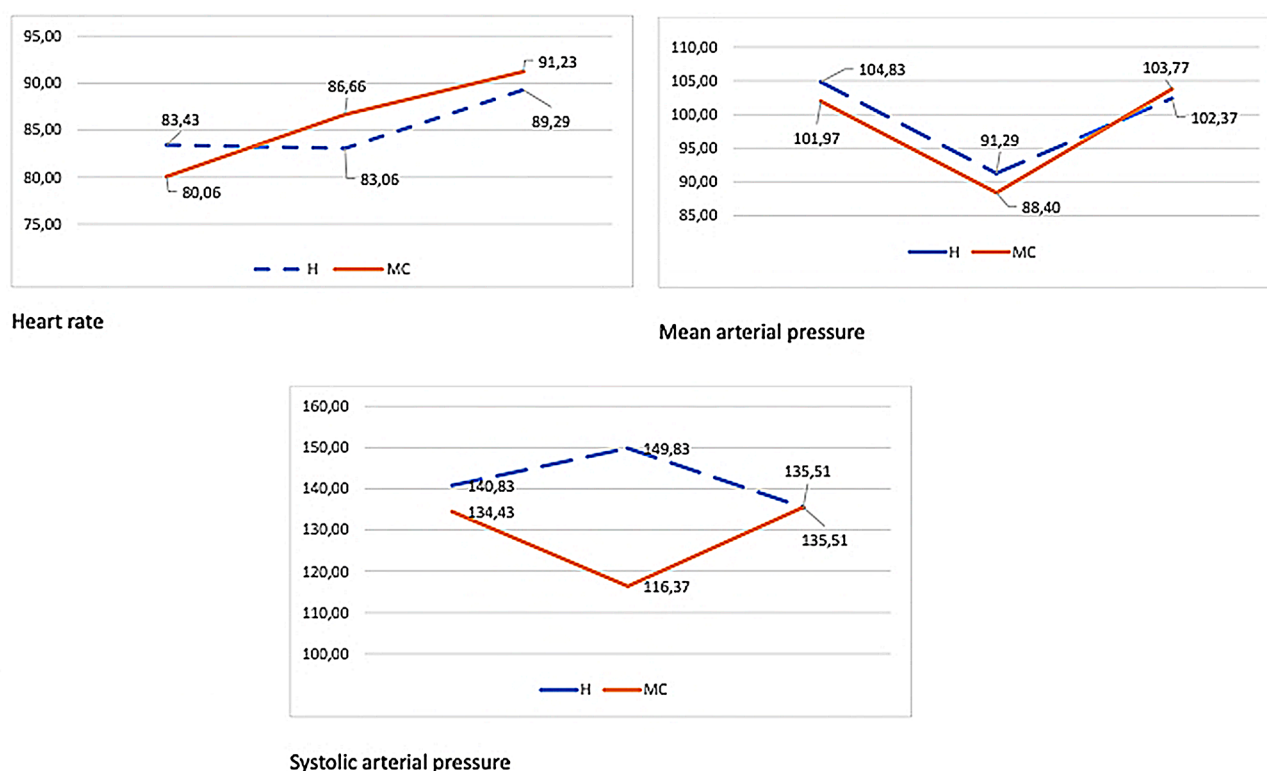


Fig. 3 ...

In this study, McGrath VL and Hugmed VL were compared in terms of laryngoscopic appearance and hemodynamic changes. This study revealed that the Hugmed VL performed better in relation to the POGO score compared to the McGrath VL.

A meta-analysis of 61 studies comprising 9,883 participants revealed that Macintosh-style laryngoscopy (MSL) reduced the incidence of failed intubation and hypoxemia while increasing the success rate of the initial intubation attempt compared to direct laryngoscopy (DL). The researchers concluded that for adults undergoing tracheal intubation, VLs provide a safer risk profile compared to direct laryngoscopy, reduce failed intubation rates, and have a higher successful intubation rate in the first attempt with better glottic views [19].

In this study, the mean of POGO score in Group H was 97.78% and in Group MC, it was 89.43% ($P < 0.05$). Better the POGO score, higher is the glottic view and lesser will be the failed intubation. The arrangements of the high-definition optical fiber in Hugmed VL gives a high quality, less fogging and wide-angle view of the glottis, the surrounding structures, and the tip of the endotracheal tube.

The number of intubation attempts was found to be similar in both the MC (1.14 ± 0.3) and H (1.11 ± 0.3) groups ($p > 0.05$), with all patients successfully intubated. The oxygen saturation was well maintained in both the

groups during laryngoscopy. This finding was supported by a prospective, randomized controlled study, Chun et al. employed McGrath VL to examine a simulated difficult airway. This was achieved by using collar to restrict neck movements and mouth opening in a group of 64 patients. In this study, which examined the ease of intubation, the necessity for optimization maneuvers and intubation time, the researchers reported that McGrath VL enhanced the quality of the laryngeal image in the group that had undergone a simulated difficult airway procedure [20].

A meta-analysis of numerous randomized controlled trials has demonstrated that VLs result in enhanced laryngeal appearance, an elevated rate of successful intubation, and a greater proportion of successful intubation on the initial attempt, while simultaneously reducing the necessity for optimization maneuvers [21–24].

The mean time for laryngeal intubation was less in Group MC (41.11 s) as compared to that of Group H (58.67 s, $P > 0.05$) but is not statistically significant. This may be because our anesthesiologist was familiar with both VLs and a significant difference was obtained in a larger number of patients. This result is supported by the results of study conducted by Sahoo et al. [25].

Both VLs enabled the attainment of optimal glottic visual visualization. There was no statistically significant difference between Group H and Group MC in Modified

Cormack-Lehane scores. Nevertheless, it was noted that the Hugemed VL yielded a favorable MCL score, with a proportionately higher Modified Cormack Lehane score 2B on direct laryngoscopic examination. McGrath and Hugemed VL with Macintosh blade can allow direct laryngoscopy.

This finding was supported by a Shine et al. The McGrath VL device provides a space for the placement of the tube in the mouth, particularly in pediatric patients. It's completely water-resistant screen and handle, disposable, transparent, thin blade structure facilitate this placement. The thin blade structure facilitates access while preventing contact with the teeth [26].

In their study comparing Macintosh blades with different types of VLs in patients with normal airways, Van Zundert et al. found that the use of a stylet was necessary in 10% of cases with the C-MAC, 76% with the McGrath and 60% with the Glidescope [27]. In the present study, a stylet was employed during intubation with both VLs.

The SAP in patients from both the groups were decreased in response to induction. This was statistically significant ($p < 0.05$). However, there was no significant difference at other time points ($p > 0.05$). These findings were comparable with other study. Sarklar et al. compared VL with DL in order to evaluate the hemodynamic response to tracheal intubation in patients undergoing major cardiac surgery. Despite the hemodynamic response being similar, the researchers found that VL resulted in a superior laryngeal image and a reduction in the number of intubation attempts [28].

The HRs and mean arterial pressure increased in response to laryngoscopy in patients in both groups, but no statistical differences were found in the between-group comparison. These findings were comparable with other study.

Yumul et al. [29] investigated the use of VL with a flexible fiberoptic device for intubation in patients with an immobilized cervical spine. The Cormack-Lehane

grade, POGO score, time required for successful intubation, number of attempts, necessity for additional airway devices, hemodynamic alterations, adverse effects and trauma to the airway were documented. It was reported that VL provided a superior view of the larynx and significantly reduced the time required for successful intubation.

The results of our study demonstrated no statistically significant difference between the Group MC and Group H in terms of hemodynamic findings.

Limitation

The intubating person could not be blinded, but the data analyzer was blinded regarding the video laryngoscope used.

We did not use TOF to confirm sufficient paralysis before intubation.

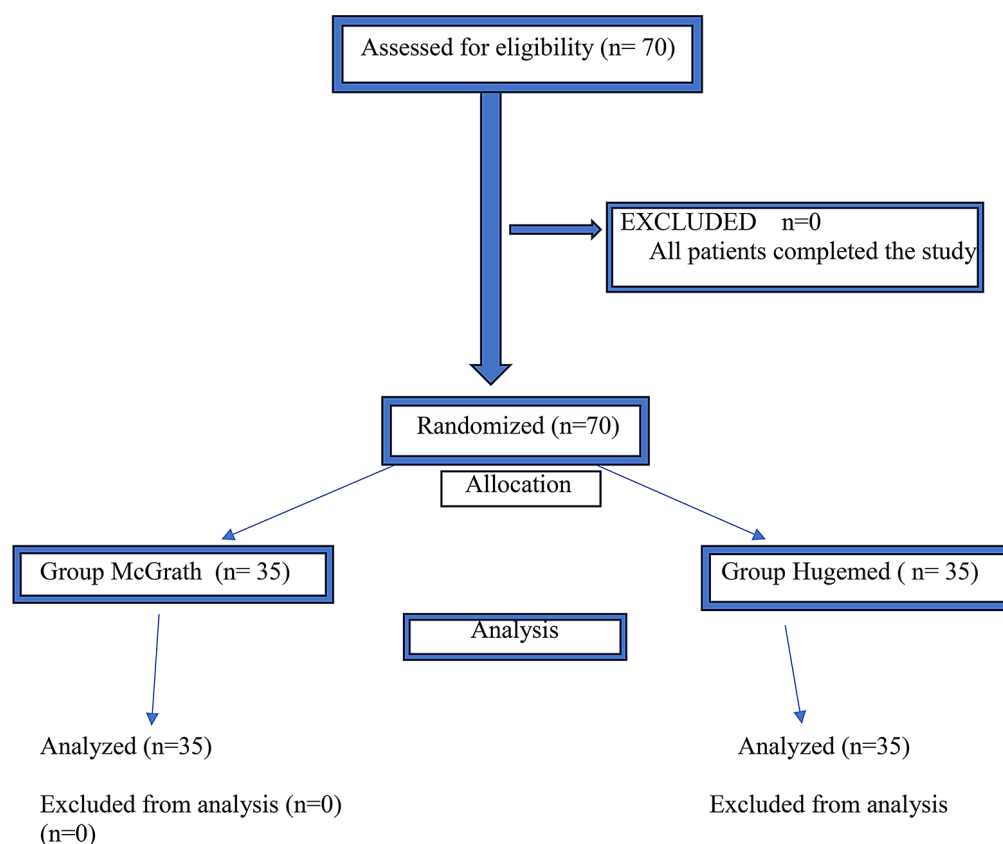
The observer was also the performing anesthesiologists and thus cannot be blinded to type of laryngoscope and the Cormack–Lehan score, POGO score, and ease of intubations were observer dependent. We also restricted difficult airway, and hence, the result may not extrapolate to the difficult airway patients.

Conclusion

In the present study, the indirect POGO score for Hugemed VL was found to be superior. This can be attributed to the larger screen size of the Hugemed VL.

McGrath VL and Hugemed VL have been shown to facilitate successful intubation with a good laryngeal view, similar hemodynamic response, with similar Cormack Lehane scores during non-difficult endotracheal intubation. It was observed that the images provided by the blades of both VLs on direct laryngoscopy allowed intubation.

Direct laryngoscopic intubation with both VLs can be performed when camera images are distorted due to fogging, secretions, etc.



The CONSORT flowchart of the study

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Author contributions

Conseption: KTS/ AS / ÖS/ GADesign: ÖS/ KTS/ AS/ TS/ GA. Supervision: KTS/ ASFindings: ÖS/ TŞ/ GA. Materials: ÖS/ TŞ/ GA/ AŞ. Data collection and/or processing: TŞ. Analysis and /or interpretation: AŞ/ AS/ TŞ/ ÖS. Literature review: ÖS/ TŞ/ GA/ AŞ. Writer: ÖS.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This prospective randomized controlled clinical trial was conducted after approval of the Kartal Dr. Lutfi Kirdar City Hospital Ethics Committee (decision no. 2018/514/124/9) and written informed consent of all the participants, according to the Good Clinical Practice guidelines and the principles of the Declaration of Helsinki.

Consent for publication

Not applicable.

Financial disclosure

There is no financial disclosure.

Competing interests

The authors declare no competing interests.

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