



The Efficacy of O-Mac[®], Patent Video Laryngoscope, and Conventional Laryngoscope for Intubation in the Operating Room

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Abstract

Edited by: Mirko Spiroski
Citation: Sepmiko J, Senapathi TGA, Wiryana M, Kurniyanta IP, Widnyana IMG, Sutawan IBKJ. The Efficacy of O-Mac[®], Patent Video Laryngoscope, and Conventional Laryngoscope for Intubation in the Operating Room. Open Access Maced J Med Sci. 2021 Aug 09; 9(B):646-650. https://doi.org/10.3889/oamjms.2021.6594
Keywords: Airway management; Conventional laryngoscope; O-Mac[®]; Mc-GRATH[™] video laryngoscope
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Received: 07-Jun-2021

Revised: 26-Jul-2021

Accepted: 29-Jul-2021

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Funding: This research did not receive any financial support
Competing Interests: The authors have declared that no competing interests exist

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BACKGROUND: Management of the airway in patients undergoing surgery is increasingly difficult. The airway management in the operating room in terms of the initial action of anesthesia is very important. Video-laryngoscopy has been shown to provide a better view of the larynx's structure compared to direct visualization.

AIM: We describe our experience using a custom made and inexpensive tool for a video-laryngoscopy.

METHODS: This is an experimental research with single randomized clinical trial conducted at the Anaesthesiology Department of Sanglah General Hospital Denpasar. There were 270 patients divides into three group with conventional, O-Mac[®] and Mc-GRATH[™] BF laryngoscope, aged 18–65 years old, with Mallampati grade 1–2, randomly selected, and signed informed consent.

RESULTS: Intubation time fastest with O-Mac[®] median 26 (15–36) s, $p = 0.000$. Laryngoscopy time fastest with O-Mac[®] median 5.5 (2–13 s), $p = 0.000$. O-Mac[®] does not use many tools, $p = 0.000$. All three did not produce tissue damage with results $p = 0.007$. Hemodynamic changes $p = 0.000$.

CONCLUSION: The O-Mac[®] is superior in terms of laryngoscope time and intubation time compared to the Mc-GRATH[™] BF blade and has the same level of safety as the patented Mc-GRATH[™] video laryngoscope, and better than conventional laryngoscopes.

Introduction

Management of the airway in patients undergoing surgery is increasingly difficult. One of the factors that make the management of the airway become difficult is excess fat around the neck. These patients will usually have limited neck mobility due to the obstructing accumulation of fatty tissue in the neck and hump of the patient.

The sophistication of equipment in the operative field has made operators more courageous to perform surgeries in the neck and its surrounding areas, so that airway management is increasingly demanded to be done immediately and anywhere.

Video-laryngoscopy is able to provide a better view of the larynx's structure compared to direct visualization. They have been shown to increase Cormack-Lehane (CL) levels in difficult laryngoscopy and improve intubation success [1]. Commercial video-laryngoscopes such as C-MAC (Karl Storz GmbH and Co., Tuttlingen, Germany), GlideScope (Verathon Medical Inc., Bothell, USA), Airtraq (Prodol Meditec,

Vizcaya, Spain), Ambu Pentax-AWS (Ambu A/S, Ballerup, Denmark), McGrath (Aircraft Medical Ltd., Edinburgh, UK), and King Vision laryngoscope (King systems, Noblesville, USA), are considered expensive hence not available in many centers [2]. We describe our experience of using a custom made and inexpensive tool (which costs under US \$80 - include complete laryngoscope set with three different sized Macintosh blades) that can be used to perform video-laryngoscopy. O-Mac[®] video laryngoscope has register number HKI. KI.05.01.02.P00202101656 and A00202100589 from industry design registration of Indonesia.

Complications during endotracheal intubation (ETI) and their association with the skill level of the intubating physician for 136 patient, the result of overall risk of complications was 39%, including: severe hypoxemia (19.1%), severe hypotension (9.6%), esophageal intubation (7.4%) and frank aspiration (5.9%) [3]. Airway management in trauma patients carries a very high risk; this finding has implications for the practice of airway management in injured patients [4]. In early 20th century, advance in anaesthesia made a laryngoscope and the skill in using it an important part of management airway [5], [6]. Video-laryngoscopy has added value for

the experienced anaesthetist, which contain miniature video-cameras improving first-time success, the view of the glottis and reducing mucosal trauma [7], [8].

Material and Methods

This study is a single randomized clinical trial conducted at the Anesthesiology Department of Sanglah General Hospital Denpasar. Health Research Ethical Clearance Committee of Sanglah General Hospital with protocol number: 1053/UN 14.2.2VII.14/LT/2021 released on April 8, 2021. There were 270 patients divide into three groups, conventional, O-Mac® and Mc-GRATH™ BF laryngoscope, aged 18–65 years old, both male and female, American Society of Anesthesiologists classification of 1–4, elective-emergency, either performed in the Central Operating Theatre/Emergency Room/Very Important Person Operating Theatre, in April 2021, randomly selected, to be involved in this study for video-laryngoscopy. This study is a prospective study. Mallampati grades of 1–2 were chosen. Difficult airway predictors, such as Mallampati and high Body Mass Index (BMI), were anticipated as difficult airways. Patients with prominent teeth, large tongue, tracheal malformation, history of difficult airway, and those who refused to be involved in the study were excluded from the study. Sampling was carried out using a non-probability consecutive sampling method with permutated block random sampling to obtain viable subjects. All patients included in this study and the laryngeal specialist will know the use of the instrument, before the study is carried out. There are 270 samples required.

All patients were prepared for intubation by performing pre-oxygenation for minutes using 100% oxygen, using the patient's spontaneous breathing. The induction was then performed with subsequent regimens: Fentanyl, as an analgesic agent, 2 mg/kilogram bodyweight (kg BW) intravenous (IV) by titration, and then waited for 5 min, followed by hypnotic agent administration Propofol 1.5 mg/kg BW IV by titration. If there is a decrease in Mean Arterial Pressure (MAP) and/or heart rate (HR) of more than 20%, a 10mg IV bolus of ephedrine was given. Immediately after the patient fell asleep by observing the eyelashes reflex, a skeletal muscle relaxant 0.5 mg/kg BW IV bolus of Atracurium was administered, followed by 4 min wait, and then followed by 1.5 mg/kg BW IV bolus of Lidocaine 2%, and then followed by 1-min wait to reach the onset of sympathetic response blunting. After that, the laryngoscopy process was carried out.

The determination of the laryngoscope's blade size was based on the length of the lips against the temporomandibular joint. This device was assembled by attaching a 5.5 millimeter (mm) diameter Wi-Fi-connected endoscopic camera (Shenzhen Technology



Figure 1: O-Mac® design section (a), O-Mac action (b), O-Mac® set (c)

Incorporation, China) to the Macintosh Laryngoscope blade sleeve to replace the bulb slot (Figure 1). The camera was installed approximately 50 mm from the tip of the laryngoscope blade by keeping the image recorded visible on the monitor screen using our tailor-made cable clamp mechanism. The videos are directly recorded on the smartphone, through Wi-Fi connectivity using the “Wi-Fi Check” software (Shenzhen Technology Incorporation).

The video was recorded in the MOV format during laryngoscopy and intubation, which were then reviewed for observation. The choice of the endotracheal tube was Polyvinyl Chloride endotracheal tube with an internal diameter (ID) of 7.5 or 7.0 mm in males and ID of 7.0 or 6.5 mm in females. The tube was used after general anesthesiology induction and muscle relaxant administration. The time needed for laryngoscopy was recorded, defined in second, taken from the time the laryngoscope blade passed the maxillary incisor to the glottis visualization. The time needed for intubation was recorded, which was defined as in seconds from the entry of the laryngoscope blade into the oral cavity through the maxillary incisors until the confirmation of the airway for ventilation. The best degree of CL is recorded before intubation was performed.

The POGO score, calculated by the writer based on the previously recorded video on the smartphone, was measured as the visualized linear glottic opening length, to obtain the best glottic view before intubation. Design of three laryngoscope is shown in Figure 2.



Figure 2: Design of laryngoscope (a); Conventional, (b); O-Mac®, (c); McGRATH™ MAC BF blade

Results

The sample of the study 270 subjects each group was 90 subjects in inclusion criteria using a non-probability-consecutive sampling technique. In this study, the overall data obtained were no sample dropout. The age characteristics were matched in the age range 18–65 years. Table 1 shown basic characteristics of research subjects and Table 2 result of Comparison results between conventional laryngoscope, patent video laryngoscope (McGRATH™ MAC BF blade) and O-Mac®.

Table 1: Basic characteristics of research subjects

Parameter	A Conventional laryngoscope n = 90	B (McGRATH™ MAC BF) n = 90	C O-Mac® n = 90
Age (years, median [minimum-maximum])	43 (18–65)	47 (18–65)	46 (18–65)
BMI kg/m ² (median [minimum-maximum])	23.2 (17.5–34.9)	22.85 (19–32)	22.3 (18.1–30)
Laryngoscope Time (seconds, median [minimum-maximum])	7 (1–40)	10 (1–60)	5.50 (2–13)
Intubation Time (seconds, median [minimum-maximum])	30 (20–90)	39.50 (30–95)	26 (15–36)
Cormack-Lehane degrees n (%)			
- Degree 1	31 (10.33)	28 (31.11)	43 (47.78)
- Degree 2	48 (53.33)	52 (57.78)	43 (47.78)
- Degree 3	11 (12.22)	10 (11.11)	4 (4.44)
POGO % median (minimum-maximum)	80 (20–100)	80 (20–100)	80 (40–100)
Use of tools/techniques for intubation aids n (%)			
- Not used	55 (61.11)	20 (22.22)	51 (56.67)
- Stylet	16 (17.78)	58 (64.44)	13 (14.44)
- ELM (Extra Laryngeal Maneuver)	14 (15.56)	5 (5.56)	2 (2.22)
- Magill Forceps	0 (0.00)	2 (2.22)	2 (2.22)
- Gum Elastic Boogie	0	1 (1.11)	0
- Magill Forceps and ELM	1 (1.11)	0	0
- ELM and Stylet	4 (4.44)	4 (4.44)	3 (3.33)
Total Attempted Intubation n (%)			
- 1 ×	84 (93.33)	72 (80.00)	84 (93.33)
- 2 ×	5 (5.55)	14 (15.56)	6 (6.67)
- 3 ×	1 (1.11)	4 (4.44)	0 (0.00)
Tissue Damage Due to Laryngoscope n (%)			
- No damage	89 (98.88)	82 (91.11)	89 (98.88)
- Airway bleeding	0	5 (5.55)	0
- Torn lips	1 (1.11)	1 (1.11)	1 (1.11)
- Glottic edema	0	1 (1.11)	0
- Broken teeth and airway bleeding	0	1 (1.11)	0
Successful Intubation	90 (100)	90 (100)	90 (100)
Delta MAP (% , median [minimum-maximum])	8 (0–60)	4 (0–42)	4 (0–8)
Delta HR ([%], median [minimum-maximum])	6 (0–44)	4 (0–21)	3 (0–9)

Discussion

In this study, the results showed that the intubation time with each of 90 subjects was obtained p = 0.000 with the fastest results facilitated by O-Mac® with a median of 26 (15–36) s while McGRATH™ MAC BF blades with a median of 39.50 (30–95) s with the slowest intubation time compared to conventional video laryngoscopes with a median of 30 (20–90) s. This is different from Luqman (2017) conventional laryngoscopes with McCoy mean ± SD (26.92 ± 5.03) s and conventional mean ± SD (40.64 ± 5.7), p < 0.001 [12]. Meanwhile, Karippacheril (2013), intubation time for patient 62 year old man with USB endoscopic camera need time 40s [13]. The commercial devices such as GlideScope: mean duration 13 (5–34) seconds

Table 2: Comparison results between conventional laryngoscope, patent video laryngoscope (McGRATH™ MAC BF blade) and O-Mac®

Parameter	Conventional laryngoscope n = 90	McGRATH™ MAC n = 90	O-Mac® n = 90	p*	Ratio (p) +
Age (years)	43 (18–65)	47 (18–65)	46 (18–65)	0.376	A B 0.335 C 0.180 B C 0.670
BMI (kg/m ²)	23.2 (17.5–34.9)	22.85 (19–32)	22.3 (18.1–30)	0.207	A B 0.739 C 0.213 B C 0.080
Laryngoscope time (s)	7 (1–40)	10 (1–60)	5.50 (2–13)	† 0.000	A B 0.052 C † 0.006 B C † 0.000
Intubation time (s)	30 (20–90)	39.50 (30–95)	26 (15–36)	† 0.000	A B † 0.000 C † 0.000 B C † 0.000
Cormack-Lehane degrees	1 (1–3)	2 (1–3)	2 (1–3)	0.024	A B 0.775 C 0.030 B C 0.011
POGO	80 (20–100)	80 (20–100)	80 (40–100)	0.048	A B 0.386 C 0.169 B C 0.011
Use of tools/techniques for intubation aids	0 (0–2)	1 (0–2)	0 (0–2)	† 0.000	A B † 0.000 C 0.655 B C † 0.000
Total Intubation Attempts	1 (1–3)	1 (1–3)	1 (1–2)	† 0.004	A B † 0.008 C 0.984 B C † 0.007
Tissue Damage Due to Laryngoscope	0 (0–1)	0 (0–2)	0 (0–1)	† 0.007	A B 0.018 C 1.000 B C 0.018
Delta MAP (%)	8 (0–60)	4 (0–42)	4 (0–8)	† 0.000	A B † 0.003 C † 0.000 B C 0.015
Delta HR. (%)	6 (0–44)	4 (0–21)	3 (0–9)	† 0.000	A B 0.014 C † 0.000 B C 0.103

Information: A: Conventional Laryngoscope, B: McGRATH™ MAC BF Blade, C: O-Mac®, * Kruskal-Wallis test, median (minimum-maximum), +Mann-Whitney, †significant

and C-MAC D-Blade: 11 (5–45) seconds. The time taken to intubation, averaging 24.48 ± 16.53 (5–65) seconds is also comparable with several studies of intubation time for GlideScope [10]. However, there is wide heterogeneity between the times obtained by the intubator [1]. On Vadhanan (2017) intubation time v-scope mean ± SD (77.25 ± 26.46 s) and intubation time miller mean ± SD (74.15 ± 26.3 s), p < 0.001 [14]. Hernandez (2020) with each sample of 15 subjects, it was known that VDL Hybrid 1.0 (GI) and Macintosh No. 3 shovels (GII) with median results of G1 27 (15–120) and GII 106 (18–120) s with p = 0.005 [15]. Bueggeney (2016) By comparing the C-Mac™ D-blade, GlideScope™, McGrath™, Airtraq™, AP Advance™, and KingVision™, the median intubation time was obtained, the results were 56 s (20–177), 60 s (17–180), 53 s (20–179), 47 s (18–179), 93 s (33–180), and 59 (31–180) with p < 0.01 This is because the tools used and the sample population are different [16].

In the O-Mac® study also looking at the relationship of intubation time with assistive tools/techniques, it was found that there was a positive linear relationship with r = 0.354 and p = 0.000. This shows that using tools/techniques to assist intubation, the required intubation time will be even longer. As for the tools/assistive techniques most widely used in this group is the use of stylet. Even without any indication of a difficult airway, it seems that due to the initial recognition of the device at the laryngoscopy, there is an incorrect indoctrination with the collection of testimonials by the laryngoscopes, that the use of Mc-GRATH™ requires embossed stylet. This explains why the intubation time required for each

laryngoscope group was significantly different, especially in the Mc-GRATH™ laryngoscope group.

In this study, the results showed that the laryngoscopy time obtained median laryngoscope time for conventional laryngoscopes of 7 (1–40) s, McGRATH™ MAC blades of BF 10 (1–60) s and O-Mac® were the most superior with a median time of 5.5. (2–13 s) with a result of $p = 0.000$. This is different from Brueggene (2016) with C-Mac™ D-blade, GlideScope™, McGrath™, Airtraq™, AP Advance™, and KingVision™ device the median laryngoscopy time was 17 (6–46) s, 19 (3–100) s, 18 (6–53) s, 20 (5–110) s, 30 (9–142) s, and 26 (7–117) s with $p < 0.01$. In Karippacheril's (2014) study using a video laryngoscope connected to a USB, the mean \pm SD (minimum-maximum) laryngoscope time was found to be 22.17 ± 12.78 (7–59) s [16]. On research, Vadhnan (2017) comparing Miller and V-scope obtained mean \pm SD laryngoscope times of 62.2 ± 25.1 and 62.2 ± 25.1 with $p = 0.25$ not significant [14]. This is because the tools used and the sample population are different, where the population average uses the Caucasian race which clearly has a greater BW than Southeast Asian races such as Indonesia. This may be a factor affecting this, although no statistical analysis was carried out between this study and other studies that have been carried out in Europe and America.

In the CL and POGO grade results, the overall results were obtained at median Grade II (I-III) and POGO with medians, respectively, conventional laryngoscope, McGRATH™ MAC BF blade, and O-Mac® 80 (20–100); 80 (20–100); 80 (40–100)%. not statistically different in the three tools with $p = 0.024$ for the CL degree and $p = 0.048$ for POGO, this is the same as the research Luqman (2017) but Karippacheril (2014) have different results where CL degree 1 degree at 9/24 and degree 2 at 15/24 with POGO mean \pm SD (deviation) 62.29 ± 28.40 (20–100)% with $p = 0.001$ on video laryngoscope - USB used [9]. In research by Brueggene (2016), in 720 patients with 120 subjects each with a C-Mac™ D-blade, GlideScope™, McGrath™, Airtraq™, AP Advance™, and KingVision™ device, the results obtained were degrees of Cormack Lehane I/IIa/IIb/III/IV (n) sequentially in each using tools (76/36/7/0/0), (80/29/3/2/3), (64/45/9/1/0), (74/30/4/0/3), (19/28/22/8/19), (63/41/7/1/4), and $p \leq 0.01$ †, for POGO the median (percentage); [90 (80; 100)], [100 (83; 100)], [90 (80; 100)], [90 (80; 100)], [60 (10; 80)], and [90 (80; 100)] with $p < 0.01$ † [16]. This research is the same as research Hernandez (2020) with each sample of 15 subjects, it was known that VDL Hybrid 1.0 (GI) and Macintosh No. 3 shovels (GII) with results of degrees I, II, III, and IV sequentially [(14, 1, 0, 0; 1, 8, 3, 3)] with $p \leq 0.0001$. In this study it is different from Vadhnan (2017) comparing Miller and V-scope obtained CL I, II, and III degrees, the results are sequentially (7, 9, 4); (16, 3, 1) with significant $p = 0.0015$ [15]. This is because in this study the subject population has been determined with limited inclusion

criteria, namely mallampati only I and II, BMI in each device with a normal median, the degree of CL I-III, the tool used has the same design, namely using Macintosh blades and allowed to use assistive tools/techniques while using the tools to get the best visualization results. The results of the CL degree relationship with the tool/technique were found to be linearly related to $r = 0.196$ with significant results with $p = 0.001$, while for POGO it was inversely related to the result of $r = -230$ with significant $p = 0.000$.

Type of video-laryngoscopes is Glidescope original, cobalt or ranger, Storz V-Mac, McGrath, Bullard, Airtraq, and Pentax-AWS and Video Macintosh System (VMS), including a standard handle housing the camera [10]. VMS having a small image-light bundle exiting from the handle is inserted and advanced two-thirds of the length of the standard. The position of the glottic structures and movements necessary to optimize exposure were obvious. Intubation was rapid and precise using this coordinated maneuver [11].

The results of using the intubation tool/technique, it is found that the McGRATH™ MAC BF blade requires at least 1 tool out of the four tools that are usually used in the form of a Stylet, BURP (Extra Laryngeal Maneuver), Magill Forceps and Gum Elastic Boogie, whereas conventional laryngoscopes and O-Mac® do not use tools much, with the result $p = 0.000$. This is due to the wrong assumption on the use of the McGRATH™ MAC BF blade which has to use one tool, with the most yields on the stylet.

The results of tissue damage due to laryngoscopes found that the three laryngoscopes did not cause damage with consecutive results between conventional laryngoscopes, McGRATH™ MAC BF blades, and O-Mac® (89 subjects [98.88%]; 82 subjects [91.11%] and 89 subjects [98.88%]), with $p = 0.007$. However, when compared to each of the 2 tools, Conventional laryngoscope and McGRATH™ MAC BF blade obtained $p = 0.018$, conventional laryngoscope and O-Mac® $p = 1,000$, McGRATH™ MAC BF blade, and O-Mac® $p = 0.018$ this indicates that each of them is not significant because the power of this study is 99%, $p = 0.01$.

The hemodynamic response pronounced clinically in the conventional laryngoscope group, but not statistically significant. The reason for this is the large CI value, requiring a larger sample size as well, by reducing the alpha value to near zero. The correlation that is clinically clear appears to be a relationship between hemodynamic responders with prolonged intubation time, intubation tools/techniques used, and tissue damage that occurs, does not appear statistically significant, so a larger sample size is needed for statistical proof.

The limitations of this study relate to the first experimental clinical trial research, so to obtain good internal and external validity requires fairly strict inclusion and exclusion criteria, so that the limitations of

this study are using subjects in certain populations and carried out in certain places, so that the results of this study cannot describe the same conditions in different populations, procedures and locations.

Conclusion

Based on the analysis and discussion of comparative research results efficacy of O-MAC[®], a patent video laryngoscope facilitated by McGRATH[™] MAC Blade BF, and conventional laryngoscope in performing intubation in the operating room of the Sanglah Hospital, Denpasar results: (1) the video laryngoscope proved to be superior in laryngoscopy time and faster intubation time (only in O-Mac[®]), fewer intubation attempts, less tissue damage, and minimal hemodynamic response, when compared to conventional laryngoscopes; (2) O-Mac[®] is no worse than a patent video laryngoscope in terms of CL degree, use of intubation aids/techniques, total intubation attempts, tissue damage due to laryngoscope, and hemodynamic changes (HR/MAP).

Supporting Information

O-Mac:

<https://youtu.be/ANNVnpu4d18>

<https://youtu.be/9gTVSTLzdV8>

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