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Comparative evaluation of the performance and outcomes of endotracheal intubation by King vision video laryngoscope vs. Macintosh direct laryngoscope for general anaesthesia

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Abstract
Background & Aims: The inability to manage difficult airways results in morbidity and mortality from hypoxic brain injury and attributes to 30% of deaths that occur under general anesthesia. Video laryngoscopes (VL) used to mitigate them have become a part of difficult airway carts. We compare the performance and outcomes of King Vision video laryngoscope (KVVL) with Macintosh direct laryngoscope (MDL) for endotracheal intubation in patients requiring general anesthesia for elective surgery.
Materials & Methods: This comparative study randomized 126 patients under general anaesthesia in two groups: KVVL and MDL (n = 63; n = 63). An airway assessment was performed on all patients. The primary endpoint was the ease of intubation measured as the number of attempts, time, and manipulation required for intubation, and the laryngeal view obtained. The secondary endpoints were hemodynamic response and airway morbidities.
Results: The KVVL group had a better first pass success rate (100% vs 93.7%, $p<0.05$), less time (10.9±2.1 vs. 16.1±3.26 seconds, $p<0.001$) and lesser manipulation (3.2% vs. 19%, $p<0.001$) required for intubation compared to the MDL group. The KVVL group showed an improved glottic visualization measured in terms of CL grading compared with the MDL group ($p<0.001$). The KVVL group had lesser hemodynamic response one-minute post-intubation in terms of pulse rate ($p<0.05$) and blood pressure ($p<0.001$), whereas airway morbidities observed were almost similar (p=0.3).
Conclusion: The performance and outcomes of KVVL in intubating patients for general anaesthesia by experienced operators were more promising with fewer airway complications compared with MDL.

Keywords: Endotracheal intubation, video laryngoscope, general anaesthesia, glottic view, first-pass intubation success

Introduction
Ensuring proper gas exchange for the patient is a primary responsibility of an anesthesiologist. Failure to adequately oxygenate for more than a few minutes can lead to severe anoxic injury. Despite advancements in airway management techniques and monitoring protocols, challenges in airway management during emergencies continue to be a major cause of significant perioperative complications. It is estimated that difficulties in managing a challenging airway account for nearly 30% of deaths directly linked to anaesthesia [1-3]. Timely identification of a difficult airway, the immediate availability of skilled professionals, and access to advanced airway management equipment are critical elements in addressing such challenges [1].
Generally, failed endotracheal intubation occurs once in every 2230 attempts [4]. The incidence is less but its potential consequences are of major importance. Video laryngoscopes (VL) and optical laryngoscopes (OL) have been increasingly used in routine and difficult airway management. They provide a better laryngoscopic view than direct laryngoscopes (DL) [1]. The role of VL in difficult intubation has been recognized in the DAS 2015 guidelines that recommend all anesthetists to be always trained and have access to VL [5, 6]. It has emerged because of the need to reduce morbidity and mortality associated

with failure to secure airways with DL.

The King Vision™ (AMBU, Denmark) (KVVL) is a novel VL device developed for managing difficult as well as routine airways quickly and safely [7]. It is a hyper-angulated VL with an anatomically shaped blade and a channel along the curvature of the blade which can be used to preload an endotracheal tube. [8] Few studies evaluate the performance and outcomes of KVVL in patients under general anaesthesia. So, we aimed to compare the performance and outcomes of KVVL with the Macintosh direct laryngoscope (MDL) for endotracheal intubation of patients under general anaesthesia.

Materials and Methods

Study Design

This prospective randomized comparative study was conducted for a period of 2 years in patients undergoing elective surgery under general anesthesia as approved by the Institutional Ethics Committee.

Patient Selection: The study enrolled patients scheduled for different elective surgeries under general anesthesia requiring endotracheal intubation. The Modified Mallampati Classification was used to assess the airway. Exclusion criteria: (a) patients undergoing emergency surgeries, (b) patients with ASA physical status 3 and 4 (c) patients with limited mouth opening. Before participation, consent was obtained from the patients and their relatives.

Randomization and Allocation Concealment: Patients who fulfilled the inclusion criteria were randomly assigned in a 1:1 ratio to either the KVVL or MDL group for general endotracheal anaesthesia. The randomization and allocation process was performed by medical personnel not involved in the study to maintain allocation concealment. To ensure a balanced number of participants in each group, the allocation sequence was generated sequentially by the author using block randomization and the sequentially numbered opaque sealed envelope (SNOSE) method.

Pre-anaesthetic Evaluation

All patients were examined a day before surgery. A systemic examination was performed to rule out any of the exclusion criteria. The hemodynamic variables such as heart rate (HR), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were recorded. Airway assessment was performed using various methods such as movements of the neck, rule of 1-2-3, teeth, and Mallampati grading in each patient. Complete blood count (CBC), chest X-ray, and electrocardiogram were performed on each patient. All the patients were connected to a pulse oximeter, non-invasive blood pressure monitor, ECG monitor, and ETCO2 monitor before induction.

Patients were premedicated with Inj. Ondansetron 0.08mg/kg, Inj. Midazolam 0.025mg/kg and Inj. fentanyl - 1μg/kg. Preoxygenation with 100% oxygen was done for three minutes using Bain's system. Anaesthesia was induced with Inj. Propofol 1.5mg/kg and Inj. succinylcholine 1.5 mg/kg. The mask was ventilated for 1 minute after the injection of succinylcholine with Bain's system. The patients in the KVVL group were intubated in a neutral position and patients in the MDL group were intubated in the sniffing position by expert anaesthetists who were well-experienced in handling both devices.

Method of laryngoscopy and intubation

King Vision Video Laryngoscope (KVVL): The KVVL channelled blade was preloaded with an appropriately sized endotracheal tube (ETT). Following preoxygenation and rapid sequence induction, the blade was introduced through the centre of the mouth and guided along the curvature of the tongue under vision. To prevent any harm to the teeth and soft tissue, the operator observed the patient's oral cavity rather than the video screen while inserting the channelled laryngoscope blade with ETT into the oropharynx.

Once the blade reached the posterior part of the oral cavity, the video screen was used to optimize the view of the glottis. By resting the blade tip near the vallecula at the base of the tongue, the ETT was smoothly passed through the laryngoscope's channel until the black mark on the tube lay beyond the glottis. Subsequently, the ETT was detached from the channel, and the KVVL was withdrawn.

Macintosh Direct Laryngoscope (MDL): The MDL handle was grasped in the left hand, and the blade was inserted into the patient's mouth on the right side. It was then advanced along the side of the tongue until the right tonsillar fossa came into view. Next, the blade tip was directed towards the midline and further advanced until the epiglottis became visible.

Once the epiglottis was in view, the blade was advanced into the vallecula. Traction was applied along the handle, at a right angle to the blade, to move the base of the tongue and epiglottis forward. This action allowed the glottis to become visible, and the intubation process was performed using an appropriately sized ETT.

General Anesthesia Maintenance Protocol: Anesthesia was sustained using a mixture of 33% oxygen (O_2) and 67% nitrous oxide (N_2O) along with isoflurane at a rate of 14-15 breaths per minute. For muscle relaxation, an initial dose of 0.08 mg/kg of vecuronium bromide was administered, and one-fourth of the loading dose was used for maintenance. To reverse the neuromuscular blockade, neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg) injections were administered intravenously, ensuring sufficient recovery from the blockade. Before extubating, the oral cavity and throat were thoroughly suctioned.

Study endpoints: The primary endpoint was the ease of intubation measured as the number of attempts, time taken, and manipulation required for intubation, and laryngeal view obtained by Cormack-Lehane (CL) grading in both groups. The secondary endpoints were examining the hemodynamic response in terms of post-induction pulse rate and changes in systolic and diastolic blood pressure (SBP/DBP) as well as the occurrence of airway morbidities.

Mallampati test: The Mallampati test has been widely used for airway assessment, providing valuable information about the available space in the oral cavity for accommodating the laryngoscope and endotracheal tube. To conduct the test, our patients were asked to open their mouths as wide as possible and stick out their tongues without phonation (such as saying "aah"), which can lower the grade by one step (e.g., grade II becomes grade I). To ensure accurate results, the patients were seated in an upright position with the head slightly forward, resembling the "sniffing" position during laryngoscopy and intubation. The observer's eye level was aligned with the patient's mouth for a proper evaluation.

The observation involves assessing the visibility of the faucial pillars, uvula, soft palate, and hard palate. Samsoon and Young modified the Mallampati grading system into four grades [9, 10]. Subsequently, the latest modification of Mallampati grading includes 5 grades as follows: Class 0 (Tip of the epiglottis visible), Class I (Faucial pillars, uvula, soft, and hard palate visible), Class II (Uvula, soft, and hard palate visible), Class III (Soft and hard palate visible), and Class IV (Hard palate visible). Classes III and IV are indicators of potentially difficult intubation. When used in isolation the Mallampati test predicts approximately 50% of difficult intubations.

Time required and number of attempts for intubation: In both groups, the time taken for intubation was recorded starting from the entry of the laryngoscope blade into the oral cavity until confirmation of endotracheal intubation through five-point auscultation. An attempt at intubation was considered as soon as the laryngoscope was introduced into the oral cavity, regardless of whether successful endotracheal intubation occurred. The operator noted the CL grading for the glottic view in both groups and the KVVL group, this assessment was also verified by the assistant experienced in anaesthesiology.

Sample Size Estimation: The sample size was determined using data from a pilot study with similar objectives, comparing KVVL and MDL. The anticipated effect size for the time taken for intubation was 0.5, with a standard deviation of two in both groups. Considering an expected mean difference of one second, we calculated a sample size of 126, with sixty-three patients in each group. The aim was to detect any significant difference between the two groups using a two-tailed α (alpha) of 0.05 and a (1 - β) (beta) of 0.80, ensuring adequate statistical power.

Statistical Analysis: Continuous variables were presented as mean ± Standard deviation (SD), while categorical variables were presented as numbers and percentages (%). Student's t-test was employed to analyze the continuous variables, and the Chi-squared ($\chi 2$) test was used to compare the categorical variables. The comparisons of changes in pulse pressure and blood pressure were made using repeated measures ANOVA. All statistical analyses were conducted using SPSS software version 22 (IBM). A significant level of 0.05 (two-tailed) was considered statistically significant.

Results

A total of 126 patients were involved and randomized into two groups (Figure 1).

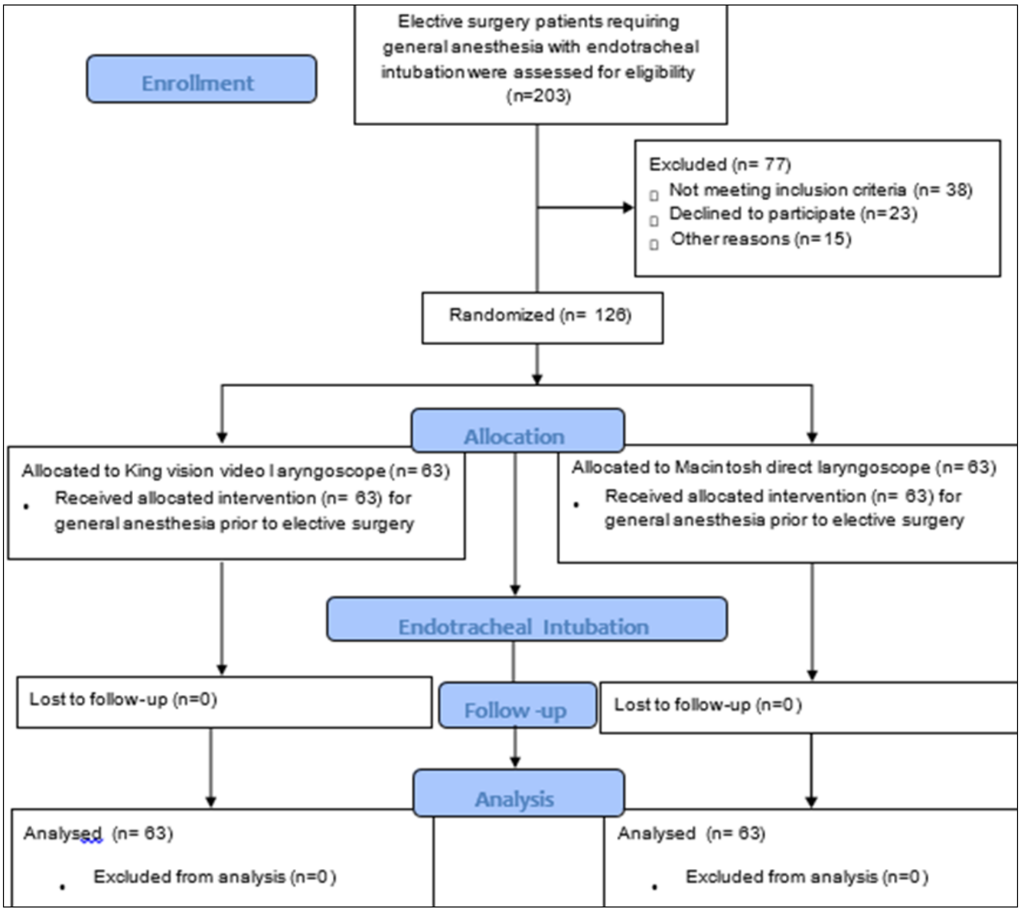

Fig 1: CONSORT flow diagram of recruitment and allocation of study subjects.

Hundred and five cases (83.3%) in our study were males being predominant in both groups. There was no significant difference between both groups in terms of age and body mass index (BMI) distribution ($p > 0.05$) (Table 1). In the KVVL group, there were significantly more patients under the modified Mallampati class-1 compared to the MDL group ($p < 0.001$). While the MDL group had a significantly higher number of patients under Class II and III ($p < 0.001$) (Table 1).

Table 1: Sub-group analysis of patient demographics and Modified Mallampati Classification for airway assessment.

Parameter	Group		p-value
	KVVL (n=63)	MDL (n=63)	
Age, (mean ± SD)	32.2±11.5	35.7±10.5	0.08
Sex, n (%)			0.03
Male	48 (76.2)	57 (90.5)	
Female	15 (23.8)	6 (9.5)	
BMI, (mean ± SD)	26.82±1.87	26.24±1.9	0.08
Modified Mallampati Class, n (%)			0.001
0	-	-	
1	50 (79.4)	15 (23.8)	
2	12 (19)	43 (68.3)	
3	1 (1.6)	5 (7.9)	
4	-	-	

KVVL - King Vision Video Laryngoscope; MDL - Macintosh Direct Laryngoscope; NM - Non - measurable, BMI - Body Mass Index

Primary endpoint (Ease of Intubation)

The first pass success rate was 100% in the KVVL group compared to the MDL group with 93.7% ($p < 0.05$) (Table 2). The mean time required for intubation was observed to be significantly lesser in the KVVL group than in the MDL group (10.9±2.1 seconds vs. 16.1±3.26 seconds, $p < 0.001$) (Table 2). A significantly better glottic visualization (CL grade 1) was assessed in all patients (100%) in the KVVL group compared to the MDL group in which 13 patients (20.65%) and 44 patients (69.84%) had CL grades 1 and 2a, respectively ($p < 0.001$) (Table 2). Worsen glottic views such as 2b and 3 were assessed in 4 (6.34%) and 2 (3.17%) patients, respectively, in the MDL group ($p < 0.001$) (Table 2).

In the KVVL group, 96.8% of cases did not require manipulation and 3.2% of cases required withdrawing scope when the lens was excessively close to the glottis. In the M DL group, 81% of cases did not require manipulation and 12% of cases required external laryngeal manipulation using manoeuvres and stylets. The KVVL group required significantly less manipulation compared to the MDL group ($p < 0.001$) (Table. 2).

Secondary endpoints (Hemodynamic response and airway morbidities)

The hemodynamic response post-induction was recorded in terms of pulse pressure and blood pressure (BP). The change in mean pulse rate was significantly less in the KVVL group (78.57±8.74 vs. 82.84±9.60 bpm, $p < 0.05$), while the MDL group had an increase in pulse rate (Table 2). In the MDL group, a significant rise in mean systolic and diastolic blood pressure was observed compared with the KVVL group ($p < 0.001$) (Table 2). There was no significant difference observed for the incidence of airway morbidities in both groups ($p < 0.05$) (Table 2). Although the KVVL group's diastolic blood pressure increased by 2.11 mmHg at one minute, it subsequently declined slightly beyond the post-induction pulse rate two minutes after intubation.

The patients in the KVVL group experienced no airway complications. Gum bleeding occurred in 1.6% (1/63) of the MDL group. However, there was no significant difference was noted in both groups (Table 2).

Table 2: Sub-group comparative analysis of primary and secondary endpoints.

Outcomes		Group		p-value
		KVVL (n=63)	MDL (n=63)	
Primary endpoints	**No. of attempts,** n (%)			0.04
	1 (first-pass success)	63 (100)	59 (93.7)	
	2	-	4 (6.3)	
	Time required to intubate, *seconds* (mean ± SD)	10.9±2.1	16.1±3.26	0.0001
	CL grade - Glottic view, n (%)			0.0001
	1	63 (100)	13 (20.65)	
	2a	-	44 (69.84)	
	2b	-	4 (6.34)	
	3	-	2 (3.17)	
	Manipulation required, n (%)			0.001
	None	61 (96.8)	51 (81)	
	Withdraw scope.	2 (3.2)	-	
	External Laryngeal Manipulation	-	12 (19)	
Secondary endpoints	**Changes in Pulse Rate, bpm (mean± SD)**			
	Post-induction	76.03±8.61	75.98±9.29	0.12
	1-min after intubation	78.57±8.74	82.84±9.60	0.04
	2-min after intubation	77.11±9.25	79.81±8.88	0.4
	Changes in Systolic BP, mmHg (mean± SD)			
	Post-induction	114.54±8.70	115.78±8.18	0.14
	1-min after intubation	117.62±8.87	139.35±8.95	0.0001
	2-min after intubation	115.21±8.36	134.43±8.67	0.0001
	Changes in Diastolic BP, mmHg (mean± SD)			
	Post-induction	79.65±6.38	81.02±3.31	0.2

	1-min after intubation	81.76±5.98	89.08±4.87	0.0001
	2-min after intubation	77.84±5.98	84.10±4.40	0.0001
	Airway morbidity, n (%)			
	Gum bleed/injury	-	1 (1.6)	0.3
	None	63 (100)	62 (98.4)	

KVVL - King vision video laryngoscope; MDL - macintosh direct laryngoscope; CL grading - cormack-lehane grading; BP - blood pressure.

Discussion

Securing the airway through endotracheal intubation is a vital step in administrating general anesthesia. MDL is used to facilitate tracheal intubation under vision. Its success depends on achieving a line of sight from the maxillary teeth to the larynx. Laryngoscopes ranging from simple rigid laryngoscopes to complex fibreoptic video laryngoscopes have been developed and studied to aid intubation.

A video laryngoscope was introduced to enhance glottic visibility for successful intubation. Intubation using MDL might be a noxious stimulus that may provoke adverse cardiac responses such as tachycardia and hypertension. In MDL, the magnitude of the response is greater with increasing force and duration of laryngoscopy. Transitory tachycardia and hypertension produce no consequences in healthy individuals but are hazardous in those with hypertension, myocardial insufficiency and cerebrovascular disease.

King Vision video laryngoscope is a fully portable video laryngoscope (VL) with high blade angulation. It has a battery-operated monitor and a disposable blade that includes a complimentary metal oxide semiconductor (CMOS) video camera. The disposable blade is available with or without a tubeguiding channel and one blade sized #3 is provided for its use in adults (Tube sizes 6.0 to 8.0 mm). The minimum mouth opening required for using a channelled blade and unchanneled blade is 1.8 cm and 1.2 cm, respectively. The KVVL allows the bystanders to view the images on an external medical monitor [11]. It belongs to the type of high blade curvature VL such as Airtraq optical laryngoscope and Pentax VL.

As per initial manikin assessment and pilot studies, recommendations suggest that all new airway devices must be compared with the current gold standard through a randomized controlled trial (RCT) [12-14]. Factors such as portability, reliability and cost per usage are crucial for any VL for its consistency and applicability. The KVVL seemed to fulfil the above factors. However, there are only a few studies that support its performance and outcomes for endotracheal intubation in patients requiring general anaesthesia for undergoing elective surgeries [15-18].

In our study, the first-pass intubation success rate was 100% in the KVVL group, while it was 93.7% in the MDL group. This result aligns with a study by Zhu H *et al.* [17] that reported success rates of 100% and 85% with KVVL and MDL, respectively. Our research further supports higher first-pass success rates with KVVL compared to MDL, consistent with prior studies. Notably, our success rates in both groups exceeded those from previous research on intubation for general anaesthesia [16-17].

The KVVL group exhibited significantly faster intubation times than the MDL group. However, both groups in our study had shorter intubation times than those reported by Ali QE *et al.* [16]. This discrepancy might stem from differing definitions of "time required for intubation." Our study defined it as the time from laryngoscope blade entry to the passage of the endotracheal tube beyond the glottis, while QE Ali *et al.* [16] included additional steps like dislodging the tube, blade removal, and capnograph connection.

A study by LD Murphy *et al.* [17] found that KVVL facilitated faster intubation (11.3 seconds) than MDL in challenging airway scenarios. However, our study focused on elective surgery under general endotracheal anaesthesia, differing from their cadaver-based approach.

In our research, all patients (100%) in the KVVL group achieved Cormack Lehane (CL) grade 1 glottic views, contrasting with the MDL group's 20.65% success rate ($p< 0.001$). This outcome aligns with Jung Bauer *et al.*'s findings, [17] where Berci-Kaplan VL yielded fewer optimizing manoeuvres during endotracheal intubation for general anaesthesia.

Predictive of easy intubation, Mallampati class 1 and 2 were observed significantly more frequently in the KVVL group compared to MDL (98.4% vs. 92.1%, $p<0.001$). The KVVL group required fewer manipulations (3.2% vs. 19%, $p< 0.001$). It is an advanced technology for higher success rates with minimal interventions compared to MDL.

The KVVL group had a lesser increase in pulse rate (PR) and blood pressure (BP) postinduction compared to the MDL group. Comparably, the MDL group showed significant increases in systolic and diastolic blood pressure compared to the KVVL group. This finding resembled Maharaj CH *et al.*'s study, which favoured Airtaq VL over MDL [14]. Similarly, in our previous study on critically ill patients, KVVL outperformed MDL with better performance and outcomes with fewer airway complications [8]. These results align with the growing evidence supporting the benefits of VLs in minimizing adverse physiological responses during intubation [8, 1-17]. Hence, our study provides comprehensive insights into the superior performance and outcomes of the KVVL compared to the MDL in the context of general endotracheal anaesthesia for elective surgeries. The KVVL's advanced technology and enhanced glottic visualization underscore its potential as an invaluable tool in modern airway management.

Limitations: Our study focuses on patients who require elective surgeries requiring endotracheal intubation for general anesthesia. So, these findings might not apply to emergency or specific patient populations where airway management is more challenging.

Further research with larger sample sizes, rigorous study design, and consideration of broader contexts are needed for the generalizability of results.

Conclusion

Our study provides evidence that the King Vision Video Laryngoscope (KVVL) handled by experienced operators offers superior first-pass success rates, faster intubation times, enhanced glottic visualization, and reduced manipulation requirements compared to the Macintosh Direct Laryngoscope (MDL). Its ability to mitigate adverse hemodynamic responses further positions the KVVL as a valuable tool for safer and more efficient airway management. The KVVL's performance should be further studied in larger trials and for intubation in various scenarios like intensive care units and emergency medicine. To further confirm its efficiency.

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Conflict Of Interest
There is no conflict of interest.

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