

Comparison of Patwashah-i Video laryngoscope with King Vision Video laryngoscope as an intubating aid in adult patients with normal airway: A prospective, randomised and comparative clinical study

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Abstract

Introduction: Patwashah-i video laryngoscope (VL) is relatively recently introduced intubating device with high resolution CMOS camera. The primary aim of this study was to compare the efficacy of Patwashah-i video VL with King vision VL regarding their utility and safety for tracheal intubation in adult patients with normal airway.

Methods: After ethical approval and informed consent, 72 patients between age of 18-60 years, of either gender and ASA grade I & II, scheduled to undergo elective general surgery were randomized to receive endotracheal intubation with either the Patwashah-I Videolaryngoscope with channelled blade (Group-P) or the King Vision video laryngoscope with channelled blade (Group-K). Parameters evaluated were video laryngoscopy time, endotracheal tube insertion time,

total time of intubation, number of intubating attempts, optimization maneuvers required for intubation, quality of visualization using Cormack and Lehane grading, hemodynamic parameters and complications if any.

Results: Video laryngoscopy time, tube insertion time and total time of intubation were statistically significantly less in group K compared to group P (p value <0.05). However, quality of glottic visualization was better with Patwashah-i VL than with King vision VL. There was no significant difference regarding attempts of intubation, optimization maneuvers score, hemodynamic parameters, and postoperative complications amongst both the groups.

Conclusion: Though statistically lesser time was taken for intubation with King Vision compared to Patwashah-i VL, it did not carry any clinical significance. Both the

devices are equally good for tracheal intubation in adult patients.

Keywords: Video laryngoscope, King Vision, Patwashah-i, Tracheal intubation

Introduction

The requirement of general anaesthesia for surgery necessitates tracheal intubation. Traditional direct laryngoscopy with McIntosh blade requires a direct line of sight thus needing morning sniffing position [1,2]. Need for blade tip placement in vallecula and relatively larger pressure application leads to hemodynamic pressure changes which are detrimental in susceptible patients [3]. Meanwhile, video laryngoscopy facilitates easy visualization of the glottis with minimal neck manipulation, less noxious stimuli and also allows anaesthesia operator to maintain an effective distance from the patient during intubation which is useful in patients with infectious diseases. The operator and assistant can coordinate their movements because each views the same image on the monitor. Thus, popularity of VLs has increased due to ease of handling, high success rate in patients with normal and with difficult airways and a steep learning curve [4, 5].

The King Vision (King Systems, Noblesville, Indiana, USA), is commonly used easily available VL. It provides the perfect view of larynx via use of video and digital technology. It is a two-piece design with reusable monitor with LED screen of size 2.4 inch which has colour display that attaches to disposable blades. It has an antifogging coating on distal lens to prevent blurring of vision.

The Patwa Shah-i VL (Hospro) is conceptualised, designed, and developed by Indian anaesthesiologists, is a very new device among VLs, arrived in May 2018 in Indian market. It has wide viewing angle, high resolution

(4,20,000 pixels) complementary metal oxide semiconductor (CMOS) camera and white LED light illumination. Blades are anatomically curved and is available in four sizes – adult channelled, adult non channelled, for obese patient and paediatric blade. Monitor has wide 7” screen to provide clear and fine panoramic view of the visualised structures.

Patwa shah-i VL is recently introduced device in market and as best to our knowledge there is no scientific study on it is available, hence, we undertook this study to evaluate and compare the efficacy and safety of Patwa shah-i video laryngoscope with commonly used King Vision video laryngoscope for tracheal intubation in adults. We hypothesised that there is no difference for time taken for intubation in both Patwa shah-i VL and King Vision VL in patients with normal airway.

Materials And Methods

After taking permission from Institutional Ethics Committee for Human Research (EC Reg No: ECR/85/Inst/GJ/2013/RR-16 dated 17/07/2018), this prospective randomized comparative clinical study was carried out from August 2018 to October 2019, in 72 adult patients of either sex, between ages of 18-60 years, belonging to ASA status I and II, with normal airway who were scheduled for elective surgical procedures under general anaesthesia. Written informed consent was obtained from all patients day before surgery.

Exclusion criteria were: age under 18 years or more than 60 years, potential risk of regurgitation, pregnancy, ASA classification > II, cervical spine disorder and patients with an anticipated difficult airway (thyromental distance less than 6 cm, sternomental distance less than 12 cm, neck circumference more than 40 cm), oropharyngeal pathology and obesity (BMI \geq 30).

Randomisation

All patients were randomly divided into two groups using the opaque envelope method and allotted to one of the groups, namely

- **Group P** -in which Patwashah-i VL with adult channelled blade was used for intubation and
- **Group K**- in which King Vision (size 3/ size 4 blade) with channelled blade was used for intubation.

Study protocol

Patients were recruited during preanesthetic checkup when a detailed medical history was taken and general examination, systemic examination and thorough airway assessment were carried out. Basic laboratory investigations were carried out as needed for surgery. On the day before the scheduled surgery, pre-anaesthetic check-up with thorough airway assessment including neck circumference, sternomental distance, thyromental distance and Mallampati scoring was done. Jaw movement was checked by the ability of anterior subluxation of mandible. Written informed consent was taken and a standard protocol for nil per oral status was followed. After taking patient inside the operation theatre, intravenous line was secured and multiparameter monitor was attached and baseline vital parameters were noted. All patients were premedicated with IV glycopyrrolate 0.2 mg, midazolam 1 mg and fentanyl 2 µg/kg.

In case of Patwashah-i VL, the handle with CMOS camera was mounted on adult channelled blade and checked for image on the monitor that was connected to blade via wire. In case of King Vision video laryngoscope, blade was mounted. The performance of

the device was checked once by pushing the on button and checking the image on monitor. For both the devices, the endotracheal tube to be used (7.0 in case of females and 8.0 in case of males) was lubricated with lubricating jelly. The respective device was preloaded with appropriate size endotracheal tube in tube guiding channel and ensured that tube was sliding smoothly through the channel.

After pre-oxygenation for 3 minutes, general anaesthesia was induced with IV propofol 2 mg/kg and IV succinylcholine 1.5 mg/kg. After disappearance of fasciculation from toes and adequate jaw relaxation, the head kept in neutral position and respective VL with preloaded ET was advanced from the centre of the tongue towards glottis by viewing on the screen of the monitor. Tip of blade was placed in vallecula without uplifting the epiglottis directly and simultaneously viewing the glottis on the centre of monitor screen, tube was advanced into the trachea under direct observation on the video screen [Figure 1 and 2].



Figure 1: Intubation with King Vision channelled Video laryngoscope.



Figure 2: Intubation with King Patwashah i Videolaryngoscope.

Intubation was attempted only if an optimal glottis view, with a POGO (percentage of glottic opening) score of $\geq 75\%$ was obtained [6]. After tube was inserted and cuff disappeared the device was detached from endotracheal tube and removed from the mouth. Endotracheal tube was attached to the closed circuit and tracheal intubation was confirmed by the continuous capnographic square wave tracing on the monitor. Intraoperatively, anaesthesia was maintained according to standard protocol. At the end of the procedure, patients were extubated after fulfilling the criteria for extubation. Two anaesthesiologists who performed intubation on study cases, performed at least 30 intubations with both video laryngoscopes on mannequin.

In case of failure to intubate with the study device, patient position was re-optimized and external laryngeal manipulation was used to facilitate intubation. Maximum 2 attempts were allowed for intubation with both VLs. More than two attempts or time elapsed more than 120 seconds were counted as failure and intubation was done by conventional direct laryngoscopy using

McIntosh blade and the case was removed from the study.

Outcome Measurement

Our primary study objective was to determine whether there is a difference in “time to intubate” for the Patwashah-i Videolaryngoscope as compared to the King Vision channelled blade. The “time for intubation (T1+T2)” was defined from the time blade tip at the incisors to the point until confirmation of the first wave of CO₂ of the capnometer was seen. Additionally, two time points before final tracheal placement were evaluated: Video laryngoscopy time (T1) was time taken from introduction of VL from patient’s incisors to optimal view of glottis (POGO score of $\geq 75\%$). Tube insertion time (T2) was defined as time taken from the optimal view of glottis till first end-tidal carbon dioxide (ETCO₂) tracing was seen on the monitor.

Secondary outcomes were number of attempts required for device insertion (maximum 2 permissible attempts); quality of visualization of glottic aperture according to Cormack and Lehane grading (Grade I: Visualization of entire vocal cords, Grade II: Visualization of posterior part of the laryngeal aperture, Grade III: Visualization of epiglottis, Grade IV: No glottic structure seen) [7]; optimization manoeuvres required for intubation like jaw thrust, external laryngeal pressure assessed on a score of 0 and 1 (Score 0- no manoeuvres required, Score 1- if intubation needed external laryngeal pressure / jaw thrust); hemodynamic parameters (heart rate, mean arterial BP and SpO₂) and complications, if any like airway trauma (trauma to lips, tooth, tongue, tonsillar pillar, valleculae, vocal cords), oral bleeding due to trauma and accidental esophageal intubation and sore throat. Hemodynamic parameters i.e., heart rate, mean arterial pressure and SpO₂ were noted at baseline, before

induction, 1min after induction, 1min after administering suxamethonium, before video laryngoscopy, at interval of 1 minute, 3 minutes, 5minutes, 10 minutes after video laryngoscopy and intubation.

Sample Size

Data generated from a pilot study done in the same institute in 16 patients fulfilling inclusion criteria (8 from each group) were used to calculate the sample size. With this pilot study, the “total time for intubation (T1+T2)” was observed to be 30.50±1.92 seconds and 29.0 ±3.55 seconds for Patwashah-I VL and King Vision VL, respectively. Assuming a two-sided alpha error of 0.05 and a power of 90%, the sample size required was 34 per group. We enrolled 36 patients per group.

Statistical Analysis

Observed data were entered into Microsoft Excel 2010 and statistical analyses were performed using SPSS. For all continuous variables, results are presented as mean ± standard deviation (SD) and categorical variables as percentage. Unpaired ‘t’ test was applied to see the statistical significance of continuous data like weight, height and intubation time between the two groups. Chi-square test was used to obtain the association between categorical variables like ASA grading, gender, attempts of intubation, first attempt success rate and optimisation manoeuvres. The significance of statistical analysis was judged by P value and P < 0.05 was considered as significant.

Results

All intubation attempts were successful with a maximum of two attempts and were completed within the time limit of 120 seconds. No participants were excluded from observation or analysis [Figure 3]. All demographic data were comparable in both groups (Figure 4). Statistically significant more time was

required in Group P compared to Group K for video laryngoscopy (T1) (15.94±2.29 sec vs 14.94±1.21 sec; p<0.05), for tube insertion (T2) (15.2±2.46 sec vs 14.2±1.12 sec, p<0.05) and total time required for intubation (T1+T2) (31.17±3.72 sec vs 29.14±1.80 sec; p=0.002176) [Figure 5].

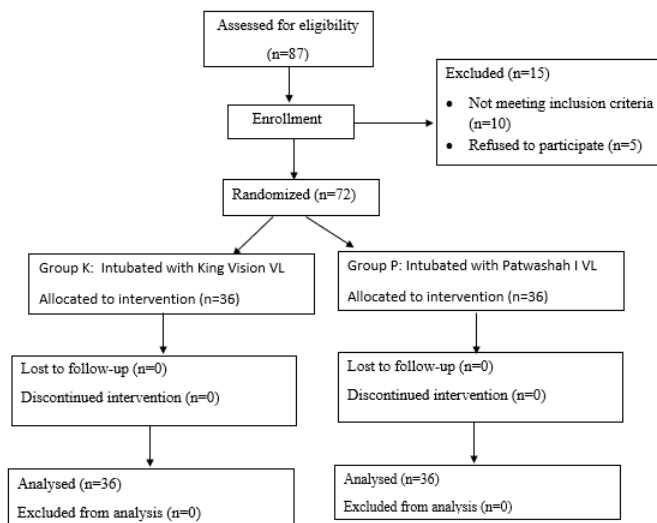


Figure 3: CONSORT diagram

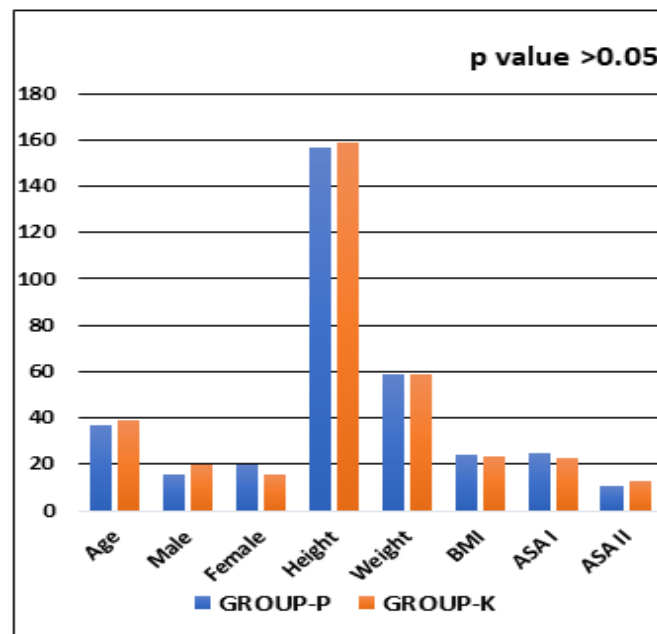


Figure 4: Comparison of demographic characteristics between two groups

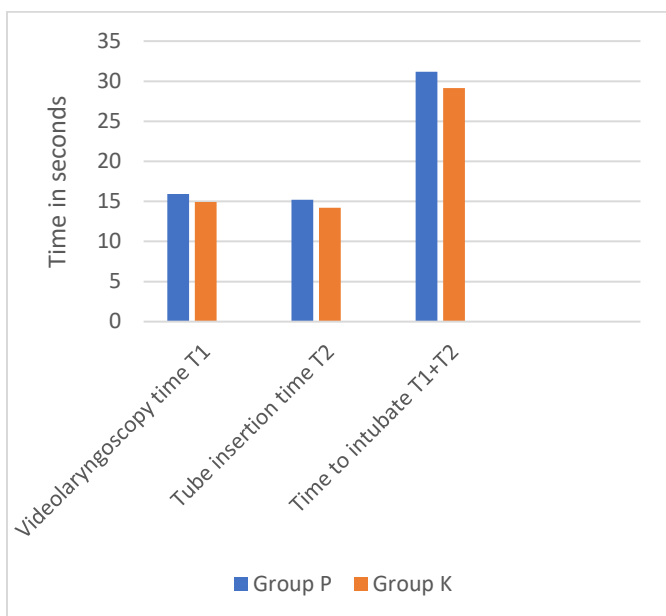


Figure 5: Comparison of time taken in both groups
 First attempt success rate was less in Patwashah I VL (33/36; 91.66%) than King Vision laryngoscope (34/36; 94.44%) although with no statistically significance ($p > 0.05$). In Group P 30 out of 36 patients (83.33%) had Grade I Cormack and Lehane view while remaining 6 (16.66%) had Grade II view. In Group K 20 (55.55%) patients had Grade I view while 16 (44.44 %) patents had Grade II view.

In Group P 16 (44.4%) patients needed jaw thrust while passing the endotracheal tube through the vocal cords; while only 13 (36.11%) patients required jaw thrust during intubation in Group K. The hemodynamic variables were comparable between the two groups [Figure 6]. There were no incidents of trauma like dental damage, laceration of tongue and buccal mucosa, aspiration, or significant desaturation in our study.

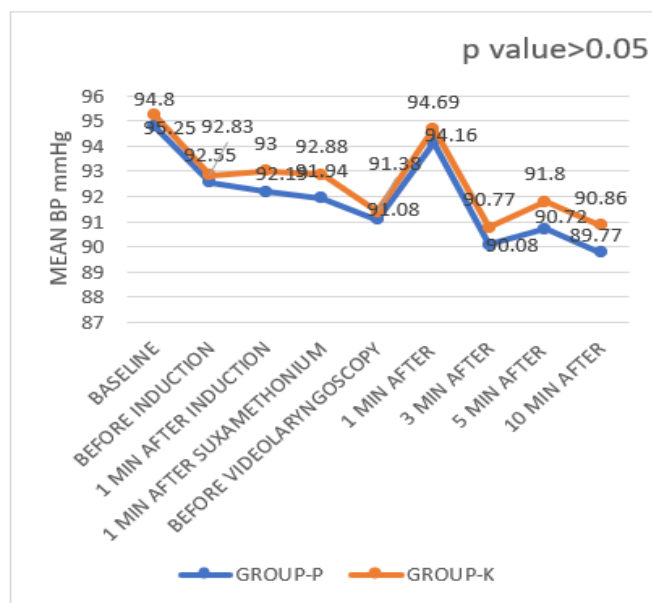


Figure 6: Mean blood pressure at various stages in both groups

Discussion

Patwashah-i VL is a new device in market with no previous literature about its clinical utility in everyday anesthesia practice. This prospective randomized controlled trial was conducted to assess the utility and safety of Patwashah-i VL in routine adult airway management by comparing it to King Vision VL which has well established safety and efficacy.

In our study, videolaryngoscopy time, tube insertion time and time to intubate the trachea were found to be higher in group of patients where Patwashah-i VL was used as compared to King vision VL.

All patients had a good grade of glottis visualization (CL grade 1 and 2). Similarly good glottis visualisation with King Vision VL had been reported in multiple studies [8-10]. Although there was a statistically significant better glottis visualisation in Patwashah-i Videolaryngoscope but it did not translate into faster intubation times. Difficulty in intubation despite good glottis visualization is a problem reported with most VLs [11]. In our study, we found that visualization of

the vocal cords was excellent, but the introduction of the tube was challenging in certain cases. Majority of cases in both the groups reported easy intubation. Sixteen out of 36 patients Patwashah I VL group and 13 out of 36 patients in King Vision VL group needed manoeuvres like jaw thrust, external laryngeal manipulation, manipulation and redirection of ETT after rotation so that it enters the glottis. These resulted in a successful intubation in the first attempt.

It was felt that better glottic visualisation by Patwashah-i VL did not translate in faster intubation times because of lack of familiarity. The King Vision VL has been in clinical practice in our department for a longer period of time as compared to Patwashah-i VL. Despite mannequin-based training, the operators in this study were relatively unfamiliar with usage of Patwashah-i VL as compared to King Vision VL. As the learning curve of any new device has a significant impact on success rate achieved, hence this would have contributed to the outcome.

In both groups there was not a significant rise of mean pulse rate from baseline during video laryngoscopy and after intubation in both groups. Hence, it can be said that video laryngoscopy did not serve as noxious stimuli during intubation in both groups, which is usually seen with direct laryngoscopy by Macintosh laryngoscope. Hence, both devices are equally good for use in patients with hypertension, ischaemic heart disease and intracranial pathology, where stress response during laryngoscopy has deleterious effect.

Chances of airway trauma are less with VLs because no forceful elevation of device is needed to align airway axis and it provides magnified view of airway structures and ease of intubation. Hence, both VLs can be considered for intubation in anticipated difficult airway.

Thus, we conclude from our study that though statistically lesser time was taken for intubation with King Vision VL compared to Patwashah-i VL, it did not carry any clinical significance as well as no difference in other parameters studied, both the devices are useful for routine intubation in adult patients. However, this is a preliminary study, hence, a large sample size needs to be evaluated for further recommendations.

The limitations of our study include the inclusion of only Mallampati grade I and II patients, and hence, the results may not be reflected in grade III and IV patients. Because of the design of this trial, the operator could not be blinded to the type of VL used, all intubation procedures were performed by an experienced anaesthesiologist to reduce the bias. Also, our results may not apply to non-channelled video laryngoscopes. Third, the standardized tube size of this trial could result in a limited generalizability for the intubation time when a larger tube size is used.

Conclusion

We conclude that Patwashah-I VL is a safe and effective airway device with a good success rate and is useful for routine intubation in adult patients with normal airway.

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