Original Article

Comparison of BlockBuster® Laryngeal Mask Airway, King Vision® Video Laryngoscope, and flexible intubation scope for orotracheal intubation in adult patients with simulated immobilised cervical spine: A randomised controlled trial

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ABSTRACT

Background and Aims: Flexible intubation scope, video laryngoscope and supraglottic airway device-guided tracheal intubation are suggested in cervical spine injury patients to avoid further exacerbation of cord injury. This study compared the intubation characteristics of BlockBuster laryngeal mask airway (BBLM), King Vision video laryngoscope (KKVL) and flexible intubation scope (FIS) in patients with simulated immobilised cervical spine. **Methods:** This study was performed on 120 adult patients with American Society of Anesthesiologists physical status I–II scheduled for elective surgery under general anaesthesia requiring orotracheal intubation. Patients were randomly allocated to Group BBLM, Group KVVL and Group FIS. Time to intubation, first-attempt success rate and complications were recorded and compared between the three groups. **Results:** There was a significant difference in the mean total time for intubation between the groups ($P < 0.0001$). The success rate of the first attempt was 75% in Group BBLM, 77% in Group KVVL and 82.5% in Group FIS ($P = 0.727$). Complications like mucosal damage, oesophageal intubation, and incidence of sore throat and cough were comparable in the three groups. **Conclusion:** Intubation time was faster with BBLM and KVVL than with FIS in patients with simulated cervical spine immobilisation. The first-attempt success rate and complications were the same for all three devices.

Keywords: Cervical spine immobilisation, flexible intubation scope, King Vision video laryngoscope, laryngeal masks, LMA BlockBuster, neck injuries, tracheal intubation

INTRODUCTION

The crucial step in airway management of patients with suspected or confirmed cervical spine injury in the emergency department or operation room is to prevent any neurological injury during laryngoscopy and tracheal intubation. Cervical spine immobilisation, either with a cervical collar or with manual in-line stabilisation (MILS) of the neck, is recommended during airway management of patients with unstable cervical spine.[1] A cervical collar or MILS of the neck precludes the alignment of oral, pharyngeal and laryngeal axes. Therefore, visualisation of vocal cords with conventional laryngoscopy in patients with cervical immobilisation is difficult.[2]

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Advanced airway techniques, such as flexible scope intubation (FSI), video laryngoscopy (VL) or intubation through supraglottic airway device (SAD), are recommended as with these techniques, endotracheal intubation is possible without much manipulation of the cervical spine.[3,4] In the last decade, FSI was replaced by alternative techniques like VL or intubation through SAD because of the limited availability of flexible intubation scope (FIS), its high cost and long learning curve. Moreover, SAD also allows ventilation during intubation attempts. Recently, a new SAD [BlockBuster laryngeal mask airway (LMA); Tuoren Medical Instrument Co., Ltd, Changyuan, China] showed better intubation time (IT) and first-pass success rate than Fastrach LMA in adult patients with normal airway.[5]

Various studies compare these alternative airway techniques, showing the superiority of one over the other.[6,7] However, no studies compare the intubation characteristics of all three recommended devices in patients with suspected or confirmed cervical spine injury.

Hence, the study was planned to compare the intubation characteristics of BlockBuster LMA with those of King Vision video laryngoscope (KVVL) and FIS in patients with simulated immobilised cervical spine. The primary objective of this study was to compare the total time for tracheal intubation (TTI) using BlockBuster LMA, KVVL and FIS in patients with simulated immobilised cervical spine. The secondary objectives were to compare the first-attempt success rate, number of intubation attempts required, and complications like trauma to oral mucosa, oesophageal intubation, cough and sore throat between the three devices. We hypothesised that BlockBuster LMA would have a shorter total IT than KVVL and FIS in patients with simulated immobilised cervical spine.

METHODS

This parallel, single-blind, randomised clinical trial was conducted after obtaining ethical clearance from the Institutional Ethics Committee (vide approval number HIMSR/IEC/018/2021 dated 19/03/2021) and Clinical Trials Registry-India registration (vide registration number CTRI/2021/08/035683, accessible at www.ctri.nic.in). The first participant in the study was recruited and randomised after CTRI registration. Written informed consent was obtained from all patients for their participation in the study and for using their data for research and educational purposes. The study adheres to the principles of the Declaration of Helinski, 2013 and Good Clinical Practice guidelines. Patients were enroled from August 2021 to September 2022.

One hundred twenty patients of either gender, aged between 18 and 65, with American Society of Anesthesiologists (ASA) physical status I–II and scheduled for elective surgery under general anaesthesia requiring orotracheal intubation were included in the study. Patients with anticipated difficult airways, pregnant patients with a body mass index (BMI) >30 kg/m^2 and patients unwilling to consent were excluded from the study.

According to a computer-generated random numbers table (using https://www.graphpad.com), patients were assigned to one of three groups of 40 each: BlockBuster LMA group (Group BBLM), KVVL group (Group KVVL) or FIS group (Group FIS). Group allocations were then transferred to sequentially numbered, opaque, sealed envelopes.

All patients underwent thorough pre-anaesthetic check-ups, and height, weight and airway parameters were recorded. Standard monitors (Philips CM10 Multipara monitor, USA) were attached in the operating room, including a three-lead electrocardiogram, a pulse oximeter (peripheral arterial oxygen saturation) and a non-invasive blood pressure cuff. Patients were preoxygenated with 100% oxygen for 3 min using a facemask ventilation. Anaesthesia was induced with intravenous (IV) fentanyl 2 μg/kg and propofol 1–2 mg/kg (until the loss of verbal response). After confirming adequate bag-mask ventilation, IV vecuronium 0.1 mg/kg was administered for neuromuscular blockade. After 3 min, cervical spine immobilisation was achieved using MILS by the anaesthesiologist not involved in the study, standing towards the left and facing the patient. The patient's head and neck were placed in a neutral position by removing the pillow, so that the patient's shoulders and occiput rested on the operation table. Both mastoid processes were grasped by the thumb and palm placed on either side of the head, and the occiput was held firmly in the hands by the fingers to avoid axial traction by applying force equal and opposite to that created by the intubating anaesthesiologist.[8] Tracheal intubations were then performed by an experienced anaesthesiologist (>20 intubations with each device).

In Group BBLM, BlockBuster LMA size 3 (Tuoren Medical Instrument Co., Changyuan, China) was used for adults weighing 30 and 50 kg and size 4 for adults weighing 50 and 70 kg. A cuffed Parker flex-tip tube (7–8 mm internal diameter) was used for tracheal intubation. In Group KVVL, channelled KVVL (King Systems, Noblesville, IN, USA), size 3 and 4 blades were used. In Group FIS, an FIS, size 5.5 × 65 (Karl Storz, Tuttlingen, Germany), was used, and the tracheal intubation was performed via oral route with an intubating Ovassapian airway. A cuffed Portex tube (7–8 mm internal diameter) was used in Group KVVL and Group FIS.

For Group BBLM, device insertion time (DIT) was defined as the time elapsed from handling of the device till confirmation by capnography. IT was defined as the time elapsed from handling the tube until the intubation was confirmed by capnography after removing LMA. TTI was defined as the time elapsed from handling the device until the tracheal intubation was confirmed by capnography after removing LMA. For Group KVVL, DIT was the time from handling VL until optimal glottic visualisation was achieved. In contrast, IT was the time elapsed between glottic visualisation and confirmation of the intubation by capnography. TTI was considered as the time from handling VL until the confirmation of intubation by capnography. For Group FIS, DIT was the time taken from placing FIS at the level of the lip to visualising the carina. Capnography confirmed the time between visualising the carina and the successful placement of the endotracheal tube. TTI was the time taken from placing FIS at the lip level to the successful placement of the endotracheal tube.

A maximum of three intubation attempts with the study devices were allowed. In case of failed intubation, the choice of further intubation technique and device was at the discretion of the attending anaesthesiologist. One unsuccessful intubation attempt was defined as oesophageal intubation or elapsed time >180 sec or saturation drop below 95% or the decision of the intubating anaesthesiologist to call it a failed attempt before 180 sec because of trauma to the airway or the bloody screen of FIS or VL.

Mask ventilation was allowed between two intubation attempts to achieve an end-tidal oxygen concentration of 0.9. Blood staining on all three devices after removal was considered as mucosal damage.

IV neostigmine 0.04 mg/kg and glycopyrrolate 0.02 μg/kg antagonised the neuromuscular blockade. Postoperative sore throat and coughing were recorded 30 min after extubation in a postoperative care unit.

The study's primary outcome was comparing the total IT between the three devices. The secondary outcomes were comparing the first-attempt success rate, the number of intubation attempts required, and complications between the groups.

The sample size was estimated using the software G*Power version 3.1.9.2. In a study conducted by Yumul *et al*.,[9] the mean total IT of flexible fibreoptic scope was 99 [standard deviation (SD): 38]. Taking this as a reference value to detect an absolute difference of 25 sec in IT in a sample size of 36 patients per group was calculated to provide 80% power of the study and a 5% level of significance. Considering a 10% attrition rate, 40 patients in each group were recruited.

The data was entered in Microsoft Office Excel worksheet version 16.0 (Excel 2016) and analysed using Statistical Package for Social Sciences, version 25.0 (IBM, Inc., Chicago, IL, USA). The categorical variables (ASA, gender, modified Mallampati classification, upper lip bite test, first-pass success rate) were presented as numbers and percentages (%). The quantitative data [age, BMI, inter-incisor distance (IID), thyromental distance (TMD), DIT, IT, TTI] were presented as mean (SD) [95% confidence interval (CI)]. The Chi-squared test was used to test the statistical difference between categorical variables like gender and airway parameters. Normal data, such as intubation characteristics, was analysed using the one-way analysis of variance test, and the Kruskal–Wallis test was used for non-normal data, such as BMI and TMD. A probability of $P < 0.05$ was considered statistically significant.

RESULTS

The Consolidated Standards of Reporting Trials flow diagram in Figure 1 shows that 120 patients were included in the study without dropouts. Table 1 shows the demographic profiles and airway characteristics of all patients. In our research, tracheal intubation was successful in all 120 patients (100%).

There was a significant difference in the mean TTI between the groups [56.88 (SD: 14.38) (95% CI: 52.42, 61.33) sec in Group BBLM, 54.05 (SD: 14.72) (95% CI: 49.48, 58.61) sec in Group KVVL and 84.05 (SD:

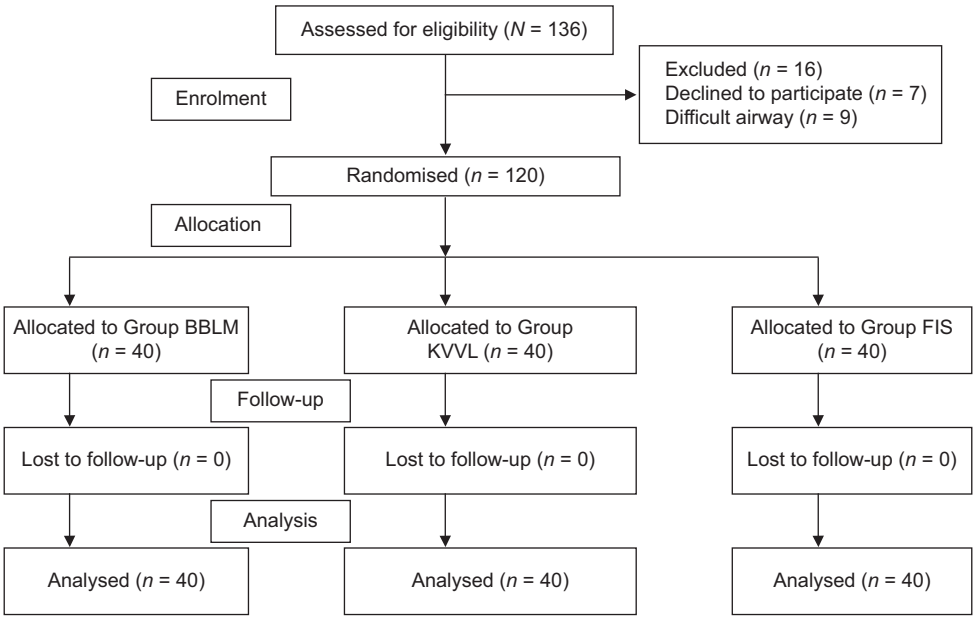

Figure 1: CONSORT flow diagram. BBLM = BlockBuster laryngeal mask airway, CONSORT = Consolidated Standards of Reporting Trials, FIS = flexible intubation scope, KVVL = King Vision video laryngoscope

Table 1: Demographic characteristics and airway parameters of the patients

Parameters	BBLM (n=40)	KVVL (n=40)	FIS (n=40)
Age (yr)	33.48 (10.42)	33.90 (11.52)	32.80 (8.41)
BMI (kg/m²)	23.17 (3.35)	24.93 (3.85)	23.22 (3.01)
ASA I/II	28 (70%)/12 (30%)	27 (67%)/13 (32%)	31 (77%)/9 (22%)
Gender M/F	8 (20%)/32 (80%)	12 (30%)/28 (70%)	10 (25%)/30 (75%)
MMC I/II	19 (47%)/21 (52%)	17 (42%)/23 (57%)	21 (52%)/19 (47%)
IID	4.61 (0.54)	4.68 (0.71)	4.85 (0.58)
TMD	10.72 (1.10)	10.31 (1.49)	10.99 (1.35)
ULBT I/II	24 (60%)/16 (40%)	22 (55%)/18 (45%)	24 (60%)/16 (40%)

Data expressed as mean (SD) or numbers (*n*) and percentage (%). ASA=American Society of Anesthesiologists, BBLM=BlockBuster laryngeal mask airway, BMI=body mass index, FIS=flexible intubation scope, IID=inter-incisor distance, KVVL=King Vision video laryngoscope, MMC=modified Mallampati classification, SD=standard deviation, TMD=thyromental distance, ULBT=upper lip bite test

27.50) (95% CI: 75.52, 92.57) sec in Group FIS, $P < 0.001$]. However, TTI was comparable in groups BBLM and KVVL ($P = 0.169$). The success rate of the first attempt was 75% in Group BBLM, 77% in Group KVVL and 82.5% in Group FIS (P 0.727) [Tables 2 and 3].

Complications like mucosal damage, oesophageal intubation and the incidence of sore throat and cough were comparable between the groups. The incidence of oesophageal intubation was maximum in Group BBLM (15%) compared to Group KVVL (7.5%) and Group FIS (2.5%), although the values were statistically insignificant ($P = 0.152$) [Table 4].

DISCUSSION

In our study, TTI was significantly longer in Group FIS. However, no significant difference was found in TTI between groups BBLM and KVVL.

In a study by Gercek *et al*.,[10] a longer time to intubation was reported for fibreoptic oral intubation than for intubating laryngeal mask airway (ILMA). However, studies comparing Fastrach ILMA with GlideScope, KVVL, Airtraq or CMAC video laryngoscope showed a significantly longer TTI in the ILMA group compared to the video laryngoscope group.[6,11-13] The probable reason for this difference could be that BlockBuster LMA was used in our study and not Fastrach ILMA. The faster intubation through BlockBuster LMA was because of its suitable anatomy and alignment of LMA with the glottic aperture, as the airway tube is >95° angulated and short, which aligns with the oropharyngeal curve. Moreover, Parker Flex, the inverted tip of the BlockBuster tube, helps to overcome the impingement of the tube to the anterior tracheal wall during intubation, which finds a way in the least resistant areas.[14]

Table 2: Comparison of intubation characteristics between the groups

Parameters	BBLM (*n*=40)	KVVL (*n*=40)	FIS (*n*=40)	*P*
DIT (sec)	18.70 (6.21) (16.77, 20.62)	16.10 (5.00) (14.55, 17.65)	63.62 (13.68) (59.38, 67.85)	<0.001
IT (sec)	38.12 (13.44) (33.95, 42.28)	37.17 (13.75) (32.90, 41.43)	24.82 (7.70) (22.43, 27.21)	<0.001
TTI (sec)	56.88 (14.38) (52.42, 61.33)	54.05 (14.72) (49.48, 58.61)	84.05 (27.50) (75.52, 92.57)	<0.001
Number of attempts (1/2/3)	30/8/2	31/9/0	33/6/1	0.970
First-pass success rate, *n* (%)	30 (75.0)	29 (77)	32 (82.5)	0.727

Data expressed as mean (standard deviation) (95% confidence interval) or *n*=numbers (percentage). BBLM=BlockBuster laryngeal mask airway, DIT=device insertion time, FIS=flexible intubation scope, KVVL=King Vision video laryngoscope, IT=intubation time, TTI=total time for intubation

Table 3: Pairwise comparison of intubation characteristics

	Pairwise comparison of subcategories of group	Adjusted *P*
DIT	BBLM–FIS	<0.001
	BBLM–KVVL	0.477
	KVVL–FIS	<0.001
Intubation time	BBLM–FIS	<0.001
	BBLM–KVVL	0.007
	KVVL–FIS	0.277
TTI	BBLM–FIS	<0.001
	BBLM–KVVL	0.169
	KVVL–FIS	<0.001

BBLM=BlockBuster laryngeal mask airway, DIT=device insertion time, FIS=flexible intubation scope, KVVL=King Vision video laryngoscope, TTI=total time for intubation

Table 4: Comparison of complications between the groups

Parameters	BBLM (*n*=40)	KVVL (*n*=40)	FIS (*n*=40)	*P*
Mucosal damage	9 (22.5)	7 (17.5)	6 (15)	0.855
Oesophageal intubation	6 (15)	3 (7.5)	1 (2.5)	0.154
Sore throat	5 (12.5)	4 (10)	3 (7.5)	0.318
Cough	4 (10)	4 (10)	6 (15)	0.823

Data expressed as numbers and percentages (%). BBLM=BlockBuster laryngeal mask airway, FIS=flexible intubation scope, KVVL=King Vision video laryngoscope

Chandy *et al*.[15] compared KVVL (channelled) and CMAC video laryngoscope in patients with cervical spine immobilisation and found TTI for KVVL to be 33.21 sec, compared to 54.05 sec found in our study. In the mentioned study, the total time was calculated from introducing the laryngoscope to visualising the black line on the endotracheal tube going past the cords. However, in the present study, the intubation was confirmed by the appearance of capnography on the monitor.

The high first-pass success rate of tracheal intubation by FIS was because tracheal intubation was performed under vision, unlike the Group BBLM, which is a blind endotracheal intubation method in our study. In Group KVVL, the reason for failure to intubate in the first attempt was poor visualisation of the glottis in three patients and inability to pass a tube through the glottis (impingement of tube on the arytenoid cartilage/aryepiglottic fold) in six patients. A multicentre study by Kleine-Brueggeney *et al*.[16] found an 87% first-attempt success rate with KVVL in patients with simulated immobilised cervical spine, compared to 77% found in our study. However, Patel and Desai[17] also reported a 70% first-attempt success rate with KVVL in patients with cervical spine instability. The first-attempt success rate of intubation by BBLM airway was 75% in our study with MILS, compared to 90% in the study by Endigeri *et al*.[5] and 94.5% in the study by Yuvaraj *et al*.[18] in patients with normal airways.

Intraoperative complications were comparable between the three groups. Our study's high incidence of mucosal damage was attributed to MILS, which decreases IID.[19] In this study, a channelled disposable blade of King Vision was used. Votruba *et al*.[20] compared non-channelled and channelled blades of KVVL in simulated cervical spine trauma and found that the channelled blade allowed faster intubation of the trachea. However, a recent review noted that although MILS was found to reduce cervical vertebral movement in uninjured volunteers, there are conflicting results in the presence of a cervical spine injury.[21]

The limitations of this study were that firstly, the observer recording the parameters and the anaesthetist providing MILS were not blinded to the device used in the study, so there could be bias. Secondly, the study was conducted in a simulated environment. Simulation might not reproduce the real scenario accurately, potentially affecting the study's external validity. Thirdly, the degree of cervical spine movement with the study devices was not assessed. Future studies with BlockBuster LMA and KVVL are warranted in patients with cervical spine injury to establish their clinical usefulness. Moreover, future research should consider using cervical collar's post-anaesthesia induction to improve clinical relevance and reproducibility.

CONCLUSION

This study showed that BlockBuster LMA and KVVL provide similar total time for intubation in patients

with simulated immobilised cervical spines. FSI takes longer than intubation through BlockBuster LMA or KVVL.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

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Conflicts of interest

There are no conflicts of interest.

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