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A study of Comparative efficacy of Double Lumen Tube and EZ Blocker for Lung Isolation Surgeries: A Randomized Comparative Study

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Abstract:

Background: Single Lung Ventilation or One-Lung ventilation (OLV) is often necessary for thoracic surgeries involving lung, esophagus, aorta, or mediastinum. Various airway devices, like DLTs and bronchus blockers, facilitate one lung ventilation, with DLTs being the most widely used globally. However, DLT intubation has drawbacks, prompting the development of bronchus blockers like EZ-Blocker. The EZ-Blocker features a Y-shaped design with cuffs on both ends, simplifying placement and reducing complications. Limited trials have compared EZ-Blocker to DLT or other blockers. This study aims to evaluate EZ-Blocker against DLT for Lung Isolation Surgeries in Indian settings, filling a gap in existing research.

Methods: 46 adult patients who had to undergo elective thoracic surgery requiring thoracotomy and SLV were included in this prospective, randomized, single-blinded study with blinding of the outcome assessor. Patients were randomly assigned to one of the 2 groups: DLT or EZ Blocker group. The time for placement of device, which included time for device preparation and time for placement of the device, was recorded along with the number of repositioning after positioning

of patient. After the surgery, the surgeon rated the quality of the collapse of lung and patient's sore throat, and hoarseness were recorded.

Results: The time for placement of DLT (170.47 sec) was significantly faster than EZ Blocker (230.7 sec), as was the time for successful intubation and time for preparation for DLT faster than EZ. Number of repositioning required were more in the EZ Blocker group (52.2%) compared to DLT Group (43.5%). Quality of lung collapse was rated better for DLT (60.9%) than EZ Blocker (39.2%) whereas post-operative complications of intubation were more in the DLT group owing to its larger external diameter.

Conclusion: EZ Blocker is a reliable option for single lung ventilation (SLV) during thoracic surgery, particularly in patients with limited mouth opening. Despite having fewer post-operative complications like sore throat and hoarseness compared to the DLT, the DLT outperforms the EZ Blocker in terms of preparation time, placement time, number of repositioning needed, and surgeon satisfaction score. Therefore, for lung isolation surgeries, the DLT is the preferred choice for achieving optimal one lung ventilation (OLV).

INTRODUCTION

Single Lung Ventilation or One-Lung ventilation (OLV) is often necessary for various thoracic procedures, including surgeries involving the lung, esophagus, aorta, or mediastinum. While not obligatory for every such procedure, OLV typically enhances surgical access and expedites the operative process. Consequently, due to advancements in anesthesiologist's proficiency in the insertion and monitoring of double-lumen tubes (DLTs), OLV is now commonly employed for nearly all thoracic surgeries involving lung manipulation or where collapsing the lung enhances surgical access. [1]

Various airway devices are available for establishing one lung ventilation during thoracic surgery, such as double-lumen intubation and bronchus blockers [2]. Among these, the double-lumen tube (DLT) technique is the most widely utilized globally [3-5]. However, DLT intubation presents certain drawbacks, including an elevated risk of airway trauma, challenges in proper sizing, and the need to replace it with a single-lumen tube (SLT) if post-operative ventilation is required in the intensive care unit (ICU). Compared to SLT intubation, DLT intubation is more demanding [3,6,7].

The limitations outlined have spurred the innovation of bronchus blockers (BBs). BBs like the Univent torque control blocker, the wire-guided Arndt endobronchial blocker, and the Cohen Flex-tip blocker are now being considered as substitutes for double-lumen tube (DLT) intubation. Alongside these established BB devices, the EZ-Blocker, endobronchial blocker (EZB) was introduced in clinical practice in 2010 [8-10]. Differing from traditional 'single-ended' BBs, the

'double-ended' EZB features a Y-shaped distal end mirroring the tracheal bifurcation, equipped with cuffs on both ends [11].

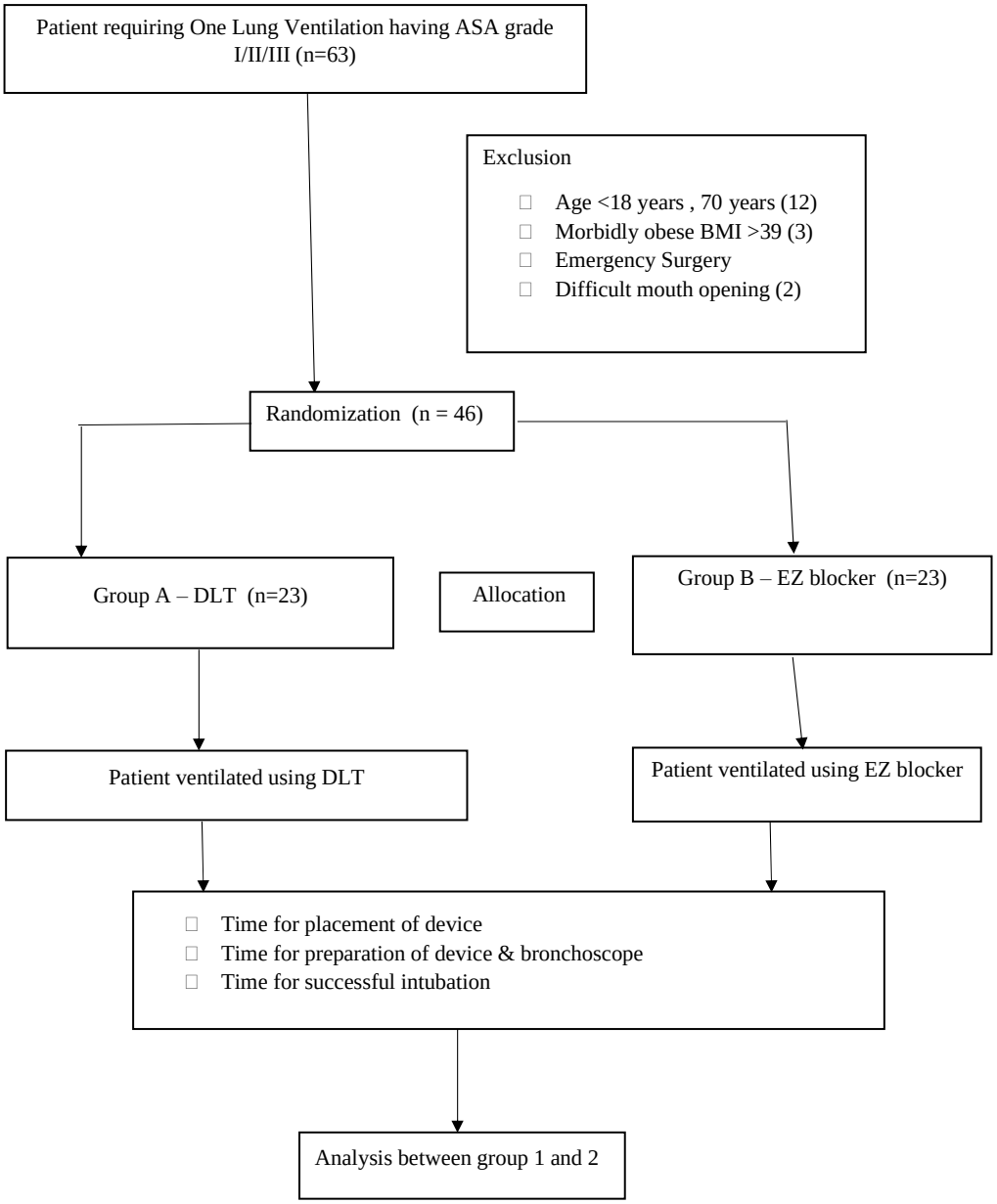
Achieving one lung ventilation involves either inflating or deflating the bifurcated cuffs positioned at the respective main bronchus of the left or right lung. The EZB is purportedly user-friendly, exhibiting a minimal occurrence of misplacement and fewer instances of displacement during repositioning and surgical manipulation [12,13]. Previous researchers have reported on the safe and straightforward utilization of the EZB [14]. Studies conducted previously have indicated that instances of severe trauma and significant complications, such as bronchial rupture, were infrequent when employing the EZB. To the best of our knowledge, only a limited number of trials have evaluated the efficacy of the EZB when compared to DLT or other bronchial blockers [15-18].

Prior investigations have examined the relative merits of Double Lumen Tubes (DLT) compared to Bronchial Blockers in various settings. However, there has been no such inquiry conducted within the Indian context to evaluate the effectiveness of DLT versus EZ Blocker. Consequently, this investigation was designed to contrast the clinical efficacy of EZ Blocker against DLT for Lung Isolation Surgeries in Indian settings.

MATERIALS & METHODS

The study was conducted in the operation theatre of General Surgery & Surgical Oncology, under the guidance of Department of Anesthesiology& Critical Care, King George’s Medical University, Lucknow after approval of the Institutional Ethics Committee, KGMU, Lucknow (Reg. No: ECR/262/Inst/UP/2013/RR-19) and registered at CTRI (CTRI/2023/08/057006) for a period of 1 year . After informed written consent, 46 adult patients undergoing elective thoracic surgery requiring thoracotomy and SLV (single lung ventlation)were included in this study.

Materials And Methods



Inclusion criteria were: ASA I/II/III, age >18 or < 70 years while Exclusion criteria were: BMI (body mass index)> 39, pregnancy, emergency status of surgery, difficult intubation, patient not giving consent.

Ours was a prospective, randomized, single-blinded study with blinding of the outcome assessor. Block randomization with variable block design was used for allocation in groups. Allocation was concealed using sequentially numbered opaque envelopes (SNOPES).The randomization of patients into groups (1:1) was based on computer-generated codes.

In the operating theatre, each patient was subjected to routine monitoring as per the American Society of Anesthesiologistsstandards, which encompassed non-invasive measurement of arterial blood pressure, monitoring of heart rate and electrocardiography (ECG), peripheral oxygen saturation (SpO2), and end-tidal carbon dioxide (EtCO2) levels. All patients were preoxygenated for at least 2 minutes with 100% Oxygen. Premedication was done with injection Fentanyl 2 mcg/kg. During the induction, patients from both groups were administered injection Propofol at a dosage of 2mg/kg and injection Vecuronium at 0.1 mg/kg. Approximately 4 minutes following the administration of the neuromuscular blocking agent, an intubation procedure was performed by a skilled anesthesiologist.

Patients allocated to the DLT cohort underwent intubation with a left-sided DLT, selecting a size that was suitable based on gender—35/37 French gauge (Fr) for women and 39/41 Fr for men. DLT was placed by conventional laryngoscopy with a fiberoptic bronchoscope in situ. As soon as the carina was visualized, DLT was rotated 90° to the left to place the bronchial cuff in the Left Main Bronchus and the tracheal cuff in the Trachea. Both cuffs were inflated sequentially, air entry was auscultated, and one lung ventilation was achieved.

Patients belonging in the EZ group were intubated with a single lumen tube of appropriate sizing (7.0/7.5 mm internal diameter (ID) for women and 8.0/8.5 mm ID for men) with a conventional direct laryngoscopy. The SLT was equipped with a multiport adapter, into which the EZB was introduced via one of the dual upper ports with its cuffs fully deflated. Concurrently, the Fiberoptic Bronchoscope was inserted through the alternate port of the same adapter. The EZ Blocker was advanced under bronchoscope guidance, placed at a position between the end of the ET tube and the tracheal carina, with the two distal ends of the EZ Blocker protruding and placed into the right and left main bronchus. The cuffs at the end of the EZ device were inflated while being watched closely to check that the device was working properly. They inflated each cuff one after the other, listened to the airflow, and managed to ventilate one lung successfully.

Parameters:

- Time for placement of device was defined as the composite sum of the time taken for device preparation, bronchoscope preparation and time for successful intubation of the patient.

- Time for device preparation was defined as the time taken before intubation for unpacking the devices, assembling required materials like syringes and clamps, and checking for patency of the cuff.
- Time for bronchoscope preparation was defined as the time taken for unpacking, assembling the bronchoscope as well as attaching suction and checking the working of the bronchoscope.
- Time for successful intubation was defined as the time taken from initiation of laryngoscopy to successful achievement of one lung ventilation.

The patient's head was gently secured, and their body was turned to lie on the side that corresponded with the lung being ventilated. During this repositioning, deflation of the EZ balloon or the cuffs of DLT was done to minimize the chance of injury-related complications.

If any discrepancy was faced during or after positioning of the patient, the device was repositioned and if repositioning was required, it was documented.

During SLV, the dependent lung was ventilated using pressure-controlled ventilation set to a peak pressure of 20–25 cm H2O and a positive end-expiratory pressure (PEEP) of 5 cm H2O. Whenever feasible, the end-tidal carbon dioxide (EtCO2) levels were maintained within a range of 40-45 mm Hg, and sevoflurane was utilized to sustain anesthesia, aiming for a mean alveolar concentration of 1.0.

Throughout the surgical procedure, the dosage of sevoflurane was regulated to ensure an adequate level of anesthesia. When single-lung ventilation (SLV) was necessary, either the EZ balloon or the bronchial cuff of the double-lumen tube (DLT) would be inflated. Following the incision into the pleura and a thorough inspection of the lungs, the thoracic surgeons assessed the degree of lung collapse, which is crucial for conducting non-traumatic surgery. The evaluations were categorized as: excellent (full collapse providing ideal surgical visibility), fair (complete collapse with minor remaining air in the lung), and poor (insufficient collapse, or incomplete collapse hindering the surgical process). Twenty minutes prior to the completion of the surgery, each patient was administered a 20 ml 0.25% intercostal nerve block by the surgeon, along with an intravenous dose of 1 gm Paracetamol. Post-surgery, patients were meticulously extubated either in the operating room or in the ICU, contingent upon meeting the criteria for extubation. A follow-up was conducted 24 hours post-surgery to monitor the occurrence and personal assessment of sore throat and voice hoarseness.

RESULTS

46 patients were enrolled in the study and were divided in 2 groups. Group 1 used DLT blocker for lung isolation surgeries, Group 2 used EZ Blocker for lung isolation surgeries.

TABLE NO.1

Average		Group 1 DLT Group (n=23)	Group 2 EZ Group (n=23)	t	P value
Weight		59.30±4.66	59.08±11.64	0.83	.934
Height		161.56±3.62	162.39±5.16	-.627	.534
BMI		22.70±1.39	23.29±2.12	-1.11	.272
Age		38.73±7.86	35.65±6.23	1.47	.147
Gender		Group 1 DLT Group (n=23)	Group 2 EZ Group (n=23)	p-value	
Male		17 (73.9%)	18 (78.3%)	1.000	
Female		6 (26.1%)	5 (21.7%)		
Variable			Group 1 DLT Group (n=23)	Group 2 EZ Group (n=23)	P value
ASA	1		8 (34.8%)	10 (43.5%)	.830
	2		9 (39.1%)	8 (34.8%)	
	3		6 (26.1%)	5 (21.7%)	
Mallampati score	1		12 (52.2%)	10 (43.5%)	.711
	2		8 (34.8%)	8 (34.8%)	
	3		3 (13.0%)	5 (21.7%)	
Cormack Lehane Grade	1		11 (47.8%)	12 (52.2%)	.530
	2A		8 (34.8%)	4 (17.4%)	
	2B		3 (13.0%)	5 (21.7%)	

	3	1 (4.3%)	2 (8.7%)	

Table no. 1 describes the shows the weight, height, BMI, age, gender distribution, ASA, Mallampati and Cormack Lehane Grade Distribution between the study participants in the two groups. Most of the study participants in group 1 and group 2 were males (73.9 % and 78.3 % respectively). There was no statistically significant difference between the study participants of group 1 and group 2 as far as gender is concerned (p=1.0000).

Out of all the study participants in group 1, 39.1% of the study participants had grade 2 ASA and out of all the study participants in group 2, majority (43.5%) of the study participants had grade 1 ASA. There was no statistically significant difference between the study participants of the two groups as far as ASA grade is concerned (p=0.830).

The Mallampati score of 1 was found amongst 52.2% of study subjects in group 1 and 43.5% in group 2. There was no statistically significant difference in the Mallampati score of the study participants between the two groups (0.711).

The Cormack Lehane Grade of 1 was reported amongst 47.8% and 52.2% of the study participants in the group 1 and group 2 respectively. There was no statistically significant difference in the Cormack Lehane Grade of the study participants between the two groups (0.530).

TABLE NO.2

Average	Group 1 DLT Group (n=23)	Group 2 EZ Group (n=23)	p-value
Placement time (sec)	170.47±20.43	230.7 ± 19.7	0.0001*
Preparation time (sec)	85.22±10.75	112.78±9.41	0.0001*
Time of successful intubation (sec)	85.26±18.50	117.91±15.87	0.0001*

Table number 2 shows the different outcome variables assessed between the study participants in the two groups. The mean±SD placement time was 170.47 ±20.43 seconds and 230.7 ± 19.7 seconds amongst the study participants in group 1 and group 2 respectively. This difference in the placement time of the study participants in the two groups was highly statistically significant (p=0.0001

The mean±SD of Preparation time was 85.22 ± 10.75 seconds amongst the study participants of group 1 and 112.78 ± 9.51 seconds amongst the study participants of group 2. This difference in the Preparation Time was statistically significant between the study participants of the two groups (p=0.0001)

The mean±SD of Time for Successful intubation was 85.26 ± 18.50 seconds amongst the study participants of group 1 and 117.91 ± 15.87 seconds amongst the study participants of group 2. The difference in the Time for Successful intubation between the study participants of the two groups was statistically significant (p=0.0001)

The time duration (mean±SD) for device preparation was 50.47 ± 9.20 seconds and 75.34 ± 8.04 seconds amongst the study participants in group 1 and group 2 respectively. There was a statistically significant difference between the study participants in the two groups as far as time for device preparation was concerned (p=0.0001).

The time duration (mean±SD) for bronchoscope preparation was 34.74 ± 6.20 seconds and 37.44 ± 4.29 seconds amongst the study participants in group 1 and group 2 respectively. There was no statistically significant difference between the study participants in the two groups as far as duration for bronchoscope preparation was concerned (p=0.094).

At least one repositioning of double lumen endotracheal tube (Table no.3) was required amongst 43.5% and amongst 52.2 % of the study participants of group 1 and group 2 respectively. There was statistically significant difference between the study participants of both the groups as far as repositioning of tubes was concerned (p=0.033).

TABLE NO.3

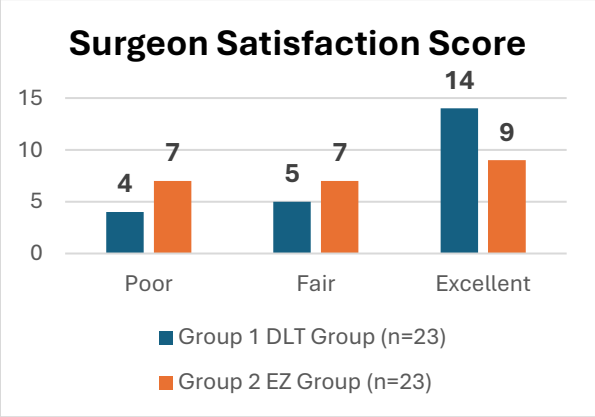
Variables		**Group 1 DLT Group (n=23)**	**Group 2 EZ Group (n=23)**	**p-value**
Repositioning required	**NO**	13 (56.5%)	11 (47.8%)	**0.033**
	YES	10 (43.5%)	12 (52.2%)	

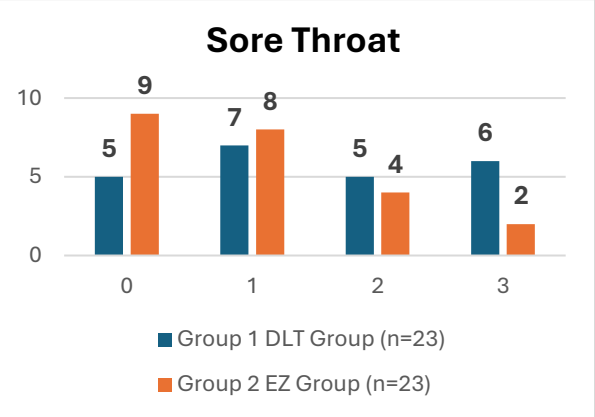
Out of all the study participants in group 1, the surgeon satisfaction score (Table no.4)was excellent for 60.9% of the study participants in group 1 and for 39.2% of the study participants in group 2. However, this difference of surgeon satisfaction score between the two groups of study participants was

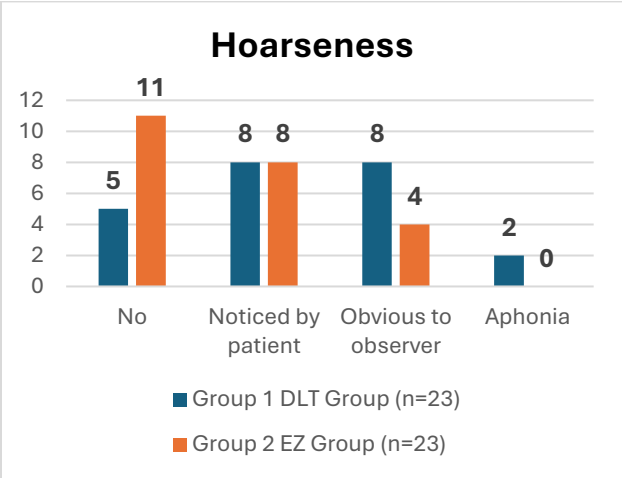
statistically significant (p=0.026).

TABLE NO.4

Variables		**Group 1 DLT Group (n=23)**	**Group 2 EZ Group (n=23)**	**p-value**
Surgeon Satisfaction Score	**Poor**	4 (17.4%)	7 (30.4%)	0.026*
	Fair	5 (21.7%)	7 (30.4%)	
	Excellent	14 (60.9%)	9 (39.2%)	







Most of the patients of group 1 had mild symptoms of sore throat (grade 1) (30.4%) followed by severe symptoms of sore throat (grade 3) (26.1%). 21.7% of group 1 had moderate (grade 2) sore throat. Most patients in group 2 had no symptoms (grade 0) of sore throat (39.1%) followed by 34.8% patient who had mild symptoms of sore throat (grade 1). There was statistically significant difference between the sore throat grading of the study participants in the two groups (p=0.035)(Table no.5)

TABLE NO.5

Sore throat Score	**Group 1 DLT Group (n=23)**	**Group 2 EZ Group (n=23)**	**p value**
0	5 (21.7%)	9 (39.1%)	**0.035***
1	7 (30.4%)	8 (34.8%)	
2	5 (21.7%)	4 (17.4%)	
3	6 (26.1%)	2 (8.7%)	

A majority (34.8%) of the study participants in group 1 had hoarseness which was noticed by patient and same percentage of patients had hoarseness obvious to observer. No hoarseness of the voice was noticed by 21.7% of the study participants in group 1 (Table no.6)

TABLE NO.6

Hoarseness	**Group 1** **DLT Group** **(n=23)**	**Group 2** **EZ Group** **(n=23)**	**p value**
No	5 (21.7%)	11 (47.8%)	**0.014***
Noticed by patient	8 (34.8%)	8 (34.8%)	
Obvious to observer	8 (34.8%)	4 (17.4%)	
Aphonia	2 (8.7%)	0 (0.0%)	

Out of all the study participants in the group 2, 47.8% of the study participants noticed no hoarseness of voice, 34.8% of the study participants had hoarseness which was only noticeable by the patient followed by 17.4% who had hoarseness obvious to observer. 0% had aphonia in group 2.

There was statistically significant difference between the study participants of the two groups as far as hoarseness of voice was concerned (p=0.014).

DISCUSSION

A variety of surgical interventions necessitate the use of general anesthesia alongside one-lung ventilation. This is particularly true for thoracic surgeries that employ progressively less invasive methods, such as video-assisted thoracoscopic surgery (VATS), as well as certain cardiac procedures. Notably, minimally invasive cardiac surgeries (MICS) often utilize the mini-thoracotomy approach. [19, 20]. One-lung ventilation is additionally employed in certain procedures involving the thorax, vascular system, and esophagus. [21,22].

Minimally invasive methods offer numerous advantages to patients, and dependable one-lung ventilation (OLV) is crucial. Thoracic surgeries are especially significant due to their unique

anesthetic requirements. These include ensuring that one lung is ventilated while adequately collapsed, a goal attained through specialized airway management techniques that involve specific endotracheal tubes and bronchial blockers. [23-27]

In this study we studied the efficacy of EZ Blocker compared with Double Lumen Tube for One-lung ventilation in Lung Isolation Surgeries. The study groups' demographic characteristics were comparable in terms of age, sex, weight, height, BMI, ASA Grade & Mallampati Score.

Time for placement of device was defined as the time from preparation of device as well as bronchoscope through laryngoscopy to confirmation of DLT/EZ Blocker placement via fiberoptic bronchoscope, the latter half of which, from the point of laryngoscopy to confirmation of device, was defined as time for successful intubation.

The time for placement of the device and the time for successful intubation was significantly faster in the DLT group (170 seconds) as compared to the EZ group (230 seconds) in our study. Similar finding was observed in a study by Ruetzler K et al., [18] which also reported significantly faster placement of DLT (85 ±55 sec) than using EZ (192 ±90 sec). Different research indicated that the duration for achieving successful intubation was considerably less in the EZB group, averaging 47 seconds (ranging from 35 to 65 seconds), compared to 69 seconds (ranging from 55 to 97 seconds) in the DLT group, with the difference being statistically significant (P=0.001). [28]

In a previous study by Campos and Kernstine, [30] Initial tube placement (ITP) for the DLT group took 128 s while for Univent Bronchial blocker (BB) it was 158 s and for Arndt BB the time was 214 s. In another study, ITP of EZ took 192 s and DLT took 85 s. [18] Henceforth, EZ tube placement time was similar as long as for Arndt and Univent BB, the difference doesn't seem to be clinically significant. Mungroop HE et al., [29] reported a mean time for EZ placement of 70 s. The disparity in intubation times can likely be attributed to the varying levels of expertise among the anesthesiologists, a sentiment echoed by Campos JH et al. [30]

In a study by Narayanaswamy M et al, it was observed that three different bronchial blockers (BBs) were just as effective as the left-sided double-lumen tubes (DLT) during procedures such as left-sided open surgeries or video-assisted thoracoscopic surgeries (VATS). The study also noted that the insertion of a BB took more time and needed more adjustments during the operation than the DLT, a result that aligns with our own observations. [31]. In a systematic review, reported that the time required to place the device in the correct position was not significantly different (RR, 0.06; P=0.91). [32]

Our study revealed that the requirement of at least 1 repositioning was more in the EZ group than the DLT group. In another study, [28] Repositioning was necessary in 10.5% of cases (4 out of 38) within the DLT group and 16.6% (6 out of 36) in the EZB group. In the EZB group, five patients experienced insufficient lung collapse, leading to failed repositioning efforts and the

subsequent need for DLT insertion. These five instances that switched to DLT subsequently demonstrated satisfactory one-lung ventilation. When lung collapse was sufficient and the DLT or EZB was correctly positioned, there were no further intraoperative dislocations reported in either group. [28]

Risse J et al., [28] found that the preparation time was significantly longer in the EZB group with 119 s [95 to 149] compared to the DLT group 76 s [64 to 111] (P=0.001). We also found a similar finding where preparation time for DLT group and EZB was significantly higher in the EZ group. Same significance was observed in time for device preparation, but the bronchoscope preparation time was comparable in both groups.

Similar to our study, where time duration (mean±SD) of one lung ventilation was 67.78 ± 18.17 minutes and 61.70 ± 12.70 minutes amongst the study participants in group one and group two respectively (p value<0.05), Risse et al, also found the times for correct one lung ventilation after intubation did not differ between the two groups. [28]

This study showed that out of all the study participants in group 1, the surgeon satisfaction score was excellent for 60.9% of the study participants in group 1 and for 39.2% of the study participants in group 2. Ruetzler et al. [18], also reported surgeon satisfaction. Surgical field and the quality of lung collapse using DLT were rated 1.3 (0.6) and EZ was rated 1.4 (0.6) (P=0.681).

In a study by Campos JH et al., [30] surgeons rated the lung collapse and described better results for DLT than the tested BB, while lung collapse in study of Risse j et al., [28] was achieved equally well using DLT and EZ.

Sore Throat and Hoarseness are well-known postoperative complaints, especially after tracheal intubation.[33] EZ group showed more number patients which had no symptom of sore throat and hoarseness. Severe sore throat and hoarseness obvious to observer were mostly seen in DLT group.

Approximately half of the patients experienced hoarseness following tracheal intubation. [34, 35] It was demonstrated that the tracheal tube size is a common risk factor for higher incidence of ST and hoarseness. [18] The wide range of incidence could be attributed to the variability of skill and experience levels of the performing anesthesiologist. In a recent study by Zhong T et al., [7] the incidence of ST of different BB was assessed (Coopdech 13%, Arndt 20%, and Univent 30%).

Interestingly, Reutzler et al., [18] no notable variances were observed in the occurrence of sore throat (ST) and hoarseness. This could be because a single skilled anesthetist carried out all the intubations in their research. In multiple clinical scenarios, intubation with DLT was apparently difficult and not uncommonly impossible. [36, 37] In these situations, Campos [30] commented that the safest alternative to accomplish SLV in an anticipated or known difficult airway is the combination of SLT and any of the independent BBs. Campos JH, [30] emphasized the

significance of the practitioner's proficiency with either the double-lumen tube (DLT) or bronchial blocker (BB), irrespective of which is used.

Ruetzler K et al., [18] also revealed on the day after surgery, the occurrence of sore throat (ST) was observed in 45% of the cases using a double-lumen tube (DLT), which equates to 9 out of 20 instances, and 47% in the EZ blocker group, or 9 out of 19 cases. The perceived severity of the sore throat did not show a significant difference between the two, with the DLT group averaging 1.3 (with a standard deviation of 0.5) and the EZ group averaging 1.2 (with a standard deviation of 0.4), (P=0.649). A systematic review and meta-analysis by Xiang et al., [32] revealed Three RCTs (n=154) recorded the incidence of postoperative sore throat. [38-40]. The incidence rate of postoperative sore throat was found to be lower among patients treated with BB than with DLT (OR 5.23; 95% CI, 2.55 to 10.75; I2=0%; P<0.00001). Risse et al., [28] also reported that sore throat (P=0.009) and hoarseness (P=0.02) were significantly lower in the EZB group.

CONCLUSION

In conclusion, although requiring comparatively more time for placement and being slightly more expensive, the EZ is an effective, successful, and easy-to-use airway device under bronchoscope guidance that provides SLV to enable thoracic surgery, especially in patients with restricted mouth opening. EZ Blocker has lesser post-operative complications of Sore Throat and Hoarseness than DLT, however the Preparation Time, Placement Time, Number of repositioningrequired and Surgeon Satisfaction Score were far better in the DLT making DLT the better clinical performer and cost-effective device to attain one lung ventilation (OLV) for Lung Isolation Surgeries.

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