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Comparison of fiberoptic bronchoscopic intubation using silicone and polyvinyl chloride double-lumen tubes

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Background: Direct insertion of a double-lumen tube (DLT) using a flexible fiberoptic bronchoscope (FOB) is an option for DLT intubation. The difficult process of fiberoptic intubation is that the different properties of polyvinyl chloride and silicone DLTs may affect railroading differently. Therefore, we aimed to compare intubation using polyvinyl chloride and silicone DLTs over an FOB.

Methods: Patients aged 19–75 years who required one-lung ventilation under general anesthesia were enrolled in this study. After induction of anesthesia, the anesthesiologist intubated the DLT using FOB. The primary outcome was the difficulty of railroading over the flexible FOB scaled into five grades (I, II-1, II-2, III, and IV). Additionally, the intubation time and mucosal damage were recorded.

Results: A total of 46 patients participated in this study, 23 each in the silicone and polyvinyl groups. The difficulty of railroading over the FOB was significantly different between the two groups (P < 0.001). In the silicone group, the grades of difficulty in railroading were limited to I and II-1; 20 patients (87%) presented no difficulty in advancing the tube. In contrast, in the polyvinyl group, 13 patients (57%) had scores of II-2 and III. Both the intubation time and mucosal damage were significantly better in the silicone group than in the polyvinyl group.

Conclusions: Intubation using a silicone DLT over an FOB was easier and faster than that with a polyvinyl chloride DLT with lesser trauma around the glottis.

Keywords: Airway management; Bronchoscopes; Intratracheal intubation; One-lung ventilation; Polyvinyl chloride; Silicones; Thoracic surgery.

Introduction

One-lung ventilation is a standard approach to improve the surgical field during thoracic surgery [1,2]. A double-lumen tube (DLT), a bronchial blocker, or a single-lumen tube inserted beyond the carina can be used in clinical practice. Among them, DLT is the most preferred method for video-assisted thoracic surgery, in which a clear surgical exposure is essential for surgical success [1,3]. Other advantages of DLTs include rapid deflation, less need for repositioning, and ease of suctioning and application of continuous positive airway pressure via the dependent lung [4–6]. However, in clinical cases that are expected to have difficulty in airway management, intubation with DLT is challenging for anesthesiologists.

Fiberoptic intubation has played a major role in the management of difficult airways in

awake, sedated, and anesthetized patients [7,8]. Therefore, direct insertion of a DLT via a flexible fiberoptic bronchoscope (FOB) could be attempted in a patient with a difficult airway. Haitov et al. [9] showed that DLT insertion via FOB was simple and safe in five cases with difficult airways. Shulman et al. [10] also reported direct fiberoptic intubation using a shortened DLT in a case where intubation using various laryngoscope blades failed. However, owing to the intuitive characteristics derived from polyvinyl chloride DLTs, such as a large shaft, long length, and low flexibility, the assumption that direct insertion of a DLT via an FOB is difficult and traumatic has long been accepted [11-17], but no comparative studies have proved this concept. In a recent study, a silicone DLT was inserted directly through an FOB as easily as a single-lumen tube and with easier railroading than with the single-lumen tube [18]. The silicone DLT has a less rigid shaft and wire spiral imbedded bronchial lumen and therefore increased flexibility compared to that of a polyvinyl chloride DLT [19]. However, to date, the outcomes of polyvinyl chloride and silicone DLTs with similar large shafts and long lengths that can be used for fiberoptic intubation have not been compared.

Therefore, we aimed to compare direct intubation using polyvinyl chloride and silicone DLTs over an FOB in patients requiring one-lung ventilation.

Materials and Methods

This study was approved by the Ethics Committee of the Ajou University Hospital (AJIRB-DEV-THE-18-440) and registered at clinicaltrials.gov (NCT03889847) and was conducted for about a year from March 2019 to February 2020. Written informed consent was obtained from all patients participating in this study. This study was conducted in accordance with the Helsinki Declaration 2013. Patients aged 19-75 years with American Society of Anesthesiologist physical status (ASA PS) class I or II who required one-lung ventilation under general anesthesia during elective surgery were enrolled in this study. Patients with upper respiratory tract malformations or tumors, history of gastroesophageal disease, risk of lung aspiration, or body mass index > 35 kg/m² were excluded. Patients were allocated into two groups, a polyvinyl chloride-based DLT group (polyvinyl group) and a silicone-based DLT group (silicone group), using a computer-generated random number. A colleague who was not associated with this study conducted this process with PASS 14 (Power Analysis and Sample Size Software 2015, NCSS, LLC, USA) with a 1:1 allocation ratio. Randomized results were revealed by calling in the operating room immediately before induction of anesthesia. In the polyvinyl group, a ShileyTM DLT (Covidien, USA) was used,

and in the silicone group, HumanBroncho® (Insung Medical, Korea) was used. In both groups, 35 and 37 Fr-sized left-sided DLTs were used for women and men, respectively, and a 4.1-mm flexible FOB (PortaView® LF-GP; Olympus Optical Company, Japan) was used. Before intubation, the flexible FOB was thoroughly lubricated with water-soluble gel lubricant (Ester Cosmetics, Korea) and inserted into the bronchial lumen of the DLTs.

Upon arrival in the operating room, the patient underwent bispectral index monitoring, electrocardiography, noninvasive blood pressure monitoring, and pulse oximetry. After pre-oxygenation, anesthesia was induced with fentanyl (1-1.5 μg/kg) and thiopental (4-5 mg/kg). After loss of consciousness, the patient was ventilated with sevoflurane in oxygen and rocuronium (0.6 mg/kg) was administered. Two minutes after injecting rocuronium, the inter-incisor distance (mouth opening) and thyromental distance were measured, and the modified Cormack-Lehane grade was determined using a direct laryngoscope [20]. The assistant opened the patient's mouth and applied jaw thrust by hand, and the anesthesiologist performed tracheal intubation using a flexible FOB with a DLT inserted. After positioning the tip of the flexible FOB above the carina, the DLT was advanced over the flexible FOB (railroading over the FOB). After placing the DLT in the final position, the flexible FOB was withdrawn from the bronchial lumen and reinserted into the tracheal lumen to confirm correct positioning of the DLT. After successful intubation with DLT, anesthesia was maintained using sevoflurane in a 50:50 air-oxygen mixture. The FOB was inserted into the mouth and tracheal lumen to check for mucosal damage around the glottis and the presence of blood inside the tube or trachea, respectively.

Intubation-related times were defined as follows: the time to FOB insertion was the time from the moment the FOB passed the incisors until its tip was positioned above the carina, railroading time was the time from the moment the FOB was positioned above the carina until the tip of the DLT was positioned above the carina and not at the final position of the DLT, the time to tracheal intubation was the sum of the time to FOB insertion and railroading time, and the total time for correct tube positioning was the time from FOB passing the incisors until DLT placement in the correct mainstem bronchus. All intubation procedures were performed by a skilled anesthesiologist, who was familiar with tracheal intubation, using a flexible FOB and recorded by another anesthesiologist using a video camera.

The difficulty of railroading over the FOB was scaled into five grades: I, no difficulty in advancing the tube; II-1, blocked while advancing the tube, withdrawn, and rotated 90° counter-clockwise; II-2, blocked despite 90° counter-clockwise rotation, re-rotated 120° counter-clockwise; III, blocked despite 120° count-

er-clockwise rotation for more than one manipulation including clockwise rotation, re-rotation, and external laryngeal manipulation, and IV, direct laryngoscopy was required [18].

Extubation was performed after surgery, and the blood staining of the DLT (blood-stained tube) was recorded. The patient was moved to the post-anesthesia care unit, and sore throat, swallowing difficulty, and hoarseness were checked before transfer to the ward.

The primary outcome in this study was the difficulty of rail-roading over a flexible FOB between the two groups. The sample size was calculated based on preliminary data from our hospital, in which the incidence of easy railroading (grade I) was 50% for polyvinyl chloride-based DLTs and a recent study in which it was 87.5% for silicone-based DLTs [18]. With 95% CI and 80% power, the minimum sample size required per group was 23. Therefore, a total of 46 patients were recruited. The secondary endpoints were as follows: time to FOB insertion; railroading time; time to tracheal intubation; total time for correct tube positioning; mucosal damage; blood-stained tube; and sore throat, difficulty in swallowing, and hoarseness in the post-anesthesia care unit.

Data were analyzed using the Statistical Package for Social Sci-

ences software (version 20.0; SPSS®, IBM Corp., USA). The data were tested for normality using the Kolmogorov–Smirnov normality test. Continuous data were analyzed using an independent t-test or Mann–Whitney U test as appropriate. Categorical data were analyzed using the Chi-square test or Fisher's exact test. The difficulty of railroading over a flexible FOB was analyzed using asymptotic Pearson's chi-square test or Fisher–Freeman–Halton's exact test, as appropriate. The level of significance was set at P < 0.05.

Results

A total of 53 patients were screened, of whom five refused to participate and two did not meet the inclusion criteria (Fig. 1). Finally, 46 patients were enrolled in this study. There was no statistically significant difference between the two groups regarding demographic and airway assessment data, such as thyromental distance, mouth opening, and modified Cormack–Lehane grade (Table 1). All patients were successfully intubated using an FOB in the first attempt.

The fiberoptic intubation data are presented in Table 2. The dif-

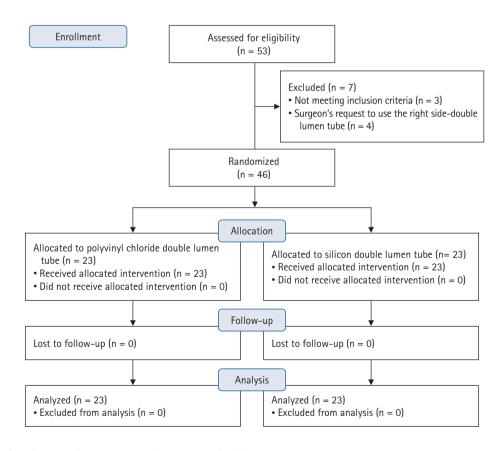


Fig. 1. CONSORT flow diagram of recruitment and assessment of study participants.

Table 1. Patient Characteristics and Airway Assessment Results

Variable	Polyvinyl group (n = 23)	Silicone group $(n = 23)$	P value
Age (yr)	38 (22, 58)	47 (41, 61)	0.214
Sex (M/F)	15/8	17/6	0.522
Weight (kg)	63.1 ± 11.3	65.2 ± 12.5	0.537
Height (cm)	168.3 ± 9.1	166.7 ± 8.5	0.526
ASA PS (I/II)	18/5	15/8	0.514
Thyromental distance (cm)	5.6 ± 0.8	5.7 ± 0.8	0.544
Mouth opening (cm)	4.6 (4.1, 5.0)	4.4 (4.0, 4.5)	0.168
C-L grade (I/II-1/II-2/III/IV) by direct laryngoscope	12/2/7/2/0	13/4/4/2/0	0.767

Values are presented as median (Q1, Q3), numbers or mean \pm SD. Polyvinyl group: tracheal intubation over FOB using a polyvinyl chloride DLT, Silicone group: tracheal intubation over FOB using a silicone DLT. FOB: fibeoptic bronchoscope, DLT: double lumen tube, ASA PS: American Society of Anesthesiologist physical status, C-L grade: modified Cormack-Lehane grade.

Table 2. Fiberoptic Intubation Data

Variable	Polyvinyl group $(n = 23)$	Silicone group ($n = 23$)	Median difference (95% CI)	P value
FOB insertion time (s)	9 (7, 10)	9 (8, 10)	0 (-2, 1)	0.409
Railroading time (s)	15 (9, 17)	7 (6, 9)	7 (4, 9)	< 0.001
Time to tracheal intubation (FOB insertion time plus railroading time; s)	23 (19, 28)	16 (16, 18)	6 (4, 10)	< 0.001
Total time for correct tube positioning (s)	39 (32, 44)	27 (26, 35)	9 (5, 14)	< 0.001
Difficulty of railroading (I/II-1/II-2/III/IV)	9/1/1/12/0	20/3/0/0/0		< 0.001
Blood-stained tube during intubation (Y/N)	16/7	2/21		< 0.001
Blood-stained tube during extubation (Y/N)	11/12	3/20		0.023
Sore throat (Y/N)	7/16	5/18		0.738
Difficulty swallowing (Y/N)	6/17	2/21		0.243
Hoarseness (Y/N)	2/21	3/20		> 0.99

Values are presented as median (Q1, Q3) or numbers. Polyvinyl group: tracheal intubation over FOB using a polyvinyl chloride DLT, Silicone group: tracheal intubation over FOB using a silicone DLT. FOB: fibeoptic bronchoscope, DLT: double lumen tube.

ficulty of railroading over the FOB was also significantly different between the two groups (P < 0.001). In the silicone group, the grades of difficulty of railroading were limited to I and II-1; 20 patients (87%) presented no difficulty in tube advancement and in the remaining three patients (13%), railroading was achieved by 90° counter-clockwise rotation. In contrast, in the polyvinyl group, 13 patients (57%) had a score of II-2 or III; in one patient, railroading was achieved by 120° counter-clockwise rotation, and 12 patients required more than one manipulation, including clockwise rotation, re-rotation, and external laryngeal manipulation, for railroading. However, direct laryngoscopic aid (grade IV) was not required.

The time to FOB insertion was comparable between the groups (P = 0.4). However, the railroading time over the FOB was significantly shorter in the silicone group than in the polyvinyl group (median difference, 7 s; P < 0.001). Consequently, the time to tracheal intubation (the time to FOB insertion plus railroading time) and the total time for correct tube positioning were significantly

shorter in the silicone group than in the polyvinyl group (median difference, 6 s; P < 0.001 and 9 s; P < 0.001, respectively).

The mucosal damage assessed using a bronchoscope around the glottis and inside the tube lumen immediately after intubation and the mucosal damage assessed as blood on the tube after extubation were significantly lesser in the silicone group than in the polyvinyl group (P < 0.001 and P = 0.023, respectively). In contrast, the incidence of hoarseness, sore throat, and difficulty in swallowing in the post-anesthesia care unit was not significantly different between the two groups.

Discussion

In this study, silicone DLTs showed superior performance compared to polyvinyl chloride DLTs with regard to the difficulty of railroading over an FOB. In addition, the railroading time, time to tracheal intubation, and total time for correct tube positioning were also significantly shorter with the silicone DLT than with the

polyvinyl chloride DLT. Moreover, the silicone group showed significantly lesser trauma around the glottis than the polyvinyl chloride group.

With regard to intubation over an FOB, there are two difficult processes: FOB insertion into the trachea and railroading of the tube through the vocal cords [17]. The difficulty associated with FOB insertion into the trachea can be solved by creating space in the oropharynx by jaw thrust, head extension, or tongue traction [17]. In this study, the jaw-thrust maneuver was routinely used, and this process was performed without any difficulty. The only difference from the single-lumen tube in this process was that in the case of DLT, the tip of the bronchial lumen entered the oropharynx owing to the greater length of the DLT that did not interfere with the manipulation of the FOB into the trachea. The major difference between silicone and polyvinyl chloride DLTs is their flexibility. This difference in flexibility did not affect the time from FOB passing the incisor to the positioning of the tip of the FOB above the carina. However, it influenced the railroading of the tube through the vocal cord.

Silicone DLTs showed better railroading during fiberoptic intubation, with better railroading difficulty scores, and lesser railroading time. The major reason for the difficulty in railroading is that the tube tip does not follow the course of the FOB and tends to move posteriorly; therefore, it impinges on the structures around the glottis, such as the arytenoid cartilage or esophageal inlet [17]. To overcome this difficulty, the suggested methods related to the characteristics of the endotracheal tube are the reduction of the gap between the FOB and the tube and the use of flexible tubes [17]. The bronchial lumens of both types of DLTs, where the FOB (4.1 mm) enters and determines the gap between the bronchoscope and tracheal tube, are non-beveled, oval, obtuse, and have a small internal diameter (silicone DLT, 37 Fr 4.9/7.5 mm, 35 Fr 4.5/7.0 mm; polyvinyl chloride DLT, 37 Fr 5.1/7.6 mm, 35 Fr 4.8/7.0 mm). The bronchial lumen of the silicone DLTs in this study had a smaller internal diameter than that of the polyvinyl chloride DLTs. Through comparative studies between single lumen tubes of 6.0 and 8.0 mm and FOBs of 3.7 and 5.0 mm [21,22], it is generally known that the smaller the gap between the tube and the bronchoscope, the easier the railroading, but how much gap makes a clinical difference is unclear. In a simulator study of tube exchange with DLTs using an airway exchanger catheter, there was no difference in railroading between polyvinyl chloride DLTs with different bronchial lumen sizes (37 Fr 4.4/6.8 mm vs. 37 Fr 5.1/7.6 mm), and in fact, silicone DLTs (37 Fr 4.9/7.5 mm) which have the size between the two previously mentioned tubes showed significantly easier railroading [19]. In other words, in this study, the 0.1-0.3 mm gap between the DLT and bronchoscope, owing to differences between manufactures, is thought to have little clinical significance. Although DLTs have a larger shaft diameter than single-lumen tubes, a smaller bronchial diameter is advantageous for direct intubation via a flexible FOB [18]. However, the difference in flexibility caused by the tube material (polyvinyl chloride vs. silicone) and wire-reinforced bronchial tip (only in silicone DLTs) seems to have had a major impact on the railroading performance. Being flexible allows the endotracheal tube to change its direction according to the curve of an orally inserted FOB [17,18,23,24]. As expected, no difficulty in advancing the tube was observed in 87% of patients in the silicone group (vs. 39% in the polyvinyl chloride group), and in the remaining three patients, railroading was achieved by only 90° counterclockwise rotation. In the polyvinyl chloride group, other methods to overcome railroading difficulties, such as several large-angle re-rotations or external laryngeal manipulation, were frequently required and required more time. However, direct laryngoscopic aid was not required, and all patients were successfully intubated in the first attempt. In this study, silicone DLTs could overcome the longheld belief that direct intubation of the DLT over an FOB is difficult and traumatic [11-17,25].

The aforementioned railroading difficulty is closely associated with the risk of mucosal damage to the glottis and surrounding tissues [17]. Resistance while advancing the tube over an FOB indicates collision of the DLT with the tissue around the glottis that may lead to bleeding [17]. We used a bronchoscope inserted via the mouth and inside the tube to check for a blood-stained mucosa and blood-stained tube immediately after intubation; additionally, the tube was inspected after extubation. As expected, significantly less mucosal damage was observed in the silicone group than in the polyvinyl chloride group at both time points. Although not clinically significant in this study, the use of a flexible tube should be actively considered so that bleeding due to mucosal damage does not make the airway more difficult when intubation is attempted in a difficult airway.

Complications, such as hoarseness, sore throat, and difficulty in swallowing, observed in the post-anesthesia care unit did not differ between the two groups. These complications are related to airway damage [26,27]; thus, the softer silicone DLTs have the potential to reduce the incidence of these side effects. However, in this study, there was no significant difference between the groups. This could be because, in addition to airway damage that occurs during intubation, many other factors such as cuff pressure, tube size, duration of surgery, and sex influence results [26], and the number of patients studied was small.

This study had some limitations. First, although the group allocation was randomized, a bias may have occurred during induction because the practitioner knew the group prior to tracheal intubation. Second, tracheal intubation over the FOB was performed in normal airways during elective surgery. The effect of tube characteristics on intubation over an FOB is expected to be maintained to some extent even in difficult airways; however, further studies are needed to verify the clinical effect in difficult airways.

In conclusion, direct insertion of DLTs over an FOB is a feasible option for patients requiring one-lung ventilation. Insertion of silicone DLTs over the FOB was easier and faster than that of polyvinyl chloride DLTs with lesser trauma around the glottis.

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None.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

Seyoon Kang (Formal analysis; Writing – original draft) Yun Jeong Chae (Conceptualization; Formal analysis; Writing – original draft)

Dae Hee Kim (Data curation; Methodology)
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