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## Original Research Article

# Evaluation of a novel device with one-way valve as integral part of anaesthesia breathing circuit to facilitate fibre-optic bronchoscopy in large goitre patients undergoing thyroidectomy

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## ABSTRACT

**Background:** Securing airway in patients with large goiter and distorted tracheal anatomy is one of the most challenging clinical scenario for anesthesiologists. Improved glottic visualization with video-laryngoscope and fiberoptic bronchoscope help in successful endotracheal intubation in such cases. Use of these gadgets requires specialized anesthetic technique which allows patient to tolerate airway instrumentation without suppressing their own respiration. Authors describe use of a novel device which allows continuous delivery of oxygen and inhaled anesthetics throughout fiberoptic intubation.

**Materials and Methods:** This prospective pilot study was conducted in a tertiary care center following ethics committee approval. Ten patients (N=10) with a predicted difficult intubation score greater than 5 were included after obtaining written informed consent. Patients were sedated using an inhalational induction technique with sevoflurane while preserving spontaneous breathing. The time required to visualize the glottic opening and carina, as well as the time for intubation with the endotracheal tube and the display of the end-tidal CO<sub>2</sub> (EtCO<sub>2</sub>) graph on the monitor, were recorded.

**Results:** Results showed that all ten patients remained hemodynamically stable throughout the procedure. The mean end-tidal sevoflurane concentrations at induction and intubation were 5.6±0.14% and 5.3±0.15%, respectively. The average times for glottic view, carinal view, intubation, and EtCO<sub>2</sub> detection were 77.9±39.9 seconds, 163.1±54 seconds, 229.6±51.7 seconds, and 267.8±56.2 seconds, respectively.

**Conclusion:** This novel device facilitates the continuous delivery of oxygen and inhaled anesthetics without leak, thanks to its one-way valve, throughout fiberoptic bronchoscopy (FOB)-guided intubation. Given that our study with a sample size of 10 reported no adverse events, it suggests that this device can be safely incorporated into anesthesia breathing circuits.

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## 1. Introduction

Airway management in patients with large goiter is always challenging due to varying degrees of tracheal compression and deviation.<sup>1,2</sup> Presence of large mass anterior to trachea may hinder surgical airway access like tracheostomy or

cricothyroidotomy. Amongst limited choices for securing airway in these cases, most commonly used is fiberoptic bronchoscope (FOB) guided intubation of a spontaneously breathing patient.<sup>3</sup>

Obscured landmarks for airway nerve blocks complicates the ease of awake fiberoptic bronchoscopy. Various other techniques have been used to facilitate fiberoptic bronchoscopy in such patients like gargle with 2%

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lignocaine viscous,<sup>4</sup> nebulization with 2-4% lignocaine solution and “spray as you go technique”.<sup>3</sup> Using 2%, 4% or 10% lignocaine spray<sup>4</sup> to anesthetize airway, prevent gag, cough and laryngospasm during airway instrumentation. Loco sedative techniques<sup>2</sup> utilizing combination of local anesthetics with intravenous sedation and varying combination of drugs like midazolam,<sup>2</sup> remifentanyl,<sup>5</sup> propofol,<sup>6</sup> and Dexmedetomidine,<sup>5,7</sup> have been used to minimize patient discomfort, bucking and coughing at the time of tracheal intubation.

In this pilot study authors present their experience of securing airway in patients of large goiter, with the aid of one way valve novel device. This device facilitates continuous delivery of oxygen and inhaled anesthetics to patient simultaneously while performing fiberoptic intubation, so that oxygen saturation and sedation level are maintained throughout and operator gets sufficient time to complete fiberoptic intubation without interruption.

## 2. Materials and Methods

### 2.1. Description of device

We have developed this device at our institution, which has a one-way fish mouth valve. It has a 5-12mm port with fish mouth valve in the center that allows passage of adult FOB and endotracheal tube of sizes 6 to 8.5mm in diameter. Since it has a one way fish mouth valve, there is no leakage of anesthetic gases or oxygen when adult FOB or endotracheal tube is passing thru it. This device has 2 ends, upper and lower, and a side port. FOB enters thru upper end. Side port is connected to side stream gas analyzer, to measure EtCO<sub>2</sub> and concentration of inhaled anesthetic agent. Lower end is connected to one limb of T connector. Remaining 2 limbs of T connector are attached to face mask and breathing circuit of circle system respectively. Both, limb of T connector and Y end of breathing system, are tubes of 22mm outer diameter, so an intervening connector with 22 mm inner diameter on both sides is required to connect them (Figure 1). Our device can allow a maximum of 12 mm through it, thus it is important to disconnect 15 mm connector of endotracheal tube before loading it over FOB as this would not pass through fish mouth valve device (Figure 2).

This device was approved by institute ethics committee for clinical use and written informed consent was obtained from patients for its use. The device is still investigational and is not approved by any agency for intended use, but is meant to improve patient safety.

### 2.2. Study design

This prospective pilot study was conducted in a tertiary care center after obtaining institutional ethics committee approval (IEC approval number: 2016-117-IP-92) and prospectively registering in clinical trial registry of India



**Figure 1:** Fish mouth valve device and various components to make it an integral part of anesthesia breathing circuit



**Figure 2:** Polyvinyl chloride endotracheal tube passing through device after removing its 15 mm connector

(CTRI registration no. 2017/08/009302). Adult patients (18-65 years) of either sex and ASA physical status I and II, scheduled for elective thyroid surgery under general anesthesia with potential predictors of difficult intubation score of >5 (Table 1) were included in the study.

To maintain uniformity in difficulty level of airway, DI score of >5 was used in accordance of the study which evaluated to find out various risk factors of difficult intubation cases in thyroid surgery patients.<sup>8</sup> All the ethical principles of human medical research were followed as

per Helsinki declaration. Patients requiring surgical airway (e.g. with obstructing laryngeal lesions like cancer or tumors), patients with craniofacial malformation (difficult mask holding), patients with significant leak around face mask while breathing spontaneously before induction of anaesthesia, patients with inter incisor gap <4 cm (unable to put bite block) and patients with significant cardio pulmonary compromise, were excluded from the study.

Difficult airway cart including different sized oral airways, endotracheal tubes, face masks, laryngeal airway masks and working suction apparatus was kept ready for use. Appropriate size endotracheal tube was selected, its connector was removed and then loaded on FOB. Patient was wheeled in the operating room, standard monitoring with ECG, noninvasive blood pressure and pulse oximetry was connected. An wide bore intravenous line was secured under local anaesthesia. All the patients were nebulized with 3ml of 4% xylocaine to obtund airway reflexes,<sup>9</sup> premedicated with Intravenous Midazolam 1-2 mg to allay anxiety and IV Glycopyrrolate 10mg/kg to decrease airway secretions. A fitting face mask was chosen. Movement of the reservoir bag and capnography helped to detect any significant leak around the face mask assembly. If no face mask was found fitting that is all available masks had significant leak, the patient was excluded from the study. Now a bite block was placed in between teeth of the patients. They were pre-oxygenated with 100% oxygen for three minutes with a face mask, attached to novel device and breathing circuit thru T-piece connector. During the entire procedure side port of one way valve was used for Capnography. Patients were sedated using Sevoflurane as per the technique followed by Bonnin et al.<sup>10</sup> Sevoflurane concentration was started with 4% for 2 minutes and increased gradually up to 6% over next 4 minutes. Spontaneous respiration was maintained during the entire induction till intubation was achieved. Sedation level was maintained by titrating end tidal sevoflurane concentration between 2.0-2.5 MAC. Two anesthesiologists were present during the procedure; one responsible for performing the FOB intubation and the other for holding the mask with chin lift and jaw thrust to maintain spontaneous breathing of patient and to prevent any airway obstruction (Figure 3). If patient developed apnoea, bag and mask ventilation was performed by anesthesiologist responsible for airway management while other anesthesiologist continued performing bronchoscopy. Anesthesiologist/investigator performing FOB guided intubation had experience of more than 100 successful intubation with FOB. FOB with preloaded ETT was introduced through the one way valve port of device, advanced through the mask to be guided into the trachea beyond the vocal cord. Spray as you go (SAYGo) technique was used with 2% lignocaine to facilitate entry of FOB through the vocal cords. The position of FOB was confirmed and secured

by the operator after identifying tracheal rings and carina. The endotracheal tube was then advanced through the one way valve and face mask into the trachea and secured at the angle of the mouth after removing the mask assembly. The ETT connector was now attached and position was reconfirmed with display of end tidal CO<sub>2</sub> on monitor and auscultation of bilateral breath sounds. This marked the end point of study protocol. IV fentanyl and muscle relaxant was given and Sevoflurane concentration was then reduced to 1-1.5 MAC for maintenance of anaesthesia. The value of end tidal sevoflurane concentration was ensured to be 2 to 2.5 MAC from the beginning of FOB insertion till the time of intubation. Beginning of FOB was marked as T<sub>0</sub>, and vital parameters were measured every minute thereafter for 10 minutes (T<sub>1</sub> to T<sub>10</sub>). The time taken for visualization of glottis, carina, and that for intubation, and detection of EtCO<sub>2</sub> from T<sub>0</sub> were noted. Standard protocol for management of any haemodynamic changes like hypotension in the form of saline bolus or intravenous Mephentramine was followed, if required. Trauma to airway, failed procedure, desaturation episodes (SpO<sub>2</sub><92%), and change in heart rate and blood pressure of more than 20% from baseline were recorded as adverse events during the procedure.



**Figure 3:** One anesthesiologist introducing fiberoptic bronchoscope through fish moth valve device and another anesthesiologist providing oxygen and inhaled anesthetics through face mask, endotracheal tube is seen preloaded over fiberoptic bronchoscope

**Table 1:** Potential predictors of intubation (DI)

S.No.	Potential predictor of DI	No risk 0 point	Moderate risk (1 point)	High risk (2 point)
1.	History of previous DI	No/not known	-	Positive
2.	Tracheal dislocation and/or stenosis (according to neck and chest x ray)	No	Moderate	Significant
3.	Larynx/vocal cord/airway (according to ENT examination)	No	Paresis/Paralysis	Dislocation
4.	Anatomic deformities of bones and joints	No	-	yes
5.	Retrognathic (recessive) mandible	No	-	yes
6.	Size, layout and position of teeth (incisors)	Normal	Long	Asymmetric
7.	Oral anomalies (small mouth, macroglossia, tumours)	No	-	Macroglossia, tumour
8.	Body mass Index	20-25kg/m2	25-30kg/m2	>30kg/m2
9.	Degree of neck mobility	>90°	80-90°	<80°
10.	Thyromental distance	>6.5cm	6-6.5cm	<6cm
11.	Interincisor gap			
	Male	>5cm	4-4.5 cm	
	Female	>4cm	3.5-4 cm	<3.5cm
14.	Maximum Protrusion of mandible over the maxilla	>0 cm	+0cm	<0 cm
15.	Neck circumference and length	Normal	Short or wide	Short and wide
16.	Mallampati score	I, II	III	IV
Maximal score R=28				

DI: Difficult intubation, ENT: Ear nose and throat

### 2.3. Sample size

The Institute's Ethics Committee has approved this device for clinical use; however, it is still under observation and has not received formal approval from any regulatory agency for its intended application, although it is anticipated to enhance patient safety. It is important to note that this device is not suitable for nasal fiberoptic bronchoscopy (FOB) intubation.

Considering these factors, along with the eligibility criteria for patients, their availability, and the necessity of obtaining successful consent, we were able to include only 10 patients in this study during the designated study period. This small sample size has been acknowledged as a limitation. Using the findings of this pilot study a study with a larger sample size, will be planned later, for a longer duration.

The patients data was analyzed using SPSS-20. Time required to obtain glottic view, carinal view, intubation and demonstration of EtCO<sub>2</sub> on monitor were expressed in mean and standard deviation. Paired T test was used to compare vital parameters at base line (T0) with those at every minute thereafter up to 10 minutes. P-value < 0.05 considered as statistically significant.

### 3. Results

Total 10 patients were included in this prospective pilot study. The demographic data of patients and intubation difficulty score are mentioned in Table 2. The mean age group of the patients were 51.1±7.3 years. The mean end-tidal Sevoflurane concentration at start of FOB insertion and

intubation were recorded to be 5.6±0.14% and 5.3±0.15% respectively. The average time taken to achieve each endpoint of visualization of glottis, carina, intubation and connection of the breathing circuit to endotracheal tube to demonstrate EtCO<sub>2</sub> is mentioned in Table 3. Heart rate was comparable to base line values throughout the study period. Although values of systolic and diastolic blood pressures were significantly high after 3 to 4 minutes of induction as compared to baseline values, however these changes were clinically insignificant and did not require any intervention. (Graph 1). SpO<sub>2</sub> and EtCO<sub>2</sub> were in safe range throughout the procedure (Table 3). No adverse events were encountered like hypoxemia, hypercarbia, tracheal mucosal injury or bleeding. Adding this fish mouth one way valve device to the breathing circuit allowed continuous delivery of oxygen and inhalational anaesthetics during fibreoptic intubation.

**Table 2:** Preoperative characteristics of patients

Parameter	Number of patients
Study participants	10
<b>Gender</b>	
Male	4/10 (40%)
Female	6/10 (60%)
Presence of tracheal deviation	10/10
Retrosternal extension of thyroid mass	4/10
<b>Difficult intubation score</b>	
Score- 6	2
Score- 7	7
Score- 8	1

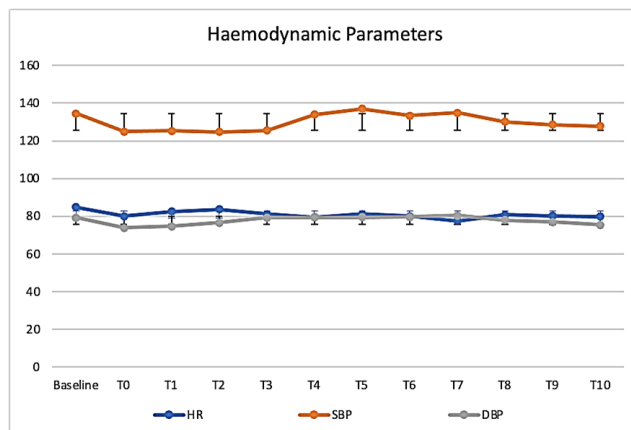


**Table 3:** Timeline of the procedure

Various endpoints during FOB guided intubation	Time taken to achieve each end point(Mean± SD)
Time taken for first glottic view (seconds)	77.90±39.9
Time taken for carinal view(seconds)	163.10±54
Time taken to complete FOB intubation (seconds)	229.60±51.7
Time taken to demonstrate ETCO <sub>2</sub> on monitor (seconds)	267.80±56.2
SPO <sub>2</sub> at the time of intubation (%)	98±0.5
First ETCO <sub>2</sub> value of patients on monitor (mm Hg)	29±1.2
No of desaturation episodes	0

FOB: Fibre optic bronchoscopy, ETCO<sub>2</sub>: end tidal co<sub>2</sub>**Table 4:** Haemodynamic data of patients during study period

	HR		SBP		DBP		SpO <sub>2</sub>	
	Mean±SD	p value	Mean±SD	p value	Mean±SD	p value	Mean±SD	p value
Baseline	84.90±10.493		134±6.023		79.20±5.007		98.80±0.919	
T0	80±6.566	0.132	124.9±6.999	0.000	73.90±5.174	0.003	99.10±0.876	0.193
T1	82±7.976	0.390	125.20±6.613	0.000	74.60±6.328	0.000	98.40±0.516	0.168
T2	83.60±5.103	0.683	124.80±8.496	0.000	76.50±7.169	0.050	98.00±0.816	0.053
T3	81.10±8.543	0.257	125.50±6.654	0.000	79.20±6.680	1	96.80±1.398	0.003
T4	79.50±9.652	0.028	133.90±8.569	0.813	79.40±7.183	0.912	96.20±1.476	0.000
T5	81.10±7.325	0.153	137±9.989	0.381	79.40±5.420	0.876	95.60±1.713	0.000
T6	80±5.437	0.113	133.40±8.488	0.689	79.70±6.075	0.718	96.10±1.197	0.000
T7	77.5±6.433	0.144	134.80±9.942	0.936	80.40±5.719	0.370	96.20±1.398	0.000
T8	80.80±6.596	0.228	130.10±6.919	0.053	77.90±4.818	0.231	97.20±1.033	0.000
T9	80.30±5.559	0.123	128.50±6.060	0.001	77±4.922	0.024	97.70±0.823	0.024
T10	79.80±4.984	0.108	127.70±5.774	0.000	75.50±4.601	0.001	98.20±0.789	0.111



Graph 1: Heart rate, systolic and diastolic blood pressure values at every minute from start till end of fibreoptic intubation FOB: Fibre optic bronchoscopy, HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

#### 4. Discussion

Enlarged and long standing goiters produce pressure changes on tracheal rings, with varying degree of stridor, orthopnea and dyspnea. Airway management of such patients pose unique challenges for anaesthesiologists.

Challenge of maintaining oxygenation and ventilation of large goitre patients was successfully met in our pilot study without any adverse events like hypoxemia, hemodynamic disturbance or airway trauma. Performing fibreoptic bronchoscopy through device assembly was safe and easy.

This device offers many advantages like; Firstly continuous supply of oxygen and inhaled anaesthetics ensures 100% saturation with maintainance of adequate level of sedation throught the procedure. 100% saturation levels allows more stress free time to the anesthesiologist at FOB. Adequate level of sedation ensures a calm patient. Secondly, although it preserves spontaneous respiration but still if patient develops apnea the device has the ability to suport positive pressure ventilation during fibreoptic intubation with no leakage of fresh gas flow. Thirdly, as the device size is 5-12 mm, tubes of varying diameter can be passed through fish mouth valve, including adult FOB (outer diameter 5 to 6 mm) and endotracheal tubes of sizes 6 to 9 mm.

There was no control group of patients in our study, where FOB guided intubation was performed without the aid of this port with one way valve, hence comparison of time taken for glottic and carina visualization as well as intubation time could not be performed. But in authors experience, use of this device facilitated completion of FOB guided intubation in a shorter time span in comparison to

intubation performed without the help of this device, which is also evident from the time reported in various studies in literature. All the patients tolerated the procedure of FOB guided intubation very well without any undue tachycardia, hypo or hypertension.

Liu et al. performed modified awake fibreoptic bronchoscopy using remifentanyl or dexmedetomidine for sedation and reported time for tracheal intubation as  $531.2 \pm 7.2$  seconds in remifentanyl group and  $673 \pm 8.3$  seconds in dexmedetomidine group, where as we could complete FOB guided intubation in just  $229.60 \pm 51.7$  seconds with the help of this assembly.<sup>11</sup>

High flow nasal canula can be utilised to deliver continuous oxygen during fibre optic bronchoscopy but these devices cannot deliver inhaled anaesthetics, are costly and not widely available.<sup>12</sup>

Inhalational induction has been proposed as one of the safer methods to consider for thyroid surgeries with concerns for airway management, as it can be titrated easily in comparison to intravenous agents.<sup>13</sup> Delivery of inhaled anaesthetics diminishes or ceases with hypoventilation or apnoea and increases with hyperventilation when patient is in light plane of anaesthesia.<sup>14</sup> Since patient's respiratory efforts autoregulate the delivery of inhaled anaesthetics it is safer than intravenous anaesthetic agents.

Literature suggests use of loco-sedative techniques which utilise lignocaine spray along with propofol for sedation as propofol rapidly provides desired depth of anaesthesia and suppresses airway reflexes to provide good intubating conditions.<sup>2</sup> At the same time propofol can produce apnea and in the absence of a definitive plan for ventilation it can become unsafe for the patients with airway concerns like enlarged goitre.<sup>10,15,16</sup> Awake fibreoptic bronchoscopy may not always be tolerated well by patients and has associated risks like hypoxemia and pulmonary aspiration.<sup>17</sup> Conscious sedation with variety of drugs like midazolam, fentanyl, dexmedetomidine have been used in the past with varying satisfaction.<sup>18</sup>

Failed fibreoptic intubations can be managed with invasive airway access, insertion of supraglottic airway device or even a combitube,<sup>19–21</sup> but the situation is not always rosy in patients with enlarged goitre that prevents front of neck access to airway. We successfully intubated all the patients in our study without requiring any rescue methods of securing airways.

This device also can be used during ERCP (endoscopic retrograde cholangiopancreatography) and EBUS (endobronchial ultrasound) procedures for better airway management under monitored anaesthesia care which can be studied in future.

The limitations of our study include its small sample size, which restricts the generalizability of the findings; however, this aspect can be further evaluated for reliability in a larger study population or through a multicentric trial.

Additionally, the device is not suitable for nasal fiberoptic bronchoscopy (FOB) intubation, limiting its use in patients with a low inter-incisor gap.

The absence of a control arm further prevents us from comparing outcome benefits effectively. Lastly, while the procedures were conducted by experienced anesthesiologists, the potential for bias related to varying skill levels could not be eliminated. This raises concerns about whether similar competency in using the device could be expected from less experienced personnel.

## 5. Conclusion

The novel device with a one-way valve can be safely integrated into the anesthesia breathing circuit to deliver oxygen and inhaled anaesthetics during fiberoptic intubation. This setup maintains oxygenation and the desired level of sedation necessary to complete the procedure without interruption, ensuring patient comfort throughout the process.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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