# Placement of tracheobronchial silicone Y-stents: Multicenter experience and systematic review of the literature

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# ABSTRACT

**Background:** Airway obstruction or tracheoesophageal fistula (TEF) near the tracheal carina requires placement of Y-shaped stents. Herein, we describe our multicenter experience with the placement of Dumon silicone Y-stents. We also conduct a systematic review for studies describing the deployment of airway silicone Y-stents. Methods: This was a retrospective analysis of consecutive subjects who underwent placement of silicone Y-stents. The clinical details including the underlying diagnosis, indication for the placement of silicone Y-stents, success of stent placement, and follow-up are presented. The PubMed and EMBASE databases were also reviewed for studies describing the placement of silicone Y-stents. Results: During the study, 27 silicone Y-stents were placed. The mean (standard deviation) age of the study population (85.2% males) was 57.7 (13.5) years. The stents were placed for airway obstruction in 77.8% and TEF in 29.6% of the patients. The most common underlying disease was carcinoma of the esophagus. The degree of airway obstruction was grade 3-4 in 18 subjects, and respiratory failure was encountered in 18 subjects. The stent was deployed successfully in all the subjects. No deaths were encountered during stent placement. Most subjects had rapid relief of symptoms following the procedure. Excessive secretions and mucostasis were the most common stent-related complications followed by the development of granulation tissue. The systematic review yielded nine studies (338 subjects with airway obstruction and/or TEF). The most common indication for silicone Y-stent placement was tracheobronchial obstruction and TEF due to malignancy. Benign disorders that necessitated stent placement included postintubation tracheal stenosis, airway malacia, and others. The stent was successfully placed in 98% with only one periprocedural death. Granulation tissue formation and mucostasis were the most common stent-related complications. Conclusion: Placement of silicone Y-stent is a safe and effective procedure that provides quick relief of symptoms in subjects presenting with airway obstruction and TEF at or near the tracheal carina.

KEY WORDS: Airway stent, central airway obstruction, esophageal cancer, lung cancer, tracheal stenosis

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## INTRODUCTION

Airway stents are indicated in various benign or malignant conditions either to restore luminal patency in central

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airway obstruction (CAO) or to maintain luminal integrity in cases of tracheoesophageal fistula (TEF).<sup>[1,2]</sup> Broadly, airway stents can be classified into two types, namely, metallic and

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silicone. The first use of silicone (tube) stents was described by Trendelenburg, who designed a prosthesis that could avoid aspiration during tracheostomy.<sup>[3]</sup> Subsequently, Montgomery described a special T-tube made of silicone rubber that was used primarily for tracheal stenosis in the subglottic region.<sup>[4]</sup> However, it was Dumon, who revolutionized the design of silicone airway stents with the description of a dedicated tracheobronchial silicone stent.<sup>[5]</sup> Airway silicone stents can either be straight or Y-shaped. The straight stent is deployed for conditions involving the upper or mid trachea or the main-stem bronchi. On the other hand, the Y-stent is best suited for lesions involving the lower trachea, tracheal carina, the main-stem bronchi, and the secondary carina.<sup>[2,6-8]</sup> Herein, we describe our multicenter experience with the placement of Dumon silicone Y-stent in the management of benign and malignant diseases involving the lower end of the trachea or the tracheal carina. We also perform a systematic review of literature for studies describing the use of silicone Y-stent for the management of CAO and TEF.

#### **METHODS**

This is a retrospective analysis of data collected between January 2012 and May 2016 at seven centers across India (Apollo Hospital, Bengaluru; Kovai Medical Center, Coimbatore; Jaipur Golden Hospital and Rajiv Gandhi Cancer Institute and Research Center, New Delhi; Century Hospital, Hyderabad; Department of Pulmonary Medicine and Sleep Disorders, All India Institute of Medical Sciences, New Delhi; and Department of Pulmonary Medicine, Postgraduate Institute of Medical Education and Research, Chandigarh). The study protocol was approved by the Institute Ethics Committee of all the participating centers. A consent waiver was allowed as this was a retrospective study describing the use of anonymized patient data. However, a procedural consent was obtained from all subjects.

#### Subjects

The bronchoscopy database of each participating center was searched for records of subjects who underwent placement of silicone Y-stents. The following information was retrieved from the database: demographic details, clinical diagnosis, presence of respiratory failure (defined as a  $PaO_2 < 60 \text{ mmHg}$  or a  $PaCO_2 > 45 \text{ mmHg}$ ), indication for the placement of silicone Y-stent, details of the Y-stent, site of airway obstruction, degree of airway obstruction, presence of TEF, duration of procedure, success of stent placement, procedure- and stent-related complications, duration of follow-up, and the final outcome.

#### Study procedure

Flexible bronchoscopy was performed for airway assessment before Y-stent placement, wherever feasible, to ascertain the airway anatomy and the site of obstruction (or TEF). The severity of obstruction was assessed by maneuvering the flexible bronchoscope across the area of obstruction and estimating the lumen size in comparison to the outer diameter of the respective bronchoscope. The degree of luminal obstruction was graded as grade 1: <50%, Grade 2: 50%–74%, Grade 3: 75%–89%, and Grade 4: 90%–100%.<sup>[9]</sup> The size of the stent was decided on the basis of the airway measurements performed on computed tomography of the thorax and flexible bronchoscopy.

#### Y-stent placement

All the subjects received a silicone Dumon Y-stent (Novatech, France) with a tracheal limb of 16–18 mm diameter and 4–6 cm length, and bronchial limbs of 13–14 mm diameter (length for the left and right main bronchi being 2.5–3.5 cm and 1.5–2 cm, respectively). The stent was deployed during rigid bronchoscopy performed under general anesthesia as previously described.<sup>[6,10]</sup>

Briefly, the trachea was intubated with a large lumen rigid bronchoscope (internal diameter, 14 mm). The stent was folded in a stent folding assembly (Tonn Tracheobronchial Stent Applicator, Novatech, France) with the right bronchial limb facing upward, and then loaded in the introducer tube with the help of a loading rod. The stent was placed using the "pull technique" wherein the distal end of the rigid bronchoscope is positioned in the left main bronchus. The introducer tube with the stent-*in-situ* was introduced into the rigid barrel, and the stent was then pushed gently with a pusher rod while simultaneously retracting the rigid bronchoscope barrel, until the entire stent was deployed. The proper placement of the stent was confirmed using flexible bronchoscopy. If required, the stent was gently manipulated with a rigid forceps.

#### Systematic review

This review was conducted in accordance with guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.<sup>[11]</sup>

#### Search strategy

We searched the PubMed and the EMBASE databases (till June 15, 2016) using the following free text terms: ("silicone y stent" OR "tracheobronchial y stent" OR "Dumon y stent" OR "bifurcation tracheobronchial stent" OR "airway silicone stents" OR "airway silicon stents"). We reviewed the reference list of all the included articles and previous review articles. In addition, we sifted through our personal files.

#### **Inclusion criteria**

We included studies that had described the use of silicone Y-stent in at least ten subjects. We excluded the following type of studies: (a) case reports, abstracts, comments, editorials, and reviews; (b) studies that did not provide details about silicone Y-stent separately; and (c) studies published in language other than English.

#### **Initial review of studies**

The electronic searches were assimilated in a reference manager package and all duplicate citations were discarded. Two authors (ISS, RA) screened these citations by review of the title and abstract to identify the relevant studies. Any disagreement was resolved by consensus between the authors. The database was then scrutinized again to include only primary articles. The full text of each of these studies was obtained and reviewed in detail.

#### Study selection and data abstraction

The data were extracted into a standard data extraction form, and the following information was catalogued: (i) publication details (authors, year of publication, country where the study was conducted); (ii) study design (randomized controlled trial or observational); (iii) number of subjects and inclusion criteria; (iv) demographic profile; (v) underlying disease and the indication for placement of silicone Y-stent; (vi) symptomatology; (vii) details of stent including the type of stent, diameter of tracheal, and bronchial limbs; (viii) outcome of stent placement; (ix) complications (procedure- and stent-related); and (x) final outcome of subjects during follow-up.

#### Data analysis

Data are presented in a descriptive fashion as mean with standard deviation (SD) or number with percentage.

#### RESULTS

During the study, 27 silicone Y-stents were placed. The mean (SD) age of the study population (85.2% males) was 57.7 (13.5) years. The indications for stent placement were CAO (77.8%) and TEF (29.6%). The most common underlying disease causing CAO was carcinoma of the esophagus (33.3%), followed by adenoid cystic carcinoma, and lung carcinoma [Table 1]. The other causes of CAO included extrinsic compression (n = 2), carcinoma breast with paratracheal mass (n = 1), tracheobronchial amyloidosis (n = 1), large cell neuroendocrine tumor of the trachea (n = 1), tracheal leiomyoma (n = 1), postintubation tracheal stenosis (n = 1), and tracheal sarcoma (n = 1). TEF was most commonly caused by tracheal/tracheobronchial invasion by carcinoma of the esophagus (n = 6). Benign causes of TEF included traumatic injury to tracheal mucosa after road traffic accident (n = 1) and endobronchial tuberculosis (n = 1).

The site of obstruction was located at the lower end of the trachea or carina in 21 (77.8%) subjects and involved origin of the left main bronchus in eight subjects. In three subjects, both the main bronchi were involved by malignant infiltration causing luminal obstruction of approximately 80%–90%. The degree of airway obstruction was grade 3–4 in 18 of the 27 (66.7%) subjects with CAO. Respiratory failure was encountered in 18 (66.7%) subjects at presentation. The mean (SD) duration of the procedure was 48.9 (17.9) min. The stent was successfully deployed in all subjects. Twenty-two (81.6%) subjects were extubated on the operating room table while five subjects required endotracheal intubation after the procedure for

# Table 1: Demographic, clinical, and procedural details of the study population (n=27)

Variables	Value
Age, years (mean±SD)	57.7±13.5
Male gender	23 (85.2)
Clinical diagnosis	
Carcinoma esophagus	9 (33.3)
Adenoid cystic carcinoma	4 (14.8)
Lung carcinoma	4 (14.8)
Extrinsic compression	2 (7.4)
Others	8 (29.6)
Indication for stent placement	
Central airway obstruction	21 (77.8)
TEF*	8 (29.6)
Site of obstruction	
Distal trachea/carina	21 (77.8)
Left main bronchus	8 (29.6)
Bilateral main bronchi	3 (11.1)
Site of TEF	
Lower trachea	6 (75)
Left main bronchus	2 (25)
Respiratory failure at presentation	18 (66.7)
Degree of airway obstruction	
Grade I	1 (3.7)
Grade II	8 (29.6)
Grade III	9 (33.3)
Grade IV	9 (33.3)
Stent size (tracheal × right × left bronchial diameter), mm	
16×13×13	12 (44.4)
18×14×14	15 (55.6)
Procedure duration, min (mean±SD)	48.9±17.9
Extubated on table	22 (81.5)
Complications	10 (37)
Procedural complications	3 (11.1)
Stent-related complications	14 (51.9)
Excess secretions and mucostasis	7 (25.9)
Granulation tissue at ends of stent	4 (14.8)
Tumor regrowth	2 (7)
Stent migration	1 (3.7)
Follow-up, weeks (mean±SD)	35.6±43.6
Final outcome	
Alive	9 (33.3)
Died during follow-up	16 (59.3)
Lost to follow-up	2 (7.4)

\*Two cases also had central airway obstruction. All the values are expressed as n (%) unless otherwise stated. SD: Standard deviation, TEF: Tracheoesophageal fistula

a mean duration of 8.9 (9.5) h. All subjects experienced relief of symptoms after the procedure, and there was rapid resolution of respiratory failure following stent deployment.

Three subjects had procedure-related complications that included trauma to teeth, increase in the size of the fistula due to inadvertent deployment of stent in the fistulous tract, and myocardial infarction. Excess secretions and mucostasis were seen in seven subjects and were managed with bronchoscopic toileting. All subjects were also advised twice daily nebulization of ambroxol (Inhalex, Cipla, India, 15 mg) and normal saline. Subjects were also encouraged to use a cough-assist device (Acapella, Smiths Medical, Kent, UK). Development of granulation tissue at either end of the stent was another common complication encountered during follow-up. Granulation tissue was treated with argon plasma coagulation (APC) and systemic steroids. One subject also developed bronchoesophageal fistula at the lower end of the left bronchial limb. The stent was removed, and the subject underwent surgical repair of the fistula. In two subjects with adenoid cystic tracheal tumor, there was recurrence of the tumor with ingrowth of the tumor at the lower end of the stent that was managed successfully using APC. In one subject, the stent migrated proximally 2 days after the procedure. The stent was then removed and redeployed successfully with no subsequent stent migration. There was no procedure-related mortality. The mean duration of follow-up was 35.6 weeks. Two subjects were lost to follow-up. Sixteen subjects died during follow-up due to progression of the underlying malignancy. The stent was removed in three subjects. In one subject, this was because of intractable cough while in two other subjects (one each with traumatic TEF and endobronchial tuberculosis), the stent was successfully removed after healing of the fistula.

#### Systematic review

Our search yielded 1006 citations, of which nine studies (338 subjects [346 silicone Y-stents] with CAO and/or TEF) have described the use of the silicone Y-stent for the treatment of tracheobronchial obstruction or TEF involving the tracheal carina or the main stem bronchi [Figure 1]. All the studies had a retrospective study design and were single-center studies. The studies have described the use of different types of silicone Y-stent [Tables 2 and 3].[10,12-19] The most common indication for deploying silicone Y-stent was tracheobronchial obstruction and TEF due to malignancy. <sup>[10,17,18,20]</sup> Postintubation tracheal stenosis, airway malacia, and others were the benign disorders that necessitated stent placement [Table 2].<sup>[12,13,15]</sup> Malignancy (285, 84.3%) was the most common underlying disease that caused CAO and/or TEF. Severe dyspnea and respiratory distress were the most common presenting symptoms. Stents could be successfully deployed in 98.3% of the cases. The placement of stent resulted in an immediate relief of symptoms in 97.8% (286/292) subjects. The deployment of Y-stent was associated with



Figure 1: Study selection process for the systematic review

complications in 16.6% (56/338) of the subjects. There were ten procedure-related complications (including one mortality) and 46 stent-related complications. The most common stent-related complication was granulation tissue formation followed by mucostasis [Table 3]. In five patients, there was migration of the stent. The mean duration of survival after stent placement ranged from 109 days to 528 days. Progression of underlying malignancy was the most common cause of death during follow-up.

#### DISCUSSION

The results of the current study and the systematic review suggest that placement of silicone Y-stents is a safe and effective treatment option in the management of benign and malignant disorders involving the lower trachea and the tracheal carina. Placement of the silicone Y-stent resulted in rapid relief of patients' symptoms including the resolution of respiratory failure. The silicone Y-stents were easily deployed with few procedure-related and stent-related complications.

The Y-stents, similar to other airway stents, are available either as metallic or silicone. The metallic Y-stents being self-expanding are easy to deploy and can be inserted either during flexible or rigid bronchoscopy.<sup>[21]</sup> They uncommonly migrate and generate considerable force to distend the airway such that airway dilatation is not always required before stent placement. Because of the aforementioned benefits, there has been a substantial reduction in the use of silicone Y-stents at all the authors' institutes.<sup>[21]</sup> The metallic stent, however, has a few limitations including difficulty in removal or repositioning of stent after epithelialization, which usually occurs at about 8 weeks.[22] In addition, the metallic stent can fracture, and the broken filaments can damage the mucosa.<sup>[23]</sup> Thus, they are primarily indicated for conditions where the survival of patient is limited as in malignant disorders. On the contrary, silicone Y-stents always require rigid bronchoscopy for deployment but are easy to remove. Hence, they can be used for both benign and malignant conditions.<sup>[6]</sup> In addition, the internal surface of the stent is varnished with silicone to reduce the porous nature of the stent. This makes the stent smooth thus minimizing the chance of retention of secretions. In the authors' opinion, silicone Y-stents are the preferred stents in any benign condition or in patients where the survival is judged to be more than four to 6 months. In all the previous studies and even in the present study, the stent could be easily placed, and a majority of the patients were relieved of their symptoms immediately after the procedure. In fact, one-third of the patients in the current study faced an imminent threat of death due to severe airway obstruction (>90%). This suggests that silicone Y-stents can be used as a palliative measure in subjects with critical airway obstruction.<sup>[14,17-20]</sup>

<b>Fable 2: Baseline characteristics of</b>	f the study	participants in studies	describing the use	of silicone Y-stent

Author/year	Place of study	Study design	Number of subjects	Age, years (mean±SD)	Gender (male:female)	Underlying disease	Indication of silicone stent	Presenting symptoms
Freitag et al., 1997 <sup>[12]</sup>	Germany	Not clear	135	Mean (range), 58.8 (12-90)	84:51	Malignant ( <i>n</i> =94), benign ( <i>n</i> =41)	Tracheobronchial obstruction, stenosis, malacia, and TEF	Severe dyspnea, cough
Lacy et al., 1999 <sup>[13]</sup>	Ireland	Retrospective	10 (14 stents)	56.8±6.2	3:7	Malignant ( <i>n</i> =9), benign ( <i>n</i> =1)	Tracheobronchial obstruction, tracheal stenosis, extrinsic compression	Severe dyspnea
Dumon and Dumon 2000 <sup>[14]</sup>	France	Retrospective	50	Mean (range), 60.3 (20-91)	43:7	Malignancy ( <i>n</i> =50)	CAO ( <i>n</i> =44), TEF ( <i>n</i> =6)	NA
Dutau et al., 2004 <sup>[10]</sup>	France	Retrospective	86 (90 stents placed, 4 subjects required replacement of Y-stent)	60.4±13.4	75:11	Malignancy ( <i>n</i> =86)	Tracheobronchial obstruction (53.4%), TEF (31.4%), extrinsic compression (14%)	Dyspnea (74.3%), cough (32.6%), hemoptysis(15.6%)
Nam et al., 2009 <sup>[15]</sup>	Korea	Retrospective	11	44.5±14.9	1:10	Benign ( <i>n</i> =11)	CAO due stenosis, tracheobronchial malacia	Dyspnea (91%), excessive sputum (36%), cough (18%)
Oki and Saka 2012 <sup>[16]</sup>	Japan	Retrospective	12	59.6±11.7	11:1	Malignancy ( <i>n</i> =12)	Tracheobronchial obstruction involving primary and secondary carina	Dyspnea (100%), respiratory failure (86%)
Oki and Saka 2013 <sup>[17]</sup>	Japan	Prospective	10	65.2±12.2	5:5	Malignancy ( <i>n</i> =10)	Tracheobronchial obstruction around carina and main stem bronchi	Dyspnea (100%), respiratory failure (40%)
Oki and Saka 2015 <sup>[18]</sup>	Japan	Retrospective	12	63.6±12.1	10:0	Malignancy ( <i>n</i> =12)	Tracheobronchial obstruction $(n=9)$ , TEF $(n=1)$ , airway bleeding $(n=1)$	Respiratory failure (58.3%)
Tsukioka et al., 2015 <sup>[19]</sup>	Japan	Retrospective	12	59.3±10.9	5:7	Malignancy ( <i>n</i> =12)	Endoluminal and extrinsic	Respiratory distress

CAO: Central airway obstruction, NA: Not available, TEF: Tracheoesophageal fistula, SD: Standard deviation

The first description of silicone Y-stent in a large series of patients was that of the dynamic Y-stent.<sup>[12]</sup> The stent is primarily made of silicone but is reinforced by metallic rings along the anterior three-fourths. The stent is placed under direct laryngoscopic vision by folding the stent with special long forceps. The stent is then negotiated through the vocal cords and placed over the carina with or without fluoroscopic guidance. The position of the stent is subsequently confirmed using the rigid bronchoscope. In the aforementioned study, the authors could successfully place the stent in all but two subjects.<sup>[12]</sup> The Dumon silicone Y-stent was first described in fifty subjects with malignant airway condition [Tables 2 and 3].[14] Subsequently, in the largest series of 86 subjects, Dutau et al. described the successful use of Dumon silicone Y stents in CAO and TEF due to underlying malignancy.<sup>[10]</sup> The other types of modified silicone Y-stents described are the T-Y-stents (tracheostomy tubes with distal Y-limbs for bronchi),<sup>[13]</sup> natural silicone-T stent,<sup>[15]</sup> double Y-stents, and hood silicone Y-stents. Oki and Saka described a novel technique wherein they placed two silicone Y-stents to treat CAO involving tracheal carina and right secondary carina.<sup>[16]</sup> In a later study, the same authors used a prototype silicone Y-stent to manage CAO involving the right secondary carina.<sup>[17]</sup> They also later described the use of smaller silicone Y-stents for the management of CAO or TEF at the left secondary carina in twelve subjects.<sup>[18]</sup> Nam *et al.* described a prototype natural Y-stent in eleven subjects that had horizontal c-shaped threads and an interposing flexible posterior wall to mimic the posterior membranous trachea.<sup>[15]</sup> Most of the study subjects had undergone a prior surgical procedure (carinal resection and anastomosis, tracheostomy or external stent placement using a vascular graft) before undergoing placement of silicone Y-stent. The stent was correctly placed in all the subjects.

The placement of silicone Y-stent was found to be safe. In fact, there was only one periprocedural death reported in the studies included in the systematic review.<sup>[12]</sup> Granulation tissue formation and mucostasis were the most common stent-related complications. This was also highlighted in the current study where mucostasis and granulation tissue formation were the most common stent-related complications. The overall survival of subjects in the current study and in the previous studies involving the silicone Y-stent is rather poor.<sup>[10,14,17,18,20]</sup> This is because most of the study subjects had advanced malignancy as the

Table 3: Technica	Tuno of store	Dismotor of tracheol	of subjects in Supported	Immodiate collict	Ding the use	<b>Of Silicone Y-Ste</b> Decodered molecular	nt Stort volated	Summer	Conco of dooth	fo (0/)
Aumonycar	type of stent	Diameter of tractical and bronchial limbs (mm)	deployment of stent, n (%)	of symptoms, $n (\%)$	rouow-up period	complication	complication	time	Cause of ucau	<i>u</i> ( 70) ur subjects alive
Freitag <i>et al.</i> , 1997 <sup>[12]</sup>	Bifurcated dynamic silicone stent with steel struts (Rusch, Kernel, Germany)	NA	135 (100)	135 (100)	3 months after last stent placement	Death (n=1), massive hemoptysis (n=5), recurrent laryngeal nerve palsy (n=3)	Stent migration ( $n=4$ ), granulation tissue ( $n=5$ ), mucous impaction ( $n=1$ ), ciliary dysfunction ( $n=5$ )	Mean, 123 (611) days	Progression of malignancy (n=79), hemoptysis (n=2), chronic hypoxenia $(n=2)$ ,	24 (17.8)
Lacy <i>et al.</i> , 1999 <sup>[13]</sup>	Bifurcated T-Y-stent (Westaby tube)	NA	(06) 6	6 (06)	Not described	Not described	Tube blockage requiring tube change ( <i>n</i> =4), TEF ( <i>n</i> =1), tracheal	Mean±SD, 75.4±139.3 weeks, range, 4-380	(n-2) $(n-2)$ $(n-2)$ $(n-2)$ $(n-5)$ , progression $(n=5)$ , $n$ major vessel $n$ and $(n-2)$ , $n$ major vessel $n$ revoin due to $n$ $(n-1)$	2 (20)
Dumon and Dumon 2000 <sup>[14]</sup>	Dumon silicone-Y-stent	15×12×12; 16×13×13; 18×13×13	50 (100)	Not described	304 days	Not described	Cough $(n=1)$ , granulation tissue	109 days	Progression of underlying	8 (16)
Dutau <i>et al.</i> , 2004 <sup>[10]</sup>	Dumon silicone-Y-stent (Tracheobronxane Y; Novatech, France)	15×12×12; 16×13×13	86 (100)	86 (100)	>3 years	None	Stent migration $(n=1)$ , severe cough $(n=1)$	Median, 181 days	Progressive disease $(n=80)$ , multiorgan failure $(n=1)$	5 (6.3)
Nam <i>et al.</i> , 2009 <sup>[15]</sup>	Natural silicone Y-stent (TNO, Korea)	11–15×9×9	11 (100)	11 (100)	Median (range), 1342 (286-1729) days	None	Fever $(n=1)$ , chest discomfort $(n=4)$ , granulation tissue $(n=7)$ , mucostasis $(n=2)$	One subject died after 286 days	Congestive heart failure	10 (90.9)
Oki and Saka 2012 <sup>[16]</sup>	Double Y-silicone stent (Dumon Y-stents, Novatech France)	16×13×13; 15×12×12	12 (100)	12 (100)	Not described	Pneumothorax ( <i>n</i> =1)	(n=1)	Median, 94.5, range (16-417) days	Progression of disease	NA
Oki and Saka 2013 <sup>[17]</sup>	Prototype silicone Y-stent (Novatech) for primary right carina	13×10×9	10 (100)	8 (80)	836 days	None	Granulation tissue $(n=1)$ , retention of secretions $(n=1)$ , pneumonia $(n=2)$ , hemoptysis $(n=1)$	Mean±SD, 300.3±297.8 days	Hemoptysis	(06) 6
Oki and Saka 2015 <sup>[18]</sup>	Dumon Y-stent (Novatech, France) at secondary left carina	14×10×10; 18×14×14	12 (100)	12 (100)	Not described	None	Retention of secretion $(n=1)$ , hemoptysis $(n=1)$	Median (range), 197 (32-1266) days	Progression of disease	2 (16.7)
Tsukioka <i>et al.</i> 2015 <sup>[19]</sup>	Dumon Y-stent (Novatech, France) and tapered Spiral Z-stent (Medico's Hirata, Japan)	Not described	12 (100)	9 (75)	Not described	Death ( <i>n</i> =1)	None	Mean±SD, 130.9±207.8 days	Progression of disease	1 (8.3)
SD: Standard deviatio	n, NA: Not available	e, TEF: Tracheoesophage	eal fistula							

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underlying cause. In the study that included cases with benign causes only, there was no death, and the patients tolerated stents for prolonged periods of time.<sup>[15]</sup> This is similar to the subjects in our study where all the patients with benign causes (traumatic TEF, amyloidosis, and postintubation tracheal stenosis) were alive at the last follow-up whereas most of the subjects with malignant disease had died due to the progression of the underlying malignancy.

Finally, our study has a few limitations. It is a retrospective study with a small sample size. In addition, we do not have information on the proportion of patients presenting with CAO to the participating centers that was selected for the placement of silicone Y-stent. However, the current study is the first multicenter study describing the perspective on outcomes of silicone Y-stent deployment from a developing country, which makes the study unique. In fact, most of the previous studies are single-center studies from authors who had actually developed the stents and the complication rates and outcomes may not be a true reflection of the actual practice elsewhere. In contrast, the current multicenter study provides perspective from several centers and is likely to reflect a real world scenario.

#### **CONCLUSION**

Placement of the silicone Y-stent is a safe procedure that provides rapid relief of symptoms in subjects presenting with critical CAO and/or TEF at or near the tracheal carina.

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#### **Conflicts of interest**

There are no conflicts of interest.

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