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Silicone stent versus fully covered metallic stent in tracheoesophageal fistula: a single-center retrospective study

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Abstract

Background In cases of tracheoesophageal fistula (TEF), closure of the fistula by tracheal stent implantation is an effective treatment. In this study, we investigated the efficacy and complications of silicone and metallic tracheal stents for TEF.

Methods We retrospectively reviewed all patients who underwent tracheal stent insertion for TEF between January 2021 and April 2024 at our institution. Complications were assessed bronchoscopically.

Results Metallic stents were placed in 21 patients (18 men, 85.7%) and silicone stents in 17 patients (14 men, 82.4%). No differences were observed between the two groups in terms of age, gender, location or size of fistula, primary disease, symptoms or comorbidities. A total of 26 fistulas were found in the metallic stent group, and 19 fistulas were found in the silicone stent group. Stent insertion was successful in all cases. The differences in efficacy and complications after stent placement were not statistically significant between the two groups. Mucus retention was the most frequent complication ($P=0.221$), followed by granulation tissue (38.1% with metallic stent and 29.4% with silicone; $P=0.734$) and migration (14.3% with metallic stent and 29.4% with silicone; $P=0.426$).

Conclusions Silicone and metallic stents are viable clinical options for treating TEF. Both are equally effective and safe and have acceptable complication rates in TEF.

Keywords Metallic stent, Silicone stent, Tracheal stent, Tracheoesophageal fistula

Background

A tracheoesophageal fistula (TEF) is defined as an abnormal connection between the main airways and the esophagus due to a variety of etiologies, ultimately resulting in the mutual flow of gas and fluid in the lumen of the digestive tract and airway [1]. If left untreated, patients often die within days to months; accordingly, prompt and effective treatment methods are required [2]. Current treatment modalities for TEF mainly include surgery and endoscopic intervention. However, only a small percentage of patients are eligible for surgery. Endoscopic intervention is the most important and optimal treatment for fistulas that are unsuitable for surgery [2]. The deployment of stent can immediately relieve the perfusion of digestive fluids, reduce lung infections, and provide an opportunity for subsequent treatment, with the advantages of less trauma, faster recovery, and fewer complications [3]. Currently, most TEFs require the deployment of tracheal stents to seal the fistula, and only a few TEFs can be sealed using esophageal stents alone. Metallic

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and silicone tracheal stents are the most frequently utilized varieties. There are more researches recommending the use of metallic stents; however, some researchers also recommend the use of silicone stents owing to their excellent material and field modifications [1, 2, 4–8]. Few studies have compared the efficacies and complications of the two stent types in TEFs. Therefore, we retrospectively analyzed the clinical data of patients who underwent metallic or silicone tracheal stent deployment due to TEF between January 2021 and April 2024 at our department. The efficacies and complications of the two types of tracheal stents in TEF were compared and analyzed.

Methods

Study design

A retrospective review was performed. Medical records, radiological files, and endoscopy images were reviewed. Wallstent stents (Micro-Tech, Nanjing, China) were used as metallic stents in this study. Dumon stents (Novatech, Aubagne, France) were used as silicone stents. Both stents were used by an experienced team. However, metallic stents were generally preferred for the following situations: irregular distortion of the lumen, maximum diameter of fistula ≥ 15 mm, or the presence of associated tracheal stenosis. Metallic stents were preferred as well in which placing a silicone stent was too difficult or impossible, or in patients with a shorter life-span expectancy. Silicone stents were applied in all other situations. However, the choice of metallic or silicone stents ultimately depended on the unique condition of patient. Patients underwent both clinical and endoscopic follow-up on days 3, 7, 30, and 60 after stent deployment and monthly to every 3 months thereafter, with a follow-up endpoint of patient death or July 2024.

Selection and description of participants

A total of 38 patients (32 men) with a median age of 65.11 ± 7.84 years (range, 45–84 years) were enrolled in this study. The inclusion criteria were as follows: (1) age ≥ 18 years; (2) having a diagnosis of TEF confirmed by thoracic computed tomography or upper digestive tract radiography combined with a tracheoscopy; (3) including both malignant and benign fistulas, in which malignant TEF required pathology or cytology to confirm the diagnosis; and (4) meeting the indications for tracheal stent deployment, with no contraindications. The exclusion criteria were as follows: (1) medical data incomplete or missing; (2) patients who had undergone surgery or used other techniques such as fibrin glue, double stents, silicone plugs, etc., for the treatment of tracheoesophageal fistulas; and (3) more than one type of stent in place simultaneously.

Definitions

The selection of a straight or Y-shaped stent was primarily based on the location of the fistula. Under certain circumstances, modification of the tracheal stent may be necessary. The stent length should extend 2 cm beyond each end of the fistula (if possible), and the diameter should be 10–20% larger than the diameter of the airway. Criteria for the evaluating efficacy were as follows: (1) complete remission: the fistula was completely sealed, and the complete remission of clinical symptoms (such as choking on drinking water or fever) lasted for one month; (2) partial remission: the fistula was partially sealed by the stent, and the clinical symptoms were partially relieved; (3) ineffective: the fistula was not sealed by the stent, and there was no remission of clinical symptoms. Complications were assessed bronchoscopically. Complications included mucus retention, granulation tissue formation and migration. Mucus retention was categorized into three levels: (I) mild, where secretions caused no obstruction and could be easily cleared using saline irrigation and suction; (II) moderate, characterized by predominantly dry secretions resulting in partial obstruction, requiring mechanical removal using other devices (e.g., bronchoscope tip or biopsy forceps) in addition to suction; and (III) severe, involving nearly complete or complete obstruction caused by thick secretions that are difficult to aspirate directly under bronchoscopy and require mechanical removal with the tip of the rigid bronchoscope and rigid suction catheters [9].

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics (Version 29.0; SPSS Inc., Armonk, NY, USA). Normally distributed continuous data were expressed as the mean ± standard deviation and non-normally distributed data as the median (Q1, Q3). Categorical variables were presented as numbers (percentages). An independent-samples *t*-test was used to compare changes in age between groups. The Mann–Whitney U test was used to compare the maximum fistula diameter between groups. The chi-squared test or Fisher's exact probability test was used to compare categorical variables. The statistical significance level was set at $P < 0.05$.

Results

Clinical features

The 38 patients who met the selection criteria were divided into two groups according to the type of treatment received: silicone stent ($n = 17$) and metallic stent ($n = 21$). The clinical characteristics of the patients in both groups are shown in Table 1. Clinical profiles were comparable in the two groups. All patients were malnourished or cachectic, and chest imaging revealed varying degrees of combined pulmonary infections. All patients

Table 1 Clinical features of 38 patients with tracheoesophageal fistula

Clinical characteristic	Metallic stent group (*n* = 21)	Silicone stent group (*n* = 17)	*P*
Age (years)	66.67 ± 7.29	63.18 ± 8.29	0.176
Male, *n* (%)	18 (85.7)	14 (82.4)	0.999
Primary disease, *n* (%)			0.211
Tracheotomy	0 (0.0)	2 (11.8)	
Esophageal cancer	15 (71.4)	13 (76.5)	
Lung cancer	4 (19.0)	1 (5.9)	
Thyroid cancer	1 (4.8)	0 (0.0)	
Cardia carcinoma	1 (4.8)	0 (0.0)	
Mediastinal tumor	0 (0.0)	1 (5.9)	
Comorbidity, *n* (%)			0.180
Hypertension	5 (23.8)	6 (35.3)	
Diabetes mellitus	2 (9.5)	4 (23.5)	
Coronary heart disease	5 (23.8)	3 (17.6)	
None	11 (52.4)	8 (47.1)	
Symptoms, *n* (%)			0.160
Fever	12 (57.1)	8 (47.1)	
Cough while drinking or eating	13 (61.9)	9 (52.9)	
Dyspnea	2 (9.5)	3 (17.6)	
Cough	8 (38.1)	8 (47.1)	
Shape of stent, *n* (%)			0.506
Straight stent	9 (42.9)	5 (29.4)	
Y-shaped stent	12 (57.1)	12 (70.6)	
Number of fistula, *n* (%)			0.999
One fistula	17 (81.0)	15 (88.2)	
Two fistulas	3 (14.3)	2 (11.8)	
Three fistulas	1 (4.8)	0 (0.0)	
Location of fistula, *n* (%)			0.441
T	9 (42.9)	10 (58.8)	
LMB	3 (14.3)	3 (17.6)	
RMB	2 (9.5)	0 (0.0)	
Carina	2 (9.5)	0 (0.0)	
Bronchus intermedius	0 (0.0)	2 (11.8)	
T + T	1 (4.8)	2 (11.8)	
T + T + T	1 (4.8)	0(0.0)	
T + Carina + LMB	1 (4.8)	0(0.0)	
LMB + RMB	1 (4.8)	0(0.0)	
Carina + Carina	1 (4.8)	0(0.0)	
Maximum diameter of fistula, (mm)	13.00 (8.00, 20.00)	10.00 (8.00, 14.00)	0.219
Size of fistula, *n* (%)			0.345
less than 10 mm	7 (26.9)	8 (42.1)	
10–20 mm	14 (53.8)	10 (52.6)	
20 mm and above	5 (19.2)	1 (5.3)	

*Mean ± standard deviation (SD) or median quartile distribution for continuous variables, number(percentage) for categorical variables. LMB: Left main bronchus; RMB: Right main bronchus; T: Trachea

with malignant tumors underwent surgery, chemotherapy, or radiation therapy. The most common symptom was cough while drinking or eating (61.9% and 52.9% in the metallic stent group and the silicone stent group, respectively), and the most common primary disease was esophageal cancer (71.4% and 76.5%, respectively). A total of 45 fistulas were found in the 38 patients, 26 in the metallic stent group and 19 in the silicone stent group. The presence of large fistulas was common in patients who had undergone radiotherapy. A typical image is shown in Fig. 1.

Efficacy of tracheal stent

All stents were successfully implanted using rigid bronchoscopy under general anesthesia. A total of 38 stents (14 straight and 24 Y-shaped) were successfully inserted

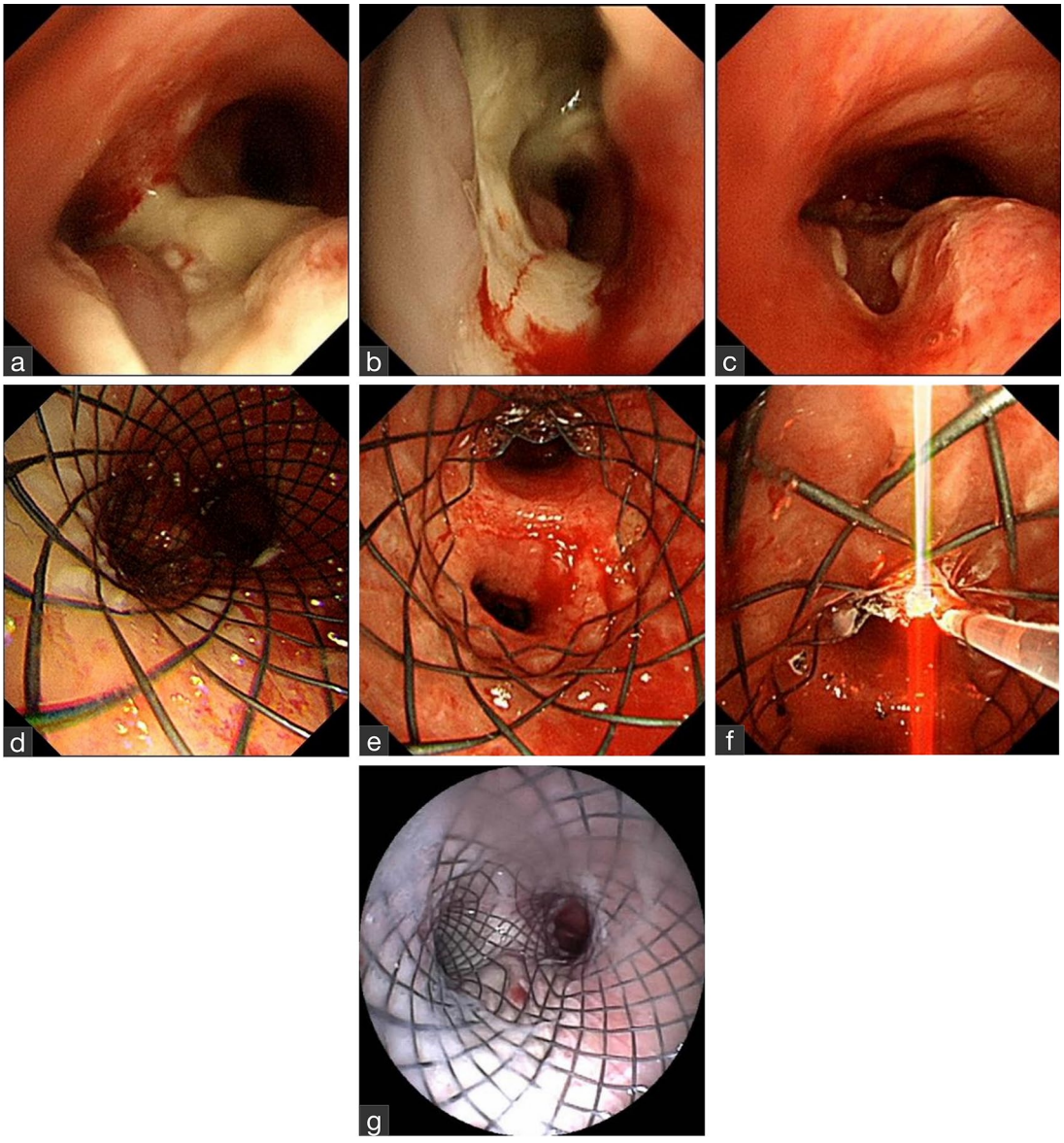

Fig. 1 A representative metallic Y-shaped stent (No.18) for treatment of a huge tracheoesophageal fistula caused by lung adenocarcinoma. A huge tracheoesophageal fistula involving the trachea, carina, and the middle and upper parts of the left bronchial trachea was observed via bronchoscopy (**a**, **b**, **c**). The maximal diameter of the fistula was approximately 40 mm. A metallic Y-shaped stent was placed to cover the fistula (**d**, carina; **e**, position of the left main branch). Following placement of the stent, the lower edge of the stent partially obscured the upper lobe of the left lung, requiring laser fenestration under tracheoscopy (**f**). A follow-up examination was conducted three days after placement of the stent (**g**). The patient succumbed to pneumonia 19 days following placement of the stent

Table 2 Efficacy of metallic stents and silicone stents

Efficacy (%)	Metallic stent group ($n=21$)	Silicone stent group ($n=17$)	*P*
Complete remission	15 (71.4)	13 (76.5)	0.999
Partial remission	5 (23.8)	4 (23.5)	
Ineffective	1 (4.8)	0 (0.0)	

in 38 patients without severe procedure-related complications. There were no statistically significant differences in the efficacy of tracheal stents between the two groups. In the silicone tracheal stent group, 13 patients (76.5%) obtained complete remission, while four (23.5%) obtained partial remission. In the metallic stent group, 15 patients (71.4%) achieved complete remission and five (23.8%) achieved partial remission. Further details are presented in Table 2.

Complications of tracheal stent

At the 3-day postoperative follow-up, two straight metallic stents (No. 19 and No. 36) migrated downward. The stent position was adjusted upward by lifting and pulling the retrieval line to cover the fistula. Four cases of migration were observed in the silicone stent group (No. 1, No. 7, No. 8, and No. 14), including three straight stents and one Y-shaped stent. One straight (No. 7) and one Y-shaped (No. 8) stent were modified by increasing the diameter of the stent, which was accomplished by suturing a half-turn silicone stent around the periphery of the original stent. One straight stent (No. 14) migrated downward and was subsequently adjusted upward using forceps and secured in vitro with buttons, while another straight stent (No. 1) migrated slightly and was adjusted upward. No further migration occurred after adjustment in any of the cases. One straight silicone stent (No. 13) exhibited granulation tissue formation at its lower edge, attributed to the large lumen diameter of the stent and the acute angle it formed with the tracheal membrane. This granulation tissue was subsequently treated with carbon dioxide cryotherapy. A Y-shaped silicone stent (No. 16) with severe mucus retention due to inadequate airway humidification was also treated with carbon dioxide cryotherapy.

At the 30-day follow-up, none of the patients in the silicon stent group had died, whereas four patients in the metallic group (No. 18, No. 22, No. 27, and No. 30) had died from pneumonia. One straight metallic stent (No. 38) migrated downward and was subsequently adjusted upwards using forceps. Despite the absence of migration in one silicone stent (No. 3), digital radiography revealed leakage of the contrast medium. Consequently, the stent was modified to increase its diameter (Fig. 2). One straight silicone stent (No. 13) exhibited granulation tissue formation on two edges; therefore, the stent was modified by reducing the diameter of its two sides, and the granulation tissue was treated with carbon dioxide cryotherapy. The metallic stent group exhibited five cases (No. 20, No. 29, No. 33, No. 35, and No. 36) of minimal granulation tissue formation near the stent, none of which underwent special treatment.

At the 60-day follow-up after stent deployment, there had been two deaths in each group. The causes of death included tumor progression, respiratory insufficiency, bleeding, and cardiac insufficiency (No. 4, No. 11, No. 19, and No. 31). One straight silicone stent (No. 2) was replaced with a Y-silicone stent due to migration. The silicone group exhibited four new cases (No. 1, No. 2, No. 3, and No. 4) of granulation tissue formation near the stent; one (No. 3) was treated with carbon dioxide cryotherapy, while the remaining three were only monitored because of the small amount of granulation tissue. In the metallic stent group, there were three new cases (No. 24, No. 34, and No. 38) of granulation tissue formation. One patient (No. 21) in the metallic stent group was readministered antitumor therapy after symptom alleviation, and a review showed that the initial fistula had enlarged and developed into a new fistula; as such, an esophageal stent was inserted. Further details are presented in Table 3. At the follow-ups conducted monthly to every 3 months, one case (No. 3) in the silicone group showed contrast leakage on upper gastrointestinal imaging 3 months after stent placement. The stent was modified to increase its diameter, and no further leakage was observed.

Removal of tracheal stent

A total of 2/17 (11.8%) silicone stents and 1/21 (4.8%) metallic stents were removed because of closure of the fistula during follow-up. One silicone stent (No. 1) was removed 3 months following its placement due to closure of the benign fistula. In another benign fistula, the stent (No. 2) was removed after 5 months. Due to concomitant airway stenosis, multiple cryotherapy procedures were conducted, and a Montgomery T-tube was placed. One metallic stent (No. 18) was removed after 2 months.

Discussion

Most TEFs present in adulthood are acquired and can be divided into malignant and benign categories [10, 11]. Malignant TEF accounts for approximately 80% of acquired TEF [12]. Esophageal cancer is the most common cause of malignant TEF, followed by lung cancer [13]. In our study, 94.7% ($n=36$) of patients had malignant TEFs, with esophageal cancer accounting for 73.7% ($n=28$) and lung cancer for 13.2% ($n=5$). The most common causes of benign TEF include tracheotomy, tracheal intubation, trauma, surgical manipulation, and infection [14]. In our study, the two cases of benign fistulas were both due to tracheotomy. Given the transient characteristic of the injury and better nutritional status, most benign TEFs are more suitable for surgical intervention, while most malignant TEFs are poor surgical candidates. In cases of inoperable TEFs, endoscopic intervention stands as the optimal treatment option [2]. The mean survival of patients with malignant TEF was only 7.3 months in a large prospective study [15], while patients with benign TEF survived a median of 41 months in a study by Marull et al. [16]. The severity of symptoms largely depends on the size, number, and location of fistulas [1, 12]. Regardless of whether the fistula is benign or malignant, the patient is unable to eat through the mouth, and the refluxed digestive fluid enters the airway repeatedly. Over time, a vicious cycle develops, wherein the fistula remains refractory to healing, and the patient experiences recurrent aspiration, acute respiratory distress, recurrent pulmonary infections, sepsis, and other serious complications [1]. If left untreated, most patients succumb to

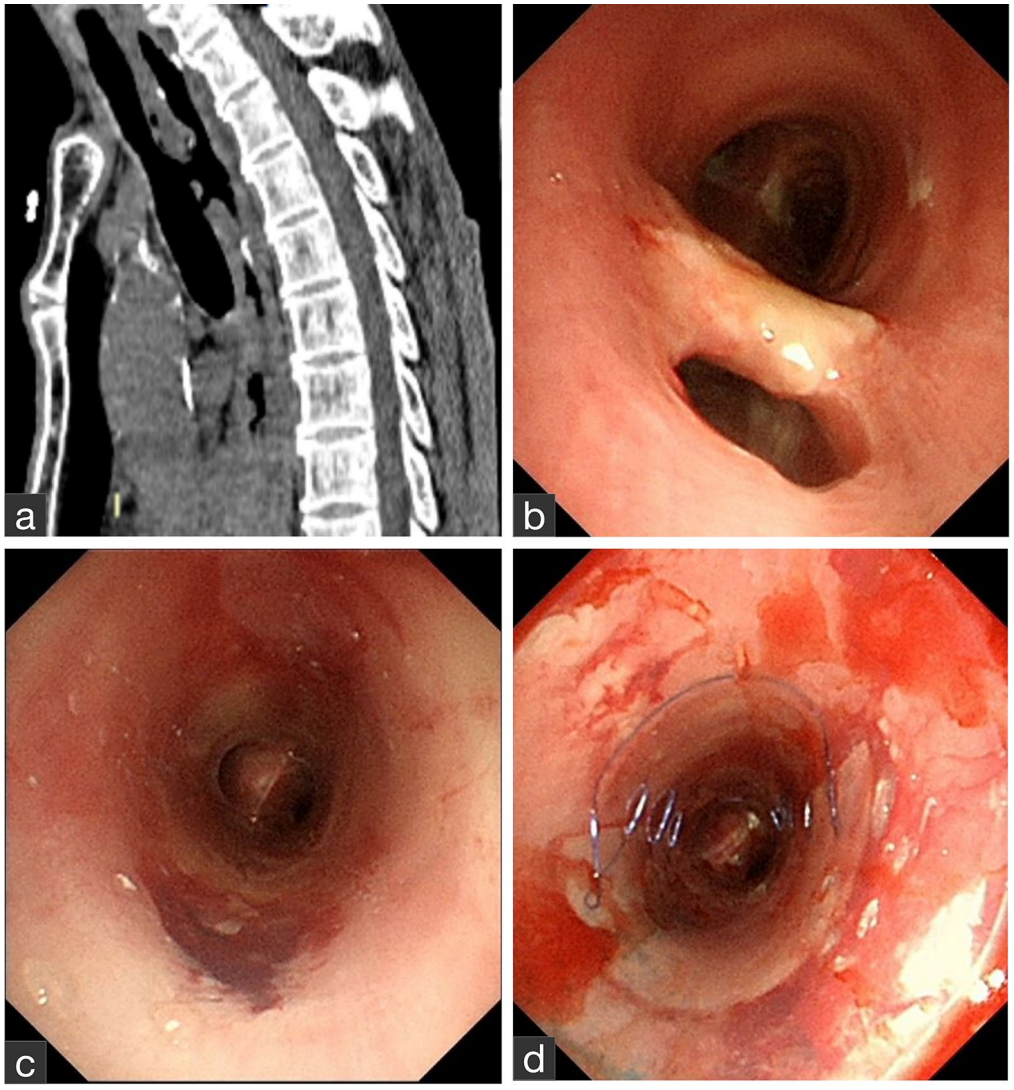

Fig. 2 A representative modified silicone Y-shaped stent (No.3) for treatment of tracheoesophageal fistula caused by esophageal cancer. Two tracheoesophageal fistulas were observed under the computed tomography mediastinal window (**a**), and a huge tracheoesophageal fistula was observed under bronchoscopy, with a maximum fistula diameter of about 15 mm (**b**). A Y-shaped silicone stent was placed to cover the fistula (**c**). One month after placement of the stent, digital radiography showed leakage of the contrast medium, and the stent was modified by suturing a half-turn silicone stent around the periphery of the original stent to increase its diameter and reinserted (**d**). The patient's survival after placement of the tracheal stent was 589 days

Table 3 Complications of metallic stents and silicone stents

Complications	Metallic stent group (*n* = 21)	Silicone stent group (*n* = 17)	*P*
Mucus retention, *n* (%)			0.221
Mild	13 (61.9)	13 (76.5)	
Moderate	8 (38.1)	3 (17.6)	
Severe	0 (0.0)	1 (5.9)	
Granulation tissue, *n* (%)	8 (38.1)	5 (29.4)	0.734
Migration, *n* (%)	3 (14.3)	5 (29.4)	0.426

their illness within 1–4 months, with over 90% of deaths attributed to pulmonary infection [2, 17–19]. Therefore, timely and effective treatment is crucial.

The treatment of TEF is a tough challenge, and the key to treatment is to seal the fistula as early as possible. The deployment of stents can facilitate the safe, rapid, and immediate closure of fistulas under direct vision, which can effectively enhance the quality of life, extend survival, and offer opportunities for potential treatment [3]. Stents can be placed in the esophagus, trachea, or both. Esophageal stents may be a viable option in patients with a certain degree of esophageal stenosis. However, esophageal stents are prone to migration when used alone in the absence of esophageal stenosis. Therefore, larger

esophageal stent diameters are necessary to minimize complications such as migration, new tracheoesophageal fistulas, or secondary enlargement of existing fistulas due to stent deployment. Consequently, tracheal stents are more suitable for TEF.

Tracheal stents are classified into two broad categories: silicone and metallic. Each type has its advantages and disadvantages. In our study, silicone and metallic stents used to treat TEF in 38 patients were equally safe and effective at reducing symptoms. A complete remission rate of 76.5% was achieved with silicone stents, which is higher than a previously reported estimate of 72.2%; this may be attributed to our appropriate patient selection [20]. In the metallic stent group, 15 patients (71.4%) achieved complete remission. In previous studies, complete closure was achieved in 45 patients (71.4%) and 28 patients (65.1%) in the metallic groups, respectively [3, 20]. Despite the meticulous execution of the stent placement procedure, stents, as foreign bodies, inevitably lead to a range of complications for the patient. In our study, the complications associated with metallic and silicone tracheal stents were manageable and nonfatal. Differences in mucus retention, granuloma formation, and migration between groups were not statistically significant and were attributed to the small sample size of this study. Migration was seen in 14.3% and 29.4% in the metallic and silicone stent groups, respectively. Five cases of silicone stent migration were observed, four of which occurred at an early stage (within 3 days) and were attributed to the use of small-sized stents. The stent was modified to increase the diameter to prevent further migration. Granulated tissues or tumors are more likely to grow through metallic stent interstices than through silicone stents [7]. The rates of granulation tissue formation were 29.4% for silicone stents and 38.1% for metallic stents. In a study involving 47 patients, granulation tissue was seen in 26.7% and 35.3% of patients in the silicone and metallic stent groups, respectively ($P>0.05$) [4]. The selection of an appropriate tracheal stent can provide significant symptomatic relief with fewer complications.

Silicone stents have several advantages: They are field-modifiable, resistant to damage, exhibit less granulomatous proliferation, offer longer treatment maintenance, provide reliable sealing, and their effectiveness is less affected by coughing [21–24]. However, silicone stents are difficult to deploy and require a rigid bronchoscope, which has high requirement for the operator [25, 26]. One of the outstanding advantages of silicone stents is their ability to be modified on-site to fit a patient's specific needs. The angle, diameter, and length of the stent can be modified without waiting for a customized stent. For airway diameter distortion or different airway angles, stent angulation can be modified by cutting and suturing. In patients with larger airway diameters, a stent patch can be wrapped around the original silicone stent to increase its diameter. Additionally, the position of the silicone stent can be easily adjusted after deployment [6]. The migration of stent is more likely to occur with straight silicone stents than with metallic stents [27]. Silicone stents have studs on their outer walls to prevent migration and reduce mucosal ischemia, but these studs may prevent complete apposition to the airway lumen and can interfere with mucociliary clearance systems and promote infection [6, 28]. In our center's experience, we prefer to remove the studs on the membrane and both sides of the stent while retaining only the studs on the opposite side of the membranous part of the stent; this helps the stent fit more closely to the airway wall and reduces the risk of migration. Compared to metallic stents, the deployment of silicone stents offers better support and a lower risk of injury, and the stent is easy to remove if the clinical situation dictates [29].

Compared with silicone stents, metallic stents are relatively simple to deploy, show a high rate of immediate symptomatic improvement (31.1–32.7%), exhibit a favorable internal-to-external diameter ratio, accommodate different tracheal sizes, have a relatively low incidence of migration, and facilitate superior clearance of secretions [7, 18, 30–33]. Metallic stents often exhibit excellent shape adaptability and expansion force, enabling them to achieve superior apposition with the airway wall. Consequently, they are suitable for nearly all types of TEF, particularly in cases where there is a distorted airway with excessive tortuosity or associated with tracheal stenosis [20]. Although metallic stents can be easily inserted, they are difficult to remove because metallic stents can suffer from metal fatigue. When a stent is placed for an extended period, the stent edges may become embedded in the tube wall, potentially leading to difficulties or even failure of stent removal. During removal, there is an increased risk of airway obstruction, asphyxiation, tracheal wall tearing, and fistula enlargement [7]. Patients with malignant TEFs generally face a shorter life life-span expectancy, which makes the worries about potential issues such as metal fatigue and stent fracture stemming from extended stent deployment largely unnecessary or unfounded.

In conclusion, the "ideal" stent has not yet been developed. Generally, the choice between silicone or metallic stent depends on various factors, including the location and size of the fistula, the presence of distorted airway or tracheal stenosis, and the diameter of corresponding airway. Accordingly, Our center's experience indicates that if the silicone stent can be placed and it fits well to surrounding wall, especial for benign TEFs, this silicone stent will be the best choice as it can be modified on site, seal a longer time and achieve better efficacy. But in the following conditions, a metallic stent is preferred when

there is a distorted airway with excessive tortuosity, associated with tracheal stenosis, the diameter of airway is more than 18 mm, the silicone stent is difficult to insert or the insertion might enlarge the fistula. Metallic stents were preferred as well in patients with a shorter life-span expectancy. Selecting an appropriate tracheal stent based on the patients specific situation is crucial for effective treatment.

Our study has some limitations. First, the amount of data is small and needs to be confirmed by a large-scale randomized controlled study. Additionally, our study is a retrospective, single-center study, making it difficult to determine the generalizability of our findings.

Conclusions

TEF is a complex, challenging condition with varying aetiologies, the closure of fistula by tracheal stent implantation is an effective treatment. The silicone and metallic tracheal stents are viable clinical options for treating TEFs; both are equally effective, safe and have acceptable complication rates in TEF.

Abbreviations

TEF	Tracheoesophageal fistula
LMB	Left main bronchus
RMB	Right main bronchus
T	Trachea

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12890-024-03434-7.

Supplementary Material 1

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Author contributions

CXB was responsible for study conception, RRM designed the overall study and collected the data, RRM and JLC analyzed data and drafted the article; CXB and JHZ revised and approved for the submission. All authors reviewed the manuscript.

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Data availability

The dataset used are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This was a retrospective observational study using anonymous patient data. The protocol has been approved by the Ethics Committee of Jining No.1 People's Hospital (No.2024-IIT-027). Contact with Prof. Cui-xia Bian, the corresponding author, via e-mail (yzbbc@126.com) is requested should any additional information be needed. All patients agreed and signed informed consent forms before stent deployment. Patients were not contacted or directly impacted by study participation, thus obtaining informed consent was not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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