Complications of silicone Y stents placed due to malignant airway stenosis

Zafer AKTAŞ 1
Ayperi ÖZTÜRK 1
Aydın YILMAZ 1
Derya KIZILGÖZ 2
Gülşah YURTEVEN 3

1 Clinic of Interventional Pulmonology, Ankara Ataturk Chest Diseases and Thoracic Surgery Training and Research Hospital, Ankara, Turkey
2 Ankara Ataturk Göğüs Hastalıkları ve Göğüs Cerrahisi Eğitim ve Araştırma Hastanesi, Girişimsel Pulmonoloji Kliniği, Ankara, Türkiye
3 Clinic of Anesthesia, Ankara Ataturk Chest Diseases and Thoracic Surgery Training and Research Hospital, Ankara, Turkey

SUMMARY
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Introduction: Malignant central airway obstruction around the main carina often requires placement of Y-shaped stents. In this study, we aimed to determine the safety of silicone Y stents placed around the main carina in the malignant airway obstruction by examining the long term complications, emergence times and treatment approaches of complications.

Materials and Methods: Between May 2012 and July 2015, 47 silicone Y stents were placed in 46 patients with malignant external compression or mixed type stenosis around the main carina. Patient stents were placed via rigid bronchoscopy under total intravenous anesthesia in operating room conditions.

Results: In the half of the patients (23/46), stents were placed under urgent conditions due to acute respiratory failure. Stents were deployed successfully in all the patients. No procedure related deaths were observed. The median time of survival following stent insertion was 157 days. The total long-term complication rate of silicone Y stents was 28.3%. Mucostasis (8.7%) and migration (2.2%) were observed within the first month after placement of the silicone Y stents (median 18 days), stent-edge granulation tissue development (13.0%) was observed at the earliest one month (median 64, range 34-386 days) and stent-edge tumor tissue development (4.3%) were observed at the earliest 3 months (median 151, range 85-217 days). A total of 7 (15.2%) stents were removed, 2 of which were due to mucostasis and 5 of which were due to granulation tissue development. One patient’s stent was replaced with a longer silicone Y stent due to stent-edge tumor tissue development.

Yazıma Adresi (Address for Correspondence)
Dr. Zafer AKTAŞ
Ankara Ataturk Göğüs Hastalıkları ve Göğüs Cerrahisi Eğitim ve Araştırma Hastanesi, Girişimsel Pulmonoloji Kliniği, ANKARA - TÜRKİYE
e-mail: zaferaktas88@gmail.com

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INtRODUCTION

Central airway obstruction occurs in 20% to 30% of patients with lung cancer (1).

Symptoms associated with airway obstruction, such as cough, dyspnea and hemoptysis in patients with advanced lung cancer, greatly reduce their quality of life (2). In these patients, acute respiratory failure, atelectasis with obstructive pneumonia, and massive hemoptysis reduce the median survival time to 1-2 months (3,4). For such complications, surgery is often contraindicated in proximal lesions, chemotherapy has vague and delayed benefits, radiotherapy solves atelectasis in half of the cases, but the results are also delayed (5). Interventions bronchoscopic treatments are now recommended in guidelines to improve quality of life and symptom palliation in these group of patients (6). Many useful interventional bronchoscopic techniques have been developed to treat the endoluminal exophytic part of the malignant tumor causing airway obstruction, such as mechanical debridement, laser, electrocautery, argon plasma coagulation (APC), brachytherapy, photodynamic therapy and cryotherapy (7). The only option for extrinsic compression type stenosis is dilatation and stent placement (8). Malignant involvement of the lower trachea, the main carina, and the mainstem bronchi, often require the placement of a Y stent (9-12) (Figure 1). However, every placed stent carries the risk of potential complications such as mucostasis, migration, stent-edge tissue developments (12). The complication rate of silicone Y stents is as high as 51.9% (12). In this study, we aimed to determine the safety of silicone Y stents placed around the main carina in the malignant airway obstruction by examining the long term complications, emergence times and treatment approaches of complications.

MATERIALS and METHODS

In our interventional pulmonology clinic, between May 2012 and July 2015 47 Dumon silicone Y stents (Tracheobronxane®, Novatech, La Ciotat, France) were placed in 46 patients with malignant external compression or mixed type stenosis around the main carina. Patients stents were placed under total intravenous anesthesia in the operating room. The patients were intubated with a large-diameter rigid bronchoscope (size 14 mm, length 43 cm, Karl Storz SE&Co. Tuttlingen, Germany). The stents were folded with the appropriate applicator (Tonn Tracheobronchial Stent Applicator, Novatech, La Ciotat, France). The stents

Conclusion: The best palliative treatment of malignant tumor stenosis around the main carina is still silicone Y stent placement, but the long-term complication rate can be high. For this group of patients, bronchoscopy to be performed at the first and third months after silicone Y stent placement may provide early detection of stent-edge tissue development.

Key words: Silicone Y stent; interventional pulmonology; complication
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were placed using the “pull technique”. Patients with coagulation problems, or low platelet count, as well as pregnant subjects, those under the age of 18, and those who did not sign the informed consent were excluded.

For every patient, we recorded the age, gender, location of stenosis, pathology of the malignant process, the duration of stent placement, outcome, overall survival duration and complications.

We evaluated each patient with a fiberoptic bronchoscope 1 day after stent placement. After placement of the stents, patients were referred to our clinic in the presence of new or heavier respiratory symptoms. Patients whose respiratory symptoms worsened following placement of the stents were evaluated with bronchoscopy. Follow-up for all patients was available until August 9, 2015, the deadline for the study.

All data were analyzed with SPSS (Statistical Package for the Social Sciences) software for Windows Version 16.0. Descriptive statistics were expressed as the mean ± standard deviation for intermittent and continuous numerical variables, and categorical variables were expressed as number of cases and “(%)”. The Kaplan-Meier method was used for survival analyses.

This study has been approved by the local ethics committee. Informed consent was obtained from all patients.

RESULTS

The mean age of the study population (93.5% males) was 63.2 ± 9.4 years. The most common malignancy causing central airway obstruction was squamous cell carcinoma of the lung (59.7%). Most of the tumors were narrowing both the distal trachea and the main carina/main bronchi (69.6%) (Figure 2) (Table 1).

Figure 1. Follow-up images of silicone Y stent who placed due to malignant airway obstruction. (A) Malignant airway stenosis at distal end of trachea, (B) Before the stent placement, the image of the stenosis in the thorax computerized tomography (close-up around the main carina), (C) Bronchoscopic view of enlarged stenosis area at 120 days after the silicone Y stent placement, (D) At 45 days post Silicone Y stent placement, a thorax computerized tomography image (close-up around the main carina).

Figure 2. Malignant airway stenosis in the thorax computerized tomography (close-up around the main carina). (A) Malignant airway stenosis at both tracheal distal end and left main bronchus, (B) Silicone Y stent appearance.
All stents were placed successfully. In the half of the patients (23/46), stents were placed under urgent conditions due to acute respiratory failure. The main symptoms of the patients were shortness of breath (93.5%), cough (2.2%) and hemoptysis (4.3%). The end of the procedures provided symptomatic favor in all patients. Thirty nine patients were died during follow-up, 7 patients were still alive at the end of the study. The average duration of a stent after placement was 117.6 (range 4-733) days. The median time of

| Variables                                      | Value                                      |
|------------------------------------------------|--------------------------------------------|
| Age, mean ± SD (range) years                   | 63.2 ± 9.4 (44-83)                         |
| Gender (female/male)                           | 3/43                                       |
| Clinical diagnosis                             |                                            |
| Squamous cell carcinoma                        | 27 (58.7%)                                 |
| Adenocarcinoma                                 | 8 (17.4%)                                  |
| Small cell carcinoma                           | 6 (13.0%)                                  |
| NSCLC not otherwise specified                 | 3 (6.5%)                                   |
| Adenosquamous carcinoma                        | 1 (2.2%)                                   |
| Renal cell carcinoma metastasis                | 1 (2.2%)                                   |
| Main symptoms                                  |                                            |
| Dyspnea                                        | 43 (93.5%)                                 |
| Cough                                          | 1 (2.2%)                                   |
| Hemoptysis                                     | 2 (4.3%)                                   |
| Site of obstruction                            |                                            |
| Lower trachea                                   | 6 (13.0%)                                  |
| Main carina and main bronchi                   | 8 (17.4%)                                  |
| Both                                           | 32 (69.6%)                                 |
| Nature of lesions                              |                                            |
| Mixed                                          | 36 (78.3%)                                 |
| Extrinsic compression                          | 10 (21.7%)                                 |
| Respiratory failure at presentation            | 23 (50.0%)                                 |
| Stent size*                                    |                                            |
| 15 x 12 x 12 mm                                | 1 (2.2%)                                   |
| 16 x 13 x 13 mm                                | 28 (63.0%)                                 |
| 18 x 14 x 14 mm                                | 17 (34.8%)                                 |
| Technical success                              | 46 (100%)                                  |
| Symptomatic favor                              | 46 (100%)                                  |
| Long-term complications                        |                                            |
| Stent overgrowth granulation tissue            | 6 (13.0%)                                  |
| Mucostasis                                      | 4 (8.7%)                                   |
| Stent overgrowth tumor                         | 2 (4.3%)                                   |
| Migration                                       | 1 (2.2%)                                   |
| Final outcome                                  |                                            |
| Died during follow-up                          | 39 (84.8%)                                 |
| Alive at the end of the study                  | 7 (15.2%)                                  |

* Tracheal × right × left bronchial diameter.
NSCLC: Non small cell lung carcinoma.
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Survival following stent insertion was 157.0 (range 4-828) days. No procedure-related deaths were observed. Following the patients, the silicone Y stent-related complication rate was 28.3%. The mean time from the placement of the stents to the development of the complications was 81.9 (range 3-386) days. The most common complication was stent-edge granulation tissue development (13.0%). Mucostasis (8.7%) and migration (2.2%) were observed within the first month after placement of the silicone Y stents (median 18, range 3-22 days), stent-edge granulation tissue development was observed at the earliest one month (median 64, range 34-386 days) and stent-edge tumor tissue development (4.3%) were observed at the earliest 3 months (median 151, range 85-217 days) (Figure 3). A total of 7 (15.2%) stents were removed, 2 of which were due to mucostasis and 5 of which were due to granulation tissue development (Table 2). Cryotherapy was applied to the resulting granulation tissues. Due to stent-edge tumor tissue...

Table 2. Complications, treatments, days

| Age/Gender | Complication               | Treatment                                                                 | Time (days) |
|------------|----------------------------|---------------------------------------------------------------------------|-------------|
| 54/Male    | Migration                  | The stent was removed, after effective ablation of the tumor on the main carina, reinserted | 14          |
| 64/Male    | Mucostasis                 | The stent was cleaned with bronchoscopy                                   | 3           |
| 75/Male    | Mucostasis                 | The stent was cleaned with bronchoscopy                                   | 22          |
| 83/Male    | Mucostasis                 | The stent was removed                                                    | 22          |
| 69/Male    | Mucostasis                 | The stent was removed                                                    | 22          |
| 57/Male    | Stent overgrowth granulation | Recurrent cryotherapies were performed on the proximal stent-edge granulation tissue | 34          |
| 51/Female  | Stent overgrowth granulation | The stent was removed. Cryotherapy was applied to the residual granulation tissues | 43          |
| 54/Male    | Stent overgrowth granulation | The stent was removed. Cryotherapy was applied to the residual granulation tissues | 58          |
| 61/Male    | Stent overgrowth granulation | The stent was removed. Cryotherapy was applied to the residual granulation tissues | 70          |
| 66/Male    | Stent overgrowth granulation | The stent was removed. Cryotherapy was applied to the residual granulation tissues | 89          |
| 80/Male    | Stent overgrowth granulation | The stent was removed. Cryotherapy was applied to the residual granulation tissues | 386         |
| 54/Male    | Stent overgrowth tumor      | Recurrent argon plasma coagulation therapies were performed on the proximal stent-edge tumor tissue | 85          |
| 57/Male    | Stent overgrowth tumor      | Replaced by a longer silicone Y stent                                      | 217         |

Figure 3. Complications in bronchoscopic view. (A) Intensive mucostasis blocking the tracheal part of the silicone Y stent, (B) Early stage stent-edge tumor tissue, (C) Extreme stent-edge granulation tissue development, stent tracheal part is not visible.
development, one patient’s stent was replaced by a longer silicone Y stent.

**DISCUSSION**

There are many useful studies on the effects of stents in malignant airway obstruction. The findings of these studies are summarized as follows: technical success was 82-97%, mean duration of benefit was 4 months, median survival was 46-181 days, average duration of a stent after placement was 122-133 days, total survival time did not increase, quality of life improved (7,10,13-25). Symptoms and signs of central airway obstruction have diminished or disappeared (7,10,13-25). The technical success, median survival time, duration of a stent after placement, symptoms and signs decrease rates in our study were consistent with the literature.

Most airway silicone stents are well tolerated. For this reason, most malignant patients with silicone stents in the airways are thought to have died due to the progress of their disease without stent complications. In the literature, the pooled complication rate was reported as 16.6% in 9 silicone Y stent studies (12). However, complications of silicone Y stents can be as high as 51.9% (12). The total complication rate we found in our study was between these two values even when we did not follow the patients after the stent placement. There is no consensus on follow-up stents placed due to malignant airway obstruction.

Mucostasis, migration, stent-edge tissue developments are common complications after stent placement (9-13,26-36). Treatment of stent complications requires patient-specific treatment plan which is usually associated with the severity of the complication. The goal of treatment is to find a solution that will allow the stent’s function to continue. If this is not possible, the stent is removed.

Silicone Y stents were less displaced (1.2-3.7%) than other silicone stents (9-18%) due to their construction (9,10,12,15). In our study only one (2.2%) Y stent migrated and the cause of stent displacement was initially inadequate debulking of the tumour on the main carina. The tumor on the main carina pushed the stent upward so stent displaced. We removed the stent, after effective ablation of the tumor on the main carina, we reinserted it. Complication did not recur. Unlike ours in other studies, the reason for migration was that the stent diameter was small. For this reason either the stents were removed or replaced with larger diameter stents (9,10,12,15).

After airway stent placement massive secretions occur due to airway irritation. Local mucociliary clearance disruption at the stent area leads to mucostasis (26,27). The mucostasis rates in the studies were between 10-40% (9,16,27,28). Although it is considered a milder complication than other stent complications, it can be life threatening (29). In our study, 2 of 4 stents occluded due to mucostasis were removed because they cause life-threatening respiratory failure. The other two stents were cleaned with bronchoscopy, did not repeat after effective mucolytic and antibiotic therapy (Figure 4). In our study, the rate of mucostasis (8.7%) was lower than other studies but the rate of severe mucostasis was high (9,16,27-29).

In our study, migration and mucostasis were found to develop during the first month after stent placement. Patients were quickly directed to our clinic because symptoms were severe and it was easy to connect them to the stent instead of the underlying malignancy due to the short time after stent placement of these symptoms.

The rate of granulation tissue development on either edges of silicone Y stents was between 3.7% and 10% and the pooled ratio was 4.1% (12). In our study, the most common complication was the formation of stent-edge granulation tissue (13.0%), which was higher than in the literature. The development of stent-edge granulation tissue of patients with silicone stents is directly proportional to the frequency of lower respiratory tract infections (32). In countries such as our country and India where lower respiratory tract infections are thought to be common, it is expected that stent edge granulation tissue development (25.0% and 14.8% respectively) is higher (12,33).

In the literature, we could not find a stent that was removed due to the stent-edge granulation tissue developed in the stents placed due to malignant airway stenosis. Granulation tissues were treated with APC or cryotherapy or laser without removal of the silicone stents (12,34,35). In one study, stents were replaced with longer stents due to the granulation tissue developed in the stents placed for benign causes (36). In our study, 5 of the 6 silicon Y stents with stent-edge granulation tissue had to remove from the patient due to excessive tissue development. In these patients, cryotherapy of the residual granulation tissue was performed after the stent and the bulky granulation tissues were removed. We did not place the stents again because of fragile and hemorrhagic tissues.
Stent-edge tumor tissue development was observed in 7.0-21.0% (10,12,37). The development time was median 108 days (37). Stent-edge tumor tissue development was treated by removal of stents or by replacement with longer stents (10,37). In our study, one of the early development of stent-edge tumor tissue (85th day) was treated with recurrent APC treatments. One late development (217th day) was treated by replacing with a longer stent.

When we considered the earliest stent-edge tissue development times in our study, we thought that we could detect these developments early by performing follow-up bronchoscopy in the first and third months after stent placement. If these complications are detected early, they can be treated with stent-protective simple procedures. This can be achieved with a good stent follow-up program but there is no consensus to follow-up the stents. Therefore, a good stent follow-up program is needed.

Our study has a few limitations. It is a retrospective study, as was the case with other silicone Y stent studies, and we did not have a stent follow-up program. A prospective randomized trial may reveal early bronchoscopic detection of stent-edge tissue developments and the benefits of these findings in simple stent-protective treatments. In this way a stent follow-up program can be created.

CONCLUSION
The best palliative treatment of malignant tumors stenosis around the main carina is still silicone Y stent placement. However, survival time is limited to the longest median 6 months. The complications seen often during this period and the interventions required for them are serious problems that reduce the quality of life and threaten the life. Bronchoscopy can be performed at the first and third months in this group of patients in order to diagnose stent-edge tissue development early.

CONFLICT of INTEREST
The authors reported no conflict of interest related to this article.

AUTHORSHIP CONTRIBUTIONS
Concept/Design: ZA, DK
Analysis/Interpretation: ZA, AY
Data Acquisition: ZA, AÖ, AY
Writting: ZA
Critical Revision: ZA, DK, GY
Final Approval: All of authors.
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