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KLİNİK ÇALIŞMA
RESEARCH ARTICLE

Complications of silicone Y stents placed due to malignant airway stenosis

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SUMMARY

Complications of silicone Y stents placed due to malignant airway stenosis

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.*

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*

ÖZET

Malign hava yolu darlığı nedeniyle yerleştirilen silikon Y stentlerinin komplikasyonları

Giriş: *Ana karina çevresindeki malign hava yolu darlıkları genellikle Y şeklinde stentlerin yerleştirilmesini gerektirir. Bu çalışmada, malign hava yolu darlıklarında ana karina çevresine yerleştirilen silikon Y stentlerinin güvenliğini, uzun dönem komplikasyonları, ortaya çıkma süreleri ve komplikasyonlarının tedavi yaklaşımlarını inceleyerek belirlemeyi amaçladık.*

Materyal ve Metod: *Mayıs 2012 ile Temmuz 2015 arasında, ana karina çevresinde malign dış bası veya mikst tip darlığı olan 46 hastaya 47 silikon Y stent yerleştirildi. Stentler ameliyathane şartlarında total intravenöz anestezi altında rijit bronkoskopi ile uygulandı.*

Bulgular: *Hastaların yarısına (23/46), akut solunum yetmezliği nedeniyle acil koşullar altında stent yerleştirildi. Stentler tüm hastalarda başarıyla uygulandı. İşleme bağlı ölüm görülmedi. Stent sonrası median sağkalım 157 gündü. Silikon Y stentlerin toplam uzun dönem komplikasyon oranı %28.3 idi. Stentlerinin yerleştirilmesinden sonraki ilk ay içinde (ortalama 18 gün) mukostasis (%8.7) ve migrasyon (%2.2), en erken bir ayda (ortalama 64, aralık 34-386 gün) stent kenarı granülasyon dokusu gelişimi (%13.0) ve en erken 3 ayda (oralama 151, aralık 85-217 gün) stent kenarı tümör dokusu gelişimi (%4.3) saptandı. İki mukostazis ve 5 stent kenarı granülasyon dokusu gelişimi nedeniyle 7 (%15.2) stent çıkarıldı. Bir hastanın stenti, stent kenarı tümör dokusu gelişimi nedeniyle daha uzun bir silikon Y stentle değiştirildi.*

Sonuç: *Ana karina etrafındaki malign tümör darlığının en iyi palyatif tedavisi hala silikon Y stent yerleşimidir, ancak uzun dönem komplikasyon oranı yüksek olabilir. Bu hasta grubu için silikon Y stent yerleştirilmesinden sonraki ilk ve üçüncü aylarda yapılacak bronkoskopi, stent kenarı doku gelişiminin erken tespitini sağlayabilir.*

Anahtar kelimeler: *Silikon Y stent; girişimsel pulmonoloji; komplikasyon*

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). Interventional 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, lenght 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

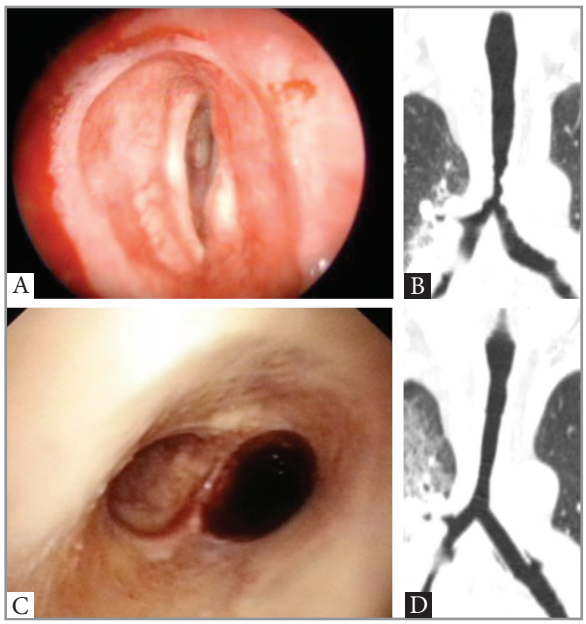

Figure 1. Follow-up images of silicone Y stent who placed due to malignant airway obstruction. **(A)** Malignant airway stenosis at distal end of trachea, **(B)** Before the stent placement, the image of the stenosis in the thorax computerized tomography (close-up around the main carina), **(C)** Bronchoscopic 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).

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).

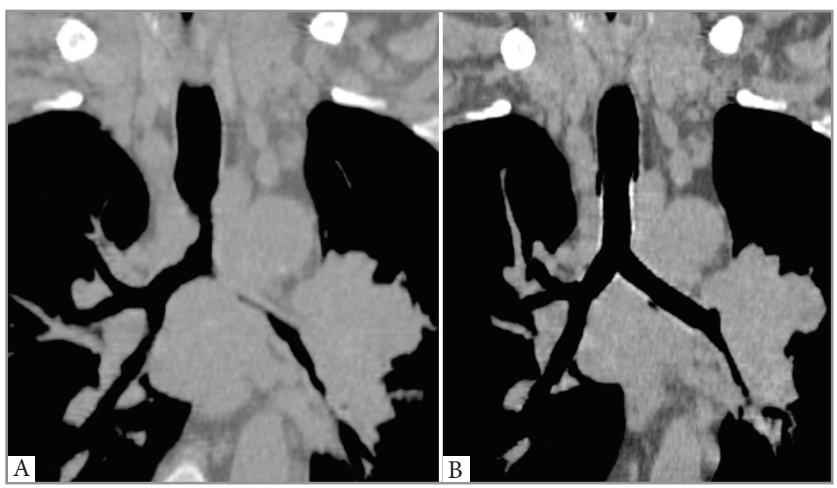

Figure 2. Malignant airway stenosis in the thorax computerized tomography (close-up around the main carina). **(A)** Malignant airway stenosis at both tracheal distal end and left main bronchus,**(B)** Silicone Y stent appearance.

Table 1. Demographic, clinical, and procedural details of the patients (n= 46)

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 othervise spesified	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		
	Mikst	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.

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

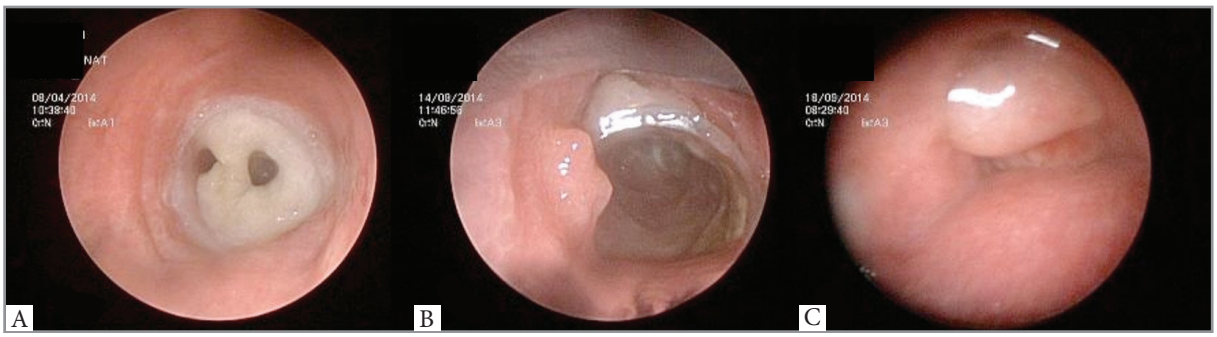

Figure 3. Complications in bronchoscopic view. **(A)** Intensive mucostasis blocking the tracheal part of the silicone Y stent, **(B)** Early stage stent-edge tumor tissue, **(C)** Extreme stent-edge granulation tissue development, stent tracheal part is not visible.

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

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

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% respectivly) 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.

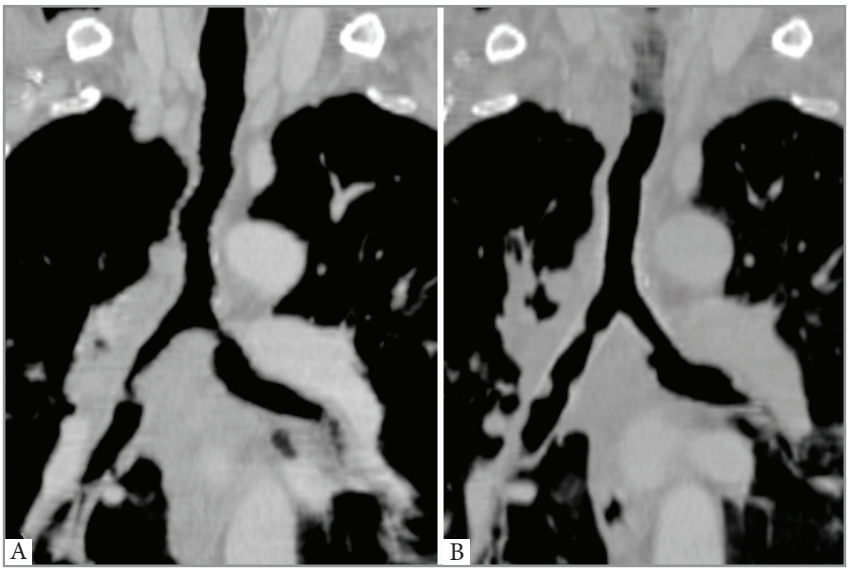

Figure 4. Mucostasis in the stent in the thorax computerized tomography (close-up around the main carina). **(A)** Before stent, **(B)** Mucostasis in the right main bronchus part of the silicone Y stent.

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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