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Bronchoscopic Cryotherapy in The Treatment of Endobronchial Typical Carcinoid

Ahmed S. Fadaly[1]*, Amr El Sayed Tawfek[1], Mamdouh Elsharawy[1], Mohammed Mehriz AboZaid[2], Ahmed Mohamed Said[2], Karim Elfakharany[1]
Departments of [1]Cardiothoracic Surgery and
[2]Chest Diseases, Faculty of Medicine, Zagazig University, Zagazig, Egypt
***Corresponding author:** Ahmed S. Fadaly, **Mobile:** (+20) 01272806252, **E-Mail:** ahmedfadalys@gmail.com

ABSTRACT
Background: Lung carcinoid tumors are low grade cancerous tumours that develop from neuroendocrine cells that have become more common recently. Endobronchial bronchoscopic cryotherapy has gained interest by cardiothoracic surgeons as an alternative to the surgical bronchotomy.
Objective: The aim of the current study is to assess the efficacy of bronchoscopic cryotherapy in the treatment of endobronchial typical carcinoid.
Patients and methods: A prospective controlled clinical trial included 30 patients presented with endobronchial typical carcinoid from the January 2021 to the August 2022. Patients were randomly divided into two equal groups. *Group A* included patients who had excision of the endobrochial mass using bronchscopic cryotherapy, and *Group B* included patients who had excision of the endobrochial mass using open surgical bronchotomy. Follow up of the patients was performed on regular basis clinically, radiologically and by bronchoscopic evaluation.
Results: The Hospitalization period was shorter in *Group A* (6±2 hours), than in *Group B* (8±3 hours) showing a statistically significant difference. There was a high statistically significant difference between both groups regarding the postoperative scar presence (0 % in *Group A* vesurs 100% in *Group B*). Intraoperative and peri-operative data showed a non-significant difference ($p>0.05$) between both studied groups.
Conclusion: Bronchoscopic cryotherapy is an efficient and safe procedure for the excision of endobronchial typical carcinoid.
Keywords: Cryotherapy, Bronchotomy, Typical carcinoid.

INTRODUCTION

Lung neuroendocrine tumours differ greatly from common carcinoid to small cell lung carcinoma. Carcinoid tumours are low grade malignant tumours of the lung that develop from neuroendocrine cells [(1)]. These cancers occur in less than 5% of all primary lung tumours. The reported incidence of pulmonary carcinoid tumour has grown over the past three decades. Afro-American and Asian people are more likely to get these tumours. It is believed that the rise in disease awareness is related to this rise in incidence [(2)].

According on mitotic number, architectural disturbances, and necrosis status, carcinoid tumours are categorized into typical and atypical subtypes. The most well-differentiated and least physiologically aggressive variety of pulmonary neuroendocrine tumours is thought to be typical carcinoid tumours of the lung. These tumours typically develop slowly and seldom spread to other organs [(2,3)].

Currently, the ideal treatment for lung carcinoid tumours is surgical excision. But with all forms of lung cancer, it is advised to spare the lung tissue as much as possible. Bronchscopic approaches were introduced as possible therapeutic options to excise the endobronchial typical carcinoids in selected cases. The commonly used techniques are laser therapy, cryotherapy and argon plasma coagulation [(4,5)].

Bronchoscopic cryotherapy has gained popularity among surgeons. It showed efficacy in the re-canalization of the partially and/or completely obstructed bronchus by a malignant tumour. The use of extremely freezing temperatures in cryosurgery is to remove aberrant or diseased tissue. This technique was detected to be a cheap, an effective and a safe procedure in the re-canalization of the obstructed airway when compared to other costly procedures [(3)].

Cryotherapy has significantly decreased the probability of local recurrence when used in early stage of non-small cell lung cancer. However, bronchoscopic excision must be done in carefully selected patients with specific criteria [(5,6)]. The aim of the current study is to assess the efficacy of bronchoscopic cryotherapy in the treatment of endobronchial typical carcinoid.

PATIENTS AND METHODS

Study design and population:

This prospective randomized controlled clinical trial was performed in 2 tertiary hospital centres (Zagazig University Hospitals and Al-Obour Hospital). These hospitals are serving multiple health centres that introduce the health services to about 12 million populations. The study was performed over 20 months from January 2021 to August 2022.

Inclusion criteria were intraluminal typical carcinoid with diameter <20 mm on computed tomography scan, volume <5 cm3, small base<1.5 cm2 and without lymph node invasion or suspected locoregional metastasis.

Exclusion criteria were atypical carcinoids, carcinoid tumours that were peripherally located, radiologically

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suspected, metastasis (either local, distant or cartilage invasion) and the tumours with a wide base on the airway.

The sample size was calculated as the following: Assuming that all patients who met the inclusion criteria were 2 patients/ month over the study duration (12 months), the calculated sample size was calculated to be 24 cases; 12 cases in each group. A total of 38 cases who were previously diagnosed to have typical carcinoid had presented to our department were initially investigated for our study.

The final analysis included 30 cases. The allocated cases were randomized using computerized randomization schedule, by one of the authors other than the operators who performed the procedures, into two groups: *Group A* (n=15) had excision of the endobrochial mass using bronchscopic cryotherapy and *Group B* (n=15) had excision of the endobrochial mass using open surgical bronchotomy (**Figure 1**). The surgeons were informed about the allocated procedure when the patient was in the operating room.

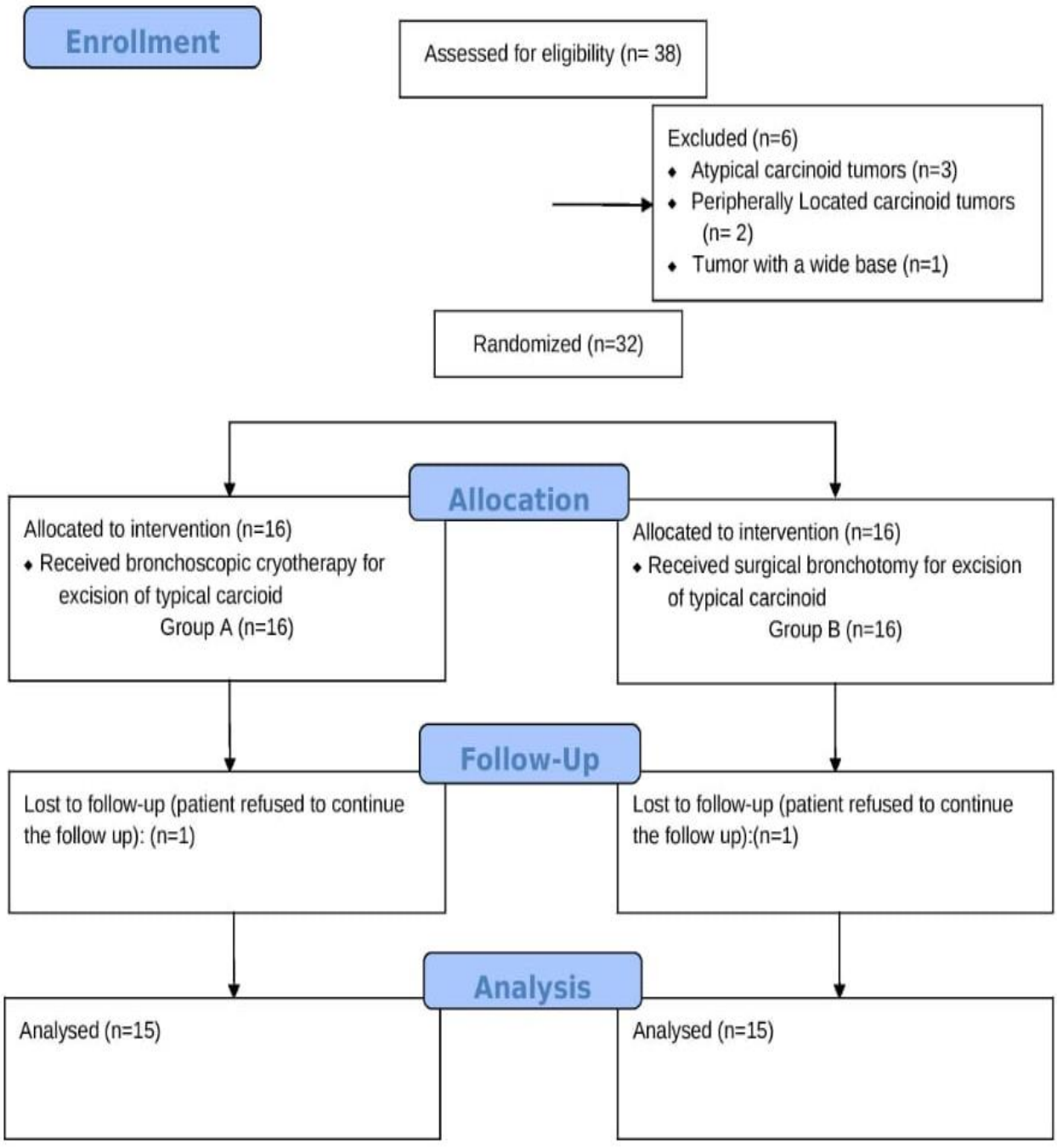

Figure (1): Flow chart of the study (CONSORT flow chart).

Preoperative preparation:

Full detailed history, physical examination, routine laboratory investigations and radiological investigations in the form of plain chest X-ray and computed tomography of the chest were done for all the patients included in our study. Rigid or flexible bronchoscope was done and a tissue biopsy was obtained to confirm the histopathology of typical carcinoid in each patient in both studied groups.

Surgical technique:

All patients were operated by two experienced surgeons (over 10 years of experience). All procedures were performed under complete aseptic precautions and under general anaesthesia.

In *Group A*, fiberoptic bronchoscope with a working channel of 2.6 mm, (BF-IT 10; Olympus America; Melville, NY) was performed first for optimum localization of the mass. Thereafter, the flexible cryoprobe was inserted with the following criteria: 2.4 mm in diameter, 90 cm in length and 7 mm tip length (ERBE USA Inc; Marietta, Ga). It was positioned either perpendicularly or tangentially in direct contact with the tumour through the working channel and actuated for about thirty seconds using a foot pedal. The tip of the bronchoscope was advanced 0.5–1.0 cm closer to the intended mass. After deactivating the foot pedal, the thawing procedure proceeds passively. Usually, this cycle was repeated two to three times at each spot followed by moving on to a nearby tumour area.

The whole tumour surface was removed, along with a 5-mm safety margin of surrounding, healthy mucosa. The cryoprobe could penetrate the wall sufficiently deep since there was around 5 mm between two neighbouring applications (**Figure 2**).

Intraoperative evaluation of severity of bleeding was important to make sure that the patient was not in need for a rescue surgical bronchotomy approach. Bleeding was considered mild if it was sufficient just to apply cold normal saline 0.9% solution at 2 °C–4 °C or ephedrine solution in a concentration of 1 mg/10 mL saline water to stop the bleeding. It was considered moderate if we had to use additional techniques like bronchus blocker. It was considered severe if additional treatment was needed to stabilize the patient's condition; for example: blood and fresh frozen plasma transfusion, coagulation factors transfusion, the use of vasopressors, convert to a rescue bronchotomy operation and the need for prolonged mechanical ventilation postoperative.

In *Group B*, fiberoptic bronchoscopy was done first for optimum localization of the mass. The patient was positioned laterally, either right or left up according to the site of the endobronchial mass. Posterolateral thoracotomy approach at the 5th intercostal space was performed. A bronchotomy was done and the mass was excised at its base. The bronchotomy was then closed using vicryl 2/0 suture. Positive ventilation test was performed with the aid of anaesthetic to evaluate the bronchotomy suture line closure. Two intercostal drains were inserted for drainage. The intercostal space was closed using vicryl 1 sutures. The soft tissues were closed in anatomical fashion using running absorbable sutures.

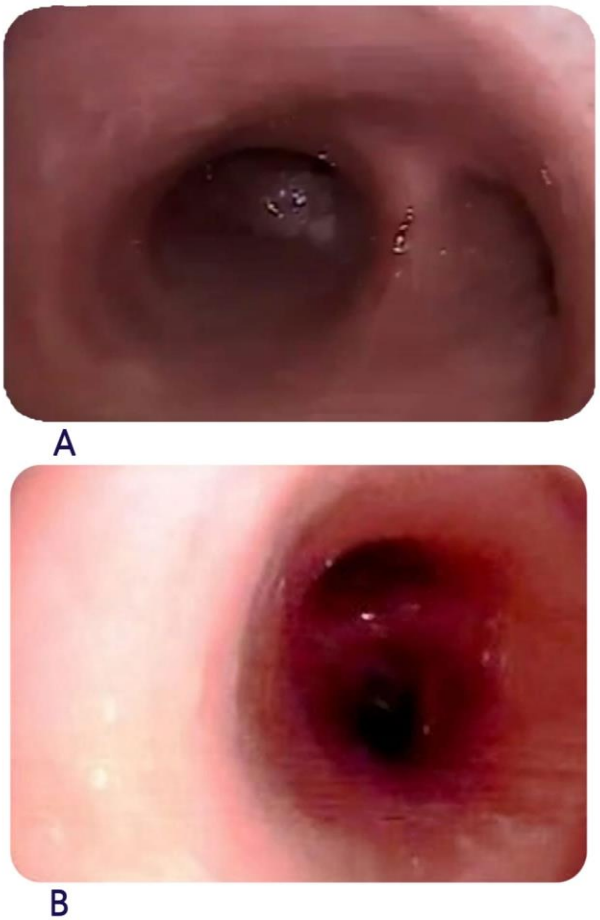

Figure (2): A) A bronchoscopic image showing an endobronchial mass bulging in the right bronchus intermedius with smooth glistening surface. **B)** A bronchoscopic image showing patent right right bronchus intermedius after excision of the endobronchial mass using bronchoscopic cryotherapy.

Early assessment of the success and safety of the procedure:

The intraoperative criteria that we followed to determine the success of cryoptherapy were: successful excision of the entire endobronchial carcinoid tumour mass allowing appropriate drainage of secretion and minimizing the stenosis of the airway. The patient did not need prolonged mechanical ventilation for longer than 2 hours following the intervention. The postoperative criteria were obvious improvement in the patient's general condition and improvement of the main complaints (dyspnoea, fever, or cough).

Postoperative follow up:

Follow up was done over 1.5 year duration clinically and radiologically. Additionally, flexible bronchoscope was done for each patient in both studied groups at regular intervals (every 3 months).

Ethical statement:

The Institutional Review Board (IRB) of Zagazig University gave its approval to this study (Approval number ZU_IRB#10016/4-1-2022). Written informed consent was obtained from all participants. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical analysis

The collected data w ere introduced and statistically analyzed by utilizing the Statistical Package for Social Sciences (SPSS) version 20 for windows. Qualitative data were defined as numbers and percentages. Chi-Square test and Fisher's exact test were used for comparison between categorical variables as appropriate. Quantitative data were tested for normality by Kolmogorov-Smirnov test. Normal distribution of variables was described as means and SD, and independent sample t-test was used for comparison between groups. P value ≤0.05 was considered to be statistically significant.

RESULTS

Demographic data:

There was non-significant difference between both groups regarding the demographic data. The presenting symptoms were pneumonia, cough, dyspnea, heamoptysis, and asthma like symptoms. No significant difference was detected between both studied groups. All the aforementioned data are summarized in **Table 1**.

Table (1): Demographic data and presenting symptoms of patients in both groups.

Variable	Group (A)	Group (B)	P-value
Age	47 ± 5	35 ± 4	N.S
Gender			
Male	6 (6.6%)	5 (33%)	N.S
Female	9 (60%)	10 (66%)	N.S
Smoking			
Yes	7 (46.6%)	6 (40%)	N.S
No	8 (53.3%)	9 (60%)	N.S
Comorbidities			
hypertension	1 (6.6%)	2 (13%)	N.S
Diabetes mellitus	2 (13%)	1 (6.6%)	N.S
COPD	2 (6.6%)	1 (6.6%)	N.S
Renal insufficiency	1 (13%)	0 (0%)	N.S
Presenting symptoms			
Pneumonia	2 (13%)	3 (20%)	N.S
Cough	3 (20%)	2 (13%)	N.S
Dyspnea	4 (26.6%)	4 (26.6%)	N.S
Haemoptysis	2 (13%)	2 (13%)	N.S
Asthma like	3 (20%)	2 (13%)	N.S
Accidental finding	2 (13%)	3 (20%)	N.S

COPD: Chronic Obstructive Lung Disease, N.S: Nonsignificant.

There was no significant difference between both groups regarding the CT findings, the shape of the tumour mass, or the degree of lumen obstruction in both studied groups. The trachea, right main bronchus, left main bronchus, right upper lobe bronchus, right bronchus intermedius, right middle lobe bronchus, right lower lobe bronchus, left upper lobe bronchus, and left lower lobe bronchus were all found to have tumour masses. However, there was no significant difference between both studied groups (**Table 2**).

Table (2): Tumour characteristics as shown in computed tomography of the chest and by bronchoscopic assessment in both groups.

Variable	Group (A)	Group (B)	P-value
Size on C.T. chest(cm)			
0.5-1	6 (40%)	7 (46.6%)	N.S
1-2	9 (60%)	8 (53.3%)	N.S
Shape			
Oval	9 (60%)	6 (40%)	N.S
Rounded	6 (40%)	9 (60 %)	N.S
Pedunculated	12 (80%)	13 (86.6%)	N.S
Sessile	3 (20%)	2 (13.3%)	N.S
Lumen obstruction			
Partial	10 (66.6%)	11 (73.3%)	N.S
Complete	5 (33.3%)	4 (26.7%)	N.S
Lesion location			
Trachea	1 (6.6%)	1 (6.6%)	N.S
Right main	6 (40%)	4 (26.7%)	N.S
Left main	4 (26.7%)	6 (40%)	N.S
Bronchus intermedius	1 (6.6%)	0 (0%)	N.S
Right upper lobe	0 (0%)	1 (6.6%)	N.S
Right middle lobe	1 (6.6%)	0 (0%)	N.S
Right lower lobe	1 (6.6%)	1 (6.6%)	N.S
Left upper lobe	0 (0%)	1 (6.6%)	N.S
Left lower lobe	1 (6.6%)	1 (6.6%)	N.S

N.S: nonsignificant.

Table 3 presents the percentage of most common intraoperative complications during excision of endobronchial tumour masses in both studied procedures. There was nonsignificant difference

between both studied groups regarding intraoperative bleeding and hypoxia.

Only 2 patients in *Group A* needed conversion to surgical bronchotomy because the base of the mass was detected wide at time of the manoeuvre. Postoperative follow up course and outcome is presented in **Table 3**.

There was a statistically significant difference between both groups in the hospital stay duration. A high statistically significant difference was detected between both studied groups regarding the postoperative surgical scar. There was nonsignificant difference between both groups regarding ICU stay/hours, the rate of 30 days mortality, presence of stricture on follow up and recurrence.

Table (3): Intraoperative complications and postoperative course in both studied groups.

Variable	Group (A)	Group (B)	P-value
Intraoperative complications			
Bleeding (%)	2 (13%)	1	N.S
Hypoxia (%)	1 (6.6%)	(6.6%)	N.S
Conversion to bronchotomy(%)	2 (13%)	2 (13%)	N.S
		0 (0%)	
Postoperative course			
ICU stay (hours)	6 ± 2	8 ± 3	N.S
Hospital stay (days)	2 ± 1	6 ± 2	S
Surgical thoracotomy scar (%)	0 (0%)	15	H.S
30 days mortality (%)	0 (0%)	(100%)	N.S
Follow up stricture (%)	1 (6.6%)	0 (0%)	N.S
Recurrence (%)	1 (6.6%)	1 (6.6%)	N.S

N.S: Nonsignificant, S: Significant, H.S: Highly significant.

DISCUSSION

Nearly 25% of patients with lung carcinoid tumours are asymptomatic. The intensity and range of symptoms are influenced by the size of the carcinoid lung tumours and the hormones they produce. Atypical carcinoid tumours are typically discovered at stage II or III (in more than 50% of cases), but typical carcinoid tumours are frequently discovered at an early stage (90% of instances). The symptoms of the patient, a chest x-ray, and a tissue biopsy are used to make the diagnosis of a carcinoid pulmonary tumour. To determine the histological nature of the tumour, there are numerous biopsy techniques available, including bronchoscopic biopsy, needle biopsy, and surgical biopsy by thoracotomy approach [7].

It was often thought that individuals with incurable conditions were the only ones who could undergo bronchoscopic removal of bronchial carcinoids. In the past, there appeared to be agreement that surgery is the best option for treating all carcinoid tumours. However, bronchoscopy has been touted as a viable therapy option for removing normal bronchial carcinoid tumours [8,9].

In this study, we evaluated the outcome of bronchoscopic cryotherapy in the excision of endobronchial typical carcinoid tumours in comparison to the most commonly used approach, the surgical bronchtomy. We also assessed the intraoperative and postoperative course of the patients included in our study.The most often documented side effects of interventional bronchoscopy include pneumothorax, bleeding, and hypoxia (10). In our study 2 patients (13%) in *Group A* had intraoperative bleeding versus 1 patient (6.6%) in *Group B*. Additionally; we were obliged to convert the procedure into surgical bronchotomy approach only in 1 patient in group A due to uncontrolled bleeding. However, the patient had smooth course after operation. Hypoxia was detected in 1 patient in *Group A* (6.6%) and 2 patients in *Group B* (13%). Only 1 patient in *Group A* needed conversion to surgical bronchotomy to control the hypoxia.

In a previous study was performed on a series of patients using the Nd:YAG laser bronchoscopy, one patient had a burn in the bronchus when he was inhaling 100% oxygen during bronchoscopic excision. Additionally, one incidence of hemorrhage-related death was reported by **Cavaliere *et al.*** [11] and **Neyman *et al.*** [12] in their investigation, which included 245 bronchoscopic excision series and 175 carcinoid tumours. **Boyaci *et al.*** [13] had reported that one patient had persistent hypoxia and the operators had to terminate the bronchoscopic excision procedure. However, it was completed in total 3 bronchoscopy sessions and no other major complications required discontinuation of the procedure were reported. Additionally, more than 50% stenosis had developed after the bronchoscopic procedure in two patients in a series of 245 patients who had benign lesions.

It was reported that in patients complaining from symptomatic malignant central obstruction of the airway, the surgeons had used laser ablation, cryotherapy, with/without airway stenting for re-canalization of airway. All patients showed airway diameter improvement. More than 80% of the airway patency was achieved in (80%) of the patients. Dyspnoea scores showed improvement in (85%) of participants. They proved that endoscopic procedures could effectively improve the dyspnoea related to central airway obstruction due to malignant tumour [14].

Our study results showed that on postoperative follow up, airway stricture was detected in one patient (6.6%) in each group after 3 months. However, both patients had responded to bronchoscopic dilatation that was successful and they showed no recurrence of the stricture on the follow up. Moreover, one year after the procedure, nearly 50 % stenosis was detected only in two patients, one patient in each group, with nonsignificant complaint. One of these patients had balloon dilatation once and stenosis did not show

recurrence. The other patient had local intervention with cryotherapy twice although they showed no clinically significant symptoms.

Dalar *et al.* [15] had used the endobronchial cryotherapy as an initial treatment approach and as a consecutive approach for the prevention of endobrochial carcinoid tumours recurrence. No recurrence was detected during the follow-up period.

Additionally, other literatures had reported that a series of 18 patients with typical bronchial carcinoids were treated using bronchoscopic cryotherapy. All patients showed no recurrence during a median follow-up of 55 months, except for only one patient who had local recurrence (5.5%) that was detected 7 years after the treatment [16].

Papaporfyriou *et al.* presented a valuable clinical study in a 35 year old male patient. His original complaint was haemoptysis. Chest computed tomography scan showed a central polypoid tumour in the left main bronchus. The histological analysis was showing typical carcinoid characteristics. The bronchoscopic approach was used for the treatment and the patient had a good postoperative course during the follow up period of 2 years with no complications or recurrence [17].

It is important to note that in patients with bronchial carcinoid, the presence of solely intraluminal disease and the size of the tumour on computed tomography scans have independently been shown to predict the efficacy of endobronchial therapy. Regardless of histological grade, patients with solely intraluminal carcinoid tumours that measure less than 20 mm in diameter on a CT scan are suitable candidates for endobronchial therapy. On the other hand, every patient with a tumour diameter of less than 20 mm should be sent for surgery as away [8].

Recent research demonstrate that therapeutic bronchoscopy is effective for symptoms associated with central airway obstruction due to malignancy with infrequent complications. Additionally, they showed the improvement in symptoms and life quality were preserved after intervention with resulting better overall survival in patients having central airway obstruction due to malignancy. Recent data also support the idea that therapeutic bronchoscopy may enable more definitive cancer treatment with further improving patient outcomes. Therefore, bronchoscopy can be safely used for therapeutic purposes in malignant central airway obstruction with effective outcomes [18].

Results of our study showed recurrence of the tumour in one patient in each group (6.6%) after 12 months postoperative. **Cavaliere *et al.*** [19] had reported that after excision, the typical carcinoid tumours showed recurrences within the 1st ten years, while the atypical carcinoid tumours showed recurrences within the 1st five years.

However, recurrence was not observed in a study that had included 35 patients who had received curative tumour excision and a follow up duration between 1 and 198 months in other case series. In another study that had included 14 patients with a mean follow up duration was 32 month (8-68), no recurrence was detected [19,20].

Consequently, endobronchial approach for tumour excision is a safe and successful treatment modality. Patient selection is extremely important. The most important criteria suitable for bronchoscopic approach are: patients who have typical carcinoid tumours that are centrally located, with no suspected local or distant metastasis, not located on the bronchi with a broad base and obviously visible by bronchoscope. Cryotherapy, in contrast to other adjuncts that have been suggested, is not linked to long-term problems such bronchial stenosis [16,19,20].

Limitations of the study: Studies on carcinoid tumours are considered challenging due to their infrequency. It is very important for the surgeons and operators to continue their investigations and publish their valuable results from such cases. However, data of patients who have appropriate conditions suitable for endobronchial bronchoscopic excision approach and the follow up duration make this study valuable.

CONCLUSION

Bronchoscopic cryotherapy is an effective and safe technique for the excision of endobronchial typical carcinoid tumours. It can be used as an alternative approach to open surgical bronchotomy with better results regarding postoperative scar and hospital stay duration. However, patient selection is an important factor that affects the outcome of the procedure.

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