



The Long-term Outcomes of Completion Pneumonectomy from a Tertiary Center

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Abstract

Aim: Completion pneumonectomy is a compelling procedure that is associated with high rates of mortality and morbidity. The aim of the present study was to investigate long-term surgical and oncologic outcomes of completion pneumonectomy.

Methods: A retrospective review was conducted of 66 patients who underwent completion pneumonectomy in our clinic between 2006 and 2016. The patients were divided into two groups. The patients undergoing classical completion pneumonectomy (n=58), 56 had a malignant disease (non-small-cell lung carcinoma) and two patients had a benign disease. Eight patients had undergone rescue completion pneumonectomy; bronchopleural fistula in five patients, pulmonary venous occlusion in two patients, and upper lobe torsion in one patient.

Results: The median follow-up period was 37.6 months. The overall mortality rate was 7.6%. The amount of intraoperative bleeding and the percentage decrease in hemoglobin levels (p=0.003) were prognostic factors affecting mortality. The postoperative complication rate was 41.4% in classical completion pneumonectomy and 50% in rescue completion pneumonectomy (p=0.64), and it was significantly higher in patients older than 65 years (p=0.04). The 5-year survival rate was 58% in malignant disease.

Conclusion: Completion pneumonectomy procedure has satisfactory oncological and surgical results when performed in experienced centers on selected patients. The morbidity and mortality rates of classical completion pneumonectomy and rescue completion pneumonectomy are similar.

Keywords: Pneumonectomy, prognosis, postoperative complications, bronchopleural fistula, lung cancer

Introduction

Completion pneumonectomy (CP) refers to the surgical removal of the remaining lung after previous ipsilateral resections of the lung parenchyma. Indications for CP are extremely rare but involve both benign and malignant diseases (1). CP is often considered a risk factor for postoperative mortality among thoracic surgeons and in studies evaluating patients undergoing pneumonectomy (2). The advent of parenchyma-preserving surgical

procedures for treating lung cancer, improvements in thoracic surgical techniques, longer patient follow-ups, increased frequency of lung cancer detection, and prolonged survival time after resection have increased the incidence of similar diseases (3). All of these secondary lesions and complications occurring after the initial operation increase the rate of CP procedures.

CP is a very complicated procedure and is associated with an increased perioperative risk. In the literature,

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there is a consensus on the application of CP surgery in experienced centers with a sufficient number of cases (2,4). CP is often performed for malignant disease, and studies on cases who underwent CP because of early complications of primary surgery, which we defined as rescue CP, are limited (1,5).

In this study, mortality, morbidity, indications, complications, results, and associated risk factors in patients undergoing classical CP (CCP) and rescue CP in our clinic were evaluated retrospectively.

Materials and Methods

Compliance with Ethical Standards

The University of Health Sciences Turkey, Istanbul Training and Research Hospital Clinical Research Ethics Committee approval of this study was acquired (decision no: 2018-KAEK-50/1259) and conducted in accordance with the principles of the Declaration of Helsinki. Informed consent was obtained from all patients.

Study Design

The records of 75 patients who underwent CP between 2006 and 2016 were analyzed. Excluded from the study were six patients who discontinued follow-up and three patients who did not undergo an anatomical resection in their first surgery. The data of the remaining 66 patients were retrospectively evaluated. The patients were divided into two groups: those undergoing (CCP, n=58) and those undergoing rescue CP because of complications (RCP, n=8) (Graph 1).

Patients undergoing complete lung resection in the initial surgery due to primary NLCLC and patients undergoing completion CP due to complications such as bronchopleural fistula, pulmonary venous occlusion, and upper lobe torsion were included in the study. CP was defined as surgery performed to remove the remaining lung tissue after a previous anatomical lung resection. Recurrent lung cancer and a second primary lung cancer were defined according to the criteria proposed by Martini and Melamed (6). Rescue CP was defined as surgery performed on a patient undergoing completion CP due to complications.

Preoperative Assessment

The surgical notes related to the patients were retrieved and reviewed. All patients underwent re-staging, for which thoracic and upper-abdominal computed tomography scans were obtained. Positron emission tomography was requested to evaluate distant metastases and the mediastinum, and a pulmonary function test was requested to evaluate pulmonary reserves. All patients underwent bronchoscopy for diagnostic purposes before surgery. The mediastinal assessment of patients operated

on for malignant disease has been made via video-assisted mediastinoscopy before the previous operations.

Surgical Approach

Endotracheal intubation with a double-lumen tube was performed in all patients following the induction of anesthesia. All patients underwent posterolateral thoracotomy in the lateral decubitus position via the previous thoracotomy incision site. The chest cavity was frequently entered from an upper intercostal area instead of the one used in the previous thoracotomy. Due to the rib separation could be difficult, subperiosteal resection of the fifth rib was performed carefully before the rib separation. With this maneuver, a wide exposure was provided for the removal of pleural adhesions. After the ribs were separated, the lung was mobilized intrapleurally or extrapleurally, depending on the pleural adhesion density. Manual and/or sharp dissection with scissors and/or electro-cautery were performed to take care of the bleeding. Extrapleural dissection was confined to a limited area due to the risk of postoperative bleeding. However, it was performed if a risk of tearing the lung or leaving its fragments on the chest wall was seen. Moreover, when the pleural adhesion density was greater than expected, dissection was advanced toward the mediastinal surface, which has fewer dense adhesions, and this was followed by pneumolysis. Resection of the pulmonary vessels was usually (n=37) resected with an intrapericardial approach due to extensive inflammation around the hilum after previous surgery. However, if the pericardium was opened during the previous surgery, an intrapericardial approach for the control of the pulmonary vessels was avoided (n=2). Moreover, if the hilum adhesion was not dense, the pericardium was not opened (n=27). After this maneuver, the main pulmonary artery was encircled with a finger. Then, a blunt clamp held on the other side was encircled. Control over the vascular structures in the hilar region was achieved in the early periods of surgery (Figure 1). The pulmonary vessels were ligated first, and then the main bronchus was divided. A systematic lymph node dissection was routinely performed in cases with a tumor.

Postoperative Follow-up

The patients were awakened from anesthesia in the operating room, and were followed up in the surgical intensive care unit until their general conditions stabilized. The chest tube was withdrawn once the discharge dropped below 300 mL per day. The histopathologic evaluations of patients who were operated on due to primary NLCLC were performed according to the 8th edition of the TNM classification (7).

Mortality and morbidity were defined as incidences occurring during post-surgery hospitalization and within

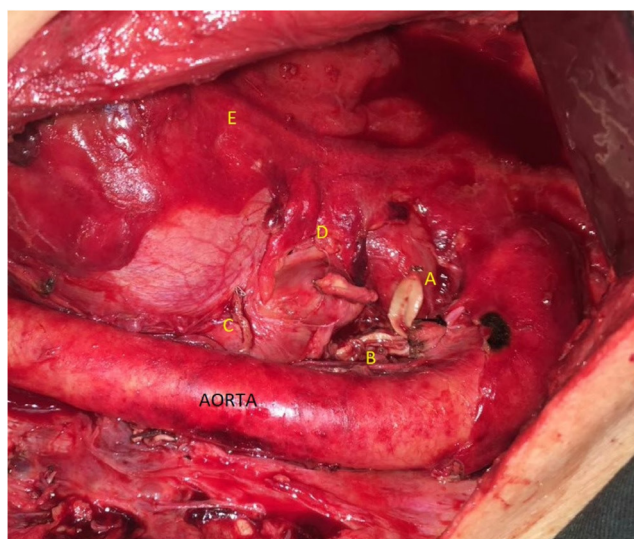
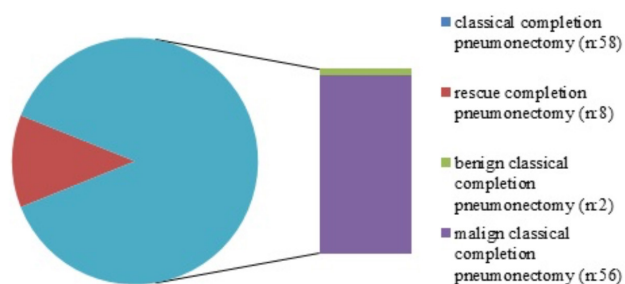


Figure 1. Completion pneumonectomy Extrapleural dissection was performed following the posterolateral thoracotomy. The pericardium was opened on the hilar side for the control of the pulmonary vessels. The pulmonary vessels were resected with intrapericardial approach

A: Left pulmonary artery, B: Left main bronchus, C: Left pulmonary vein inferior, D: pericardium



Graph 1. Subgroup description of completion pneumonectomy

the postoperative 30 days. Morbidities included respiratory failure, hemothorax, BPF, pyothorax, arrhythmia, and wound infections. Patients with a malignant disease were followed up in collaboration with the department of oncology during the postoperative period. Our postoperative treatment policy for patients with stage IIA.

IIIB NLCLC is to be administered only in adjuvant chemotherapy. In the presence of chest wall invasion and N2 disease, radiotherapy is also administered in addition to chemotherapy. Patients were followed up with thoracic CT scans and physical examinations every three months for the first two years, and every six months after that.

Statistical Analysis

Descriptive statistics were used for the demographic and clinical data. A chi-square test was used to evaluate

the relationship between categorical variables, and a Student's t-test, Mann-Whitney U test, and Kruskal-Wallis test were used to evaluate continuous variables. A Kaplan-Meier test was used for the survival analysis, and a log-rank test was used to compare factors. A p-value below 0.05 was considered statistically significant in the study. The SPSS software package (version 22, SPSS Inc., Chicago, IL, USA) was used for the statistical analysis.

Results

The mean age of the patients was 55.80 ± 10.9 years. Among the patients undergoing CCP, 56 (83.3%) had a malignant disease non-small-cell lung carcinoma (NSCLC) and two patients (4.5%) had a benign disease. One of the benign diseases destroyed the lung with aspergilloma, and the other was bronchiectasis with hemoptysis. The reasons for undergoing RCP were BPF in five patients; pulmonary venous occlusion in two patients; and upper lobe torsion in one patient. The causes of primary surgery were NSCLC in the RCP group. Comorbidities were observed in 51 patients (77.3%), the most common of which were cardiac pathologies (42.2%) (Table 1a).

Initial Operation and Completion Pneumonectomy

The mean time between the initial surgery and the second surgery was 41.3 months (minimum: 1.3, maximum: 183 months) in the CCP group. The most frequent initial surgical procedure was right upper lobectomy (n=22, 33.4%), with one patient (1.5%) undergoing right middle lobectomy, one (1.5%) undergoing a sleeve right inferior bilobectomy, and nine (13.2%) undergoing a right inferior bilobectomy 10 (15.2%) were undergoing right inferior lobectomy, 13 (19.7%) were undergoing left upper lobectomy, and 10 (15.2%) were undergoing left lower lobectomy. When the histopathological diagnoses of patients undergoing CP due to malignant causes were evaluated, 20 (36.4%) had adenocarcinoma, 31 (56.4%) had squamous cell carcinoma, and five (7.3%) had other histopathological diagnoses. Among the patients undergoing CCP due to malignant causes, the N stage was reported as N0 in 39 patients (69.6%), N1 in 14 patients (25%), and N2 in three patients (5.4%). The most common tumor stage after CP in malignant CCP was stage 1 (n=26, 46.4%), whereas 20 patients (35.7%) had stage 2 and 10 (17.8%) had stage 3 disease (n=T4N0: 7, n=T3N2: 1, n=T1N2: 2).

Morbidity

While postoperative complications occurred in 28 patients (42.2%), with the most common complication being atrial fibrillation (19.7%), the postoperative complication rate was 41.4% in CCP and 50% in RCP (p=0.6). Aged >65 years was identified as a significant

prognostic factor affecting postoperative complications ($p=0.04$) (Table 1b).

A total of four patients underwent revision surgery due to bleeding. No bleeding focus was detected in two patients, whereas one patient suffered a leaking hemorrhage in which hemostasis was later achieved. In the one patient who experienced bleeding from the bronchial artery, bleeding was controlled through the ligation of the bronchial artery. Furthermore, two patients (3%) developed acute renal failure and two (3%) experienced postoperative hemoptysis. The patients underwent bronchoscopy, but no active bleeding focus was detected, and these patients subsequently recovered under medical therapy. Additionally, two patients (3%) developed wound site infections; and six patients (9.1%) developed pneumonia and were treated with non-invasive mechanical ventilation. Empyema was encountered in eight patients (12.1%) postoperatively. A chest tube was inserted in the patients who developed empyema and were treated with the appropriate antibiotherapies.

Following the completion of pneumonectomy, BPF was detected in 10 patients (15.2%). The BPF rate was 15.5% ($n=9$) in CCP and it was 12.5% ($n=1$) in RCP ($p=0.8$). Furthermore, three patients with BPF underwent fistula closure with omentoplasty, and two patients developed microfistulas and underwent chest tube insertion. The fistulae were observed to close because of closed drainage and antibiotherapy. Of the total, three patients underwent Eloesser flaps, and another patient underwent an Eloesser flap after developing recurrent BPF following

omentoplasty. Additionally, one patient died of pneumonia after BPF. Supporting the bronchial stump with any tissue significantly reduced the risk of developing BPF ($p=0.01$), diabetes mellitus ($p=0.03$), and adjuvant therapy following initial surgery ($p<0.001$), and significantly increased the incidence of BPF. BPF was observed in 10 of 43 patients in whom the bronchial stump was not supported by tissue, and was detected in nine patients (36%) who received adjuvant therapy following initial surgery. The type of completion procedure ($p=0.82$), operation side ($p=0.28$), bronchial closure technique ($p=0.13$) and age ($p=0.06$) had no effect on the development of BPF.

Mortality and Follow-up

The median follow-up period was 37.6 months. Mortality occurred in five patients (7.6%). The rate of mortality was 6.9% among patients undergoing CCP and 12.5% among those undergoing RCP. There was no significant difference in mortality rates between CCP and RCP ($p=0.57$). The rate of mortality was 8.6% in patients undergoing CP due to NSCLC. Of the total, four patients died of respiratory failure and one died of pneumonia that developed after a bronchopleural fistula. The amount of intraoperative bleeding and the percentage decrease in Hb level were identified as prognostic factors affecting mortality (Table 2). The 5-year survival rate was 59.6% (81 months) in patients undergoing CCP. The mean survival was 70 months in patients undergoing CCP due to NSCLC. The 5-year and 10-year survival rates were 58.1% and 25.3%, respectively. Tumor diameter greater than 7 cm ($p=0.05$) and the stage of the second tumor

Table 1a. Demographic characteristics of the patients

Variables		CCP		RCP		p-value
		n	%	n	%	
Gender	Male	54	88.5	7	11.5	0.48
	Female	4	80	1	20	
The mean FEV1 of the patients		2.05±0.4 L				
Smoking history (packet/year)		30.6±22.9		21.2±24.8		
	No	13	72.2	5	27.8	0.017
	Yes	45	93.8	3	6.3	
Hospitalization (day) mean ± SD		10.6±6.6		12.5±8.7		0.50
Causes of CP	Benign	2	3.4	0	0	0.32
	Malign	56	96.6	8	100	
Comorbidities		44	75.9	7	87.5	0.46
	Cardiac disease	25	43.1	3	37.5	0.76
	Respiratory disease	12	20.7	4	50	0.70
	Serebrovascular disease	2	3.4	1	12.5	0.24
	Diabetes mellitus	14	24.1	2	25	0.95
	Peripheral vascular diseases	5	8.6	0	0	0.38

CCP: Classical completion pneumonectomy, SD: Standard deviation, FEV1: Forced expiratory volume in 1s s. Smoking was significantly more common in patients undergoing CCP. No statistically significant difference was found in terms of any other demographic characteristics

Variables		Complication (no)		Complication (yes)		p-value
		n	%	n	%	
Age (years)	<65	36	62.1	22	37.9	0.04
	>65	2	25	6	75	
Gender	Male	35	57.4	26	42.6	0.90
	Female	3	60	2	40	
Comorbidity	No	7	46.7	8	53.3	0.33
	Yes	31	60.8	20	39.2	
Type of CP	CCP	34	58.6	24	41.4	0.64
	RCP	4	50	4	50	
Second operation resection type	Sleeve CP	3	37.5	5	62.5	0.22
	CP	35	60.3	23	39,7	
Operation side	Right	25	58.1	18	41.9	0.89
	Left	13	56.3	10	43.5	
Supporting the bronchial stump	No	23	53.5	20	46.5	0.43
	Yes	14	60.9	9	39.1	
Bronchial stump closure	Stapled	23	67.6	11	32.4	0.08
	Hand-sutured	15	46.9	17	53.1	
Operation time (minutes) mean ± SD		342.7±1190.3		372.5±142.0		0.49
Intraoperative bleeding (mL) Mean ± SD		353.8±158.4		434.6±222.6		0.09
Percentage decrease in Hb (%) Mean ± SD		10.3±10		13.8±12.1		0.13

Aged above 65 years was identified as a significant prognostic factor affecting postoperative complications (p=0.04).
RCP: Rescue completion pneumonectomy, CCP: Classical completion pneumonectomy, SD: Standard deviation, Hb: Hemoglobin

(p=0.01) were identified as prognostic factors affecting survival. The mean interval between the two operations was 37±34.6 months (p=0.42) (Table 3).

Discussion

High surgical mortality and postoperative complication rates have been reported in almost all series of patients undergoing CP due to benign or malignant lung disease (2,8). The overall mortality rate in the large series published in this field ranges between 3.4% and 21% (4,9-11) and reported intraoperative mortality rates range from 0% to 5.4% (9,12-14). There are different opinions on the factors affecting mortality. Chataigner et al. (15) reported obesity, coronary artery disease, right-sided surgery, and renal failure as factors affecting postoperative mortality. Some studies in the literature have found a link between mortality and postoperative complications, particularly bronchopleural fistula, and there are also studies that link increased mortality to advanced age and the use of adjuvant therapy after initial surgery (11,16). No intraoperative mortality occurred in this study, and the overall mortality rate was found to be 7.6%.

The mortality rate in patients undergoing CP to treat complications after an initial surgery was reported to be as high as 37.5% by Muysoms et al. (17), 27% by Pan

et al. (5) and 33% by Jungraithmayr et al. (12). This rate was only 12.5% among the patients undergoing RCP in our series, which can be attributed to both the small patient sample and the strict inclusion criteria applied in the selection of patients.

There was no significant difference in mortality rates between CCP and RCP. The operation site, age, development of BPF and administration of adjuvant therapy following initial surgery had no effect on mortality in this study. The amount of intraoperative bleeding and the percentage decrease in Hb levels were identified as prognostic factors affecting mortality. Bleeding exceeding 720 mL and a more than 25% decrease in hemoglobin levels increased mortality. Significant pleural and sometimes pericardial adhesions associated with previous surgeries may complicate hilar exposure during CP. In other words, catastrophic hemorrhage and significant vessel injuries are possible. Extrapleural dissection may be required to achieve intraoperative pneumolysis. For the above reasons, intraoperative blood loss is significantly higher in patients undergoing CP than in those undergoing standard pneumonectomy (5,13,14). The primary goal in our center is to gain access to and start pneumolysis from the mediastinum, due to there being fewer dense adhesions on the mediastinal surface in such patients.

Variables		Mortality (No)		Mortality (Yes)		p-value
		n	%	n	%	
Age (years)	<65	53	91.4	5	8.6	0.38
	>65	8	100	0	0	
Comorbidity	No	13	86.7	2	13.3	0.33
	Yes	48	94.1	3	5.9	
Gender	Male	56	91.8	5	8.2	0.50
	Female	5	100	0	0	
Type of CP	CCP	54	93.1	4	6.9	0.57
	RCP	7	87.5	1	12.5	
Operation side	Right	40	93	3	7	0.80
	Left	21	91.3	2	8.7	
Supporting the bronchial stump	No	39	90.7	4	9.3	0.65
	Yes	21	91.4	2	8.6	
Bronchial stump closure	Stapled	32	94.1	2	5.9	0.59
	Hand-sutured	29	90.6	3	9.4	
Tumor diameter (cm)	<7 cm	44	89.8	5	10.2	0.60
	>7 cm	6	85.7	1	14.3	
Operation time (minutes)		351.9±83.7		370.7±38.7		0.42
Intraoperative bleeding (mL) mean ± SD		360±157.9		720±297		0.003
Percentage decrease in Hb (%) mean ± SD		10.6±10.2		25.9±11.6		0.003
The time interval (between primary surgery and occurrence of lesion) month		38.2±35.6		29.7±16.5		0.80

The amount of intraoperative bleeding and the percentage decrease in Hb levels were prognostic factors affecting mortality.
RCP: Rescue completion pneumonectomy, CCP: Classical completion pneumonectomy, SD: Standard deviation

There is no widely accepted factor for complications, despite the many large surgical series subjected to study (1,18). Complication rates following CP have been reported to range between 24% and 62% in the literature (10,14-16), with the most common being empyema and cardiopulmonary complications (8,14). The rate of complications in our series was 42.2%, and the most common complication was atrial fibrillation (19%). There was no significant difference in complication rates between CCP and RCP. It can be seen that the rate of postoperative complications is significantly higher in those aged above 65 years. Although common and serious complications are seen after completion of pneumonectomy, better results can be obtained with proper management of complications.

A bronchopleural fistula is a significant complication after CP. The rates of BPF in CP have been reported to be between 10% and 24% (15,19). A higher rate of BPF has been reported in RCP patients by Pan et al. (5) (36%) and Yazgan et al. (19) (40%). There is strong consensus regarding the preservation of the bronchial stump as a means of preventing the development of a bronchopleural fistula after pneumonectomy. These series recommend

supporting the bronchial stump as much as possible with pericardial fat tissue, azygos, parietal pleura, and omental flaps (20,21). Despite this information, supporting the bronchial stump with the surrounding tissue is not routinely applied by every surgeon. Chataigner et al. (15) identified a relationship between the development of BPF and right-sided surgery and no support of the bronchial stump with any tissue. Another study found a relationship between the administration of adjuvant therapy following initial surgery and the high incidence of bronchopleural fistula (22). In this study, the incidence of BPF was 15.5% in CCP while it was 12.5% in RCP, and it was shown that the support of the bronchial stump with any tissue significantly reduced the risk of developing BPF. Furthermore, diabetes mellitus and adjuvant therapy following initial surgery significantly increased the incidence of BPF. The type of completion procedure, operation site, and the bronchial closure technique had no effect on the development of BPF. The authors consider that, apart from supporting the bronchial stump with any tissue, avoiding excessive dissection and strict control of diabetes may be effective in preventing BPF. Bronchial stump coverage with any tissue was not practiced as a standard in this study, as ours is an

Variables		5-year survival (%)	10-year survival (%)	Mean survival (month)	95% CI	p-value
Age (years)	<65	66.9	22.9	81	54-107	0.25
	>65	31.3	15.6	17	0-40	
Tumor diameter (cm)	<7 cm	62.9	29.1	81	48-113	0.05
	>7 cm	50	0	11	0-49	
Operation side	Right	62.8	19.2	70	55-84	0.34
	Left	58.1	46.5	111	47-174	
The time interval (between primary surgery and occurrence of lesion) years	<2	50.4	36	111	0-222	0.42
	2-4	62.7	0	67	40-93	
	>4	84.6	21.2	81	7-154	
N Stage	N0	63.4	32.9	117	32-201	0.38
	N1-N2	57.8	16.8	70	25-114	
Histopathology	Squamous cell carcinoma	70.5	34.2	92	47-136	0.10
	Adenocarcinoma	46.5	11.6	49	24-73	
Second op. stage	1	51.1	34	74	48-100	0.01
	2	73.3	37.9	97	74-121	
	3	50	0	43	19-66	
Adjuvant therapy (after second operation)	No	53.8	0	67	14-119	0.08
	Yes	66	27.4	92	29-154	

A tumor diameter greater than 7 cm (p=0.05) and the stage of the second tumor (p=0.01) were prognostic factors affecting survival.
CI: Confidence interval, Op: Operation

education hospital, and the surgeons adopted different approaches.

Five-year survival rates were reported to be between 18% and 57% in patients undergoing CP due to a malignant disease (13,23). Pan et al. (5) reported a five-year survival rate of 30% in patients undergoing CP due to a malignant disease and showed better survival in patients with stage I and II disease than in patients with stage III disease. In a multicenter study, five-year survival rates of 49% and 24% were reported in patients with squamous cell cancer and adenocarcinoma, respectively (p=0.04) (8). In a recent study published in 2022 (2), the five-year survival rate was reported as 51% in patients who underwent CP for malignant disease, and prolongation of resection, pathological stage, T, and N factors were associated with survival. In this interesting study examining the effects of induction therapy on postoperative outcomes in patients undergoing CP, better survival outcomes were reported in the group that received induction therapy before resection (2).

In our current study, the five-year survival for CP was 59.6% in patients undergoing CCP while it was 87.5% in RCP, and there was no significant difference between the two groups in terms of survival. The mean survival was 70 months in patients undergoing CCP due to a malignant disease in this study, and the five-year survival rate was 58%. Contrary to other studies (2,8), in our series, there

was no difference in survival rates between patients with squamous cell carcinoma and those with adenocarcinoma. A tumor diameter greater than 7 cm and the stage of the second tumor were identified as prognostic factors affecting survival. Receiving adjuvant therapy recorded better survival, but the difference was not significant. Although the interval between the two operations affects survival, this study found no significant difference.

Study Limitations

The limitations of the study include its retrospective study design; it is difficult to have reliable statistical conclusions with a small and heterogeneous cohort within a retrospective study. Despite these limitations, our study has several strengths. Our study included data from a center that was experienced in lung resection. Although the number of patients in studies on complementary pneumonectomy is quite limited, the number of patients in our study was sufficient for a valid evaluation.

Conclusion

For the reasons mentioned earlier, the list of indications for CP has expanded, and this has increased our experience of CP, which is gaining in popularity owing to its low mortality rate and long-term survival. RCP and CCP have a similar risk ratio in terms of mortality and morbidity. Bronchopleural fistula is the most significant complication

after completion of pneumonectomy. The CP procedure has achieved satisfactory oncological and surgical results. To obtain satisfactory results from CP, it is necessary to minimize the risk factors as much as possible. The prevention of intraoperative hemorrhage, strict glycemic control, and coverage of the bronchial stump with tissue will further improve the outcomes of complementary pneumonectomy.

Ethics

Ethics Committee Approval: The University of Health Sciences Turkey, Istanbul Training and Research Hospital Clinical Research Ethics Committee approval of this study was acquired (decision no: 2018-KAEK-50/1259).

Informed Consent: Informed consent was obtained from all patients.

Peer-reviewed: Internally and externally peer-reviewed.

Authorship Contributions

Concept: Y.A., N.C., M.A.B., M.M., Design: O.S., V.E., L.C., Data Collection and/or Processing: Y.A., V.E., A.C.K., A.P., Analysis and/or Interpretation: N.C., C.B.S., A.C.K., Literature Research: O.S., M.M., A.P., Writing: Y.A.

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