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Results of superior vena cava resection for lung cancer
Analysis of prognostic factors

Lorenzo Spaggiari[a,*], Pierre Magdeleinat[b], Haruhiko Kondo[c], Pascal Thomas[d], Maria Elena Leon[e], Gilles Rollet[d], Jean Francois Regnard[b], Ryosuke Tsuchiya[c], Ugo Pastorino[a]

[a] *Department of Thoracic Surgery, European Institute of Oncology, Via Ripamonti 435, 20141 Milan, Italy*
[b] *Department of Thoracic Surgery, Hotel-Dieu Hospital, Paris, France*
[c] *Department of Thoracic Surgery, National Cancer Center, Tokyo, Japan*
[d] *Department of Thoracic Surgery, Sainte Marguerite University Hospital, Marseille, France*
[e] *Department of Biostatistics, European Institute of Oncology, Milan, Italy*

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Summary *Aims:* The benefits of superior vena cava (SVC) resection for lung cancer remain controversial. Data obtained in four international centers were analyzed in order to identify prognostic factors and thus guide in future patient selection. *Materials and methods:* Retrospective study. Prognostic factors were examined by logistic regression for postoperative morbidity/mortality using the Kaplan–Meier method (log rank test) and the Cox proportional-hazard model for survival. *Results:* From 1963 to 2000, 109 patients underwent SVC resection. Induction treatment was given to 23 (21%) patients. The SVC was resected for T involvement in 78 (72%) cases and for N involvement in 31 (28%) cases. Fifty-five (50.5%) patients underwent pneumonectomy (20 with carinal resection), while the remaining underwent lobar resections. Prosthetic SVC replacement was performed in 28 (26%) patients; partial resection with running suture (53%), vascular stapler (13%), or patch (7%) was performed in 80 patients; 1 patient did not undergo reconstruction. Pathological examination identified direct involvement (T4) in 66 (60%) patients and N2 disease in 55 (50%) patients. Major postoperative morbidity and mortality were 30 and 12%, respectively. Median intensive care unit stay was 3 days, while median hospital stay was 16 days. Five-year survival was at 21%, with median survival at 11 months. In multiple regression analysis, induction treatment was associated with an increased risk of major complications ($P = 0.016$). None of the factors assessed demonstrated an association with postoperative death. In multivariate survival analysis, both pneumonectomy and complete resection of the SVC with prosthetic replacement were associated with a significant increased risk of death ($P = 0.0013$ and 0.014, respectively). *Conclusions:* The radical resection of lung cancer involving the SVC may result in a permanent cure in carefully selected patients. The type of pulmonary resection (i.e., pneumonectomy) and the

*Corresponding author. Tel.: +39-02-57489666; fax: +39-02-57489698.
E-mail address: lorenzo.spaggiari@ieo.it (L. Spaggiari).

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type of SVC resection (i.e., complete resection with prosthetic replacement) are the prognostic factors with the greatest adverse effect on survival.

1. Introduction

Superior vena cava (SVC) system invasion by non-small cell lung cancer (NSCLC) has, for a long time, been considered a contraindication for surgical resection [1]. However, in the 1970s and 1980s, experimental animal research and clinical case reports demonstrated the technical feasibility of such an extended surgery for mediastinal and pulmonary malignancies, resulting in long-term survival in some instances [2—9].

In the 1990s and at the beginning of 2000, eight series with more than six patients operated on for NSCLC were reported on in the English-language literature [10—17] (Table 1). According to this review, 119 patients underwent resection of the SVC for NSCLC, of which 41 patients underwent complete SVC resection with prosthetic replacement. Postoperative mortality ranged from 0 to 22%, with the 5-year probability of survival ranging from 24 to 31%. Due to the low number of patients studied in this review, it was difficult to identify any prognostic factors, thus leaving the choice of surgery without guidelines.

In 2000, a multicenter retrospective study was designed with the objective of studying prognostic factors. In 2002, we published the preliminary results of a subgroup from patients ($n = 28$) who underwent complete SVC resection with prosthetic replacement [18], with the intent of investigating the technical aspects of such an extended surgery and its influence on postoperative outcome. The present paper presents an analysis of the overall population (partial and complete SVC resection for lung cancer), with particular attention to the oncological results, in order to identify the prognostic factors for patient selection and to establish a useful, historical benchmark for future clinical studies.

2. Material and methods

From 1963 to 2000, 109 patients underwent resection of the SVC system for NSCLC in four international departments of thoracic surgery (Table 2). All patients in these centers who underwent SVC resection for NSCLC were enrolled. The raw data for each patient were input to the database form and subsequently collected and analyzed by the Department of Biostatistics of the European Institute of Oncology.

There were 97 (89%) male and 12 female patients with an overall median age of 64 years (range: 36—78 years). Twenty-one (19%) patients underwent mediastinal investigation 20 by cervical mediastinoscopy and 1 by left anterior mediastinotomy; all but 2 patients were operated on after 1991 (19/64 (30%) after 1991 versus 2/45 (4%) before 1991). Twenty-three (21%) patients received preoperative medical treatment: there were 19 chemotherapies, mainly cisplatin-based regimens, 3 chemo-radiotherapies and 1 radiotherapy. All but 1 patient were treated after 1991 (22/64 (35%) after 1991 versus 1/45 (2%) before 1991).

Table 1 English-language literature review (1990—2001): full papers with more than six patients [10—17]

Reference	Patients	Prosthetic graft	Mortality (%)	Five-year probability (%)
Piccione et al. [10]	6	0	17	—
Thomas et al. [11]	15	4	7	24
Tsuchiya et al. [12]	32	7	22	?
Dartevelle [13]	14	14	7	31
Fukuse et al. [14]	8	3	[a]	[a]
Spaggiari et al. [15][b]	25	7	12	29
Spaggiari and Pastorino [16][c]	11	3	0	[a]
Bernard et al. [17]	8	2	[a]	25
Overall	119	41		

[a] Not specified in the text.
[b] Marie Lannelongue Hospital, Paris, experience.
[c] European Institute of Oncology, Milan, experience.

Table 2 Superior vena cava system resection for NSCLC: international dataset

Center	Number of patients	Years of surgery (range)
European Institute of Oncology, Milan, Italy	18	1998–2000
Hotel-Dieu Hospital, Paris, France	25	1983–1999[a]
National Cancer Center, Tokyo, Japan	41	1963–1997
Sainte Marguerite University Hospital, Marseille, France	25	1986–1999

''Years of surgery (range)'', according to the different centers.
[a] This series represents the experience of Prof. J.F. Regnard and Dr. P. Magdeleinat during their period at the Marie Lannelongue Hospital, Paris, France.

2.1. Operative procedures

The surgical approach was the standard posterolateral thoracotomy in 79 (72.5%) patients, muscle sparing lateral thoracotomy in 16 (14.6%) patients, hemi-clamshell in 4 (3.7%) patients, and sternotomy in 10 (9.2%) patients. An associated cervico-thoracic approach was used in 14 (13%) patients: there were 2 transmanubrial approaches, 4 transclavicular approaches, 4 cervicotomy approaches, and 4 sternotomies.

Fifty-five (50.5%) pneumonectomies (20 (18.3%) with carinal resection) and 54 (49.5%) lobar (32 lobectomies, 15 sleeve lobectomies, 2 tracheal sleeve lobectomies) or sublobar (5 segmentectomies) resections were done. A further extended resection was performed to the left atrium in nine cases, to the innominate artery in three cases, and to the subclavian artery in two cases. Eleven patients had an associated resection of the chest wall.

2.2. Superior vena cava operative description

The indication for SVC resection was direct tumor invasion (T4, full thickness invasion) in 78 (72%) patients, while in the remaining 31 (28%) patients, the vessels were resected for bulky mediastinal lymph nodes involvement of the vessel (N2).

There were 80 partial SVC resections; the reconstruction was done using a simple running suture in 58 (53%) patients, a vascular stapler in 14 (13%) patients, and a patch in 8 (7%) patients; in the patch group, 5 patients received a pericardial patch, while the remaining 3 patients received a polytetrafluoroethylene (PTFE) patch. Three patients in this group also underwent a complete SVC system clamping after the positioning of a venous shunt. Twenty-eight (26%) patients underwent complete resection of the vessel with prosthetic replacement. One patient did not undergo SVC reconstruction.

Technical and operative data concerning the group of patients who underwent SVC prosthetic replacement have been previously reported [18]. Data concerning anticoagulant therapy during the postoperative period, on the other hand, are incomplete. In the Italian center, intravenous sodium heparin (0.5 mg/kg) was used before clamping in all patients requiring prosthetic replacement; afterwards, anticoagulation therapy was continued using low-weight heparin (enoxaparin 4000 IU, twice daily) for 1 month. Then, the low-weight heparin was exchanged with coumadin for 6 months. Patients who underwent partial SVC resection without prosthetic replacement did not undergo anticoagulation therapy.

There were 65 squamous cell carcinomas, 35 adenocarcinomas, and 9 other large cell carcinomas. Sixty-six (60%) patients had direct tumor involvement of the SVC (T4, full thickness invasion); in the other cases, T status was T3 in 22 cases, T2 in 17 cases and, T1 in 4 cases. Invasion of the mediastinal lymph nodes (N2 disease) was found in 55 (50%) patients. The remaining patients showed N0 disease in 26 cases, N1 in 24 cases and N3 in 4 cases.

The resection was complete (R0) in 80 (73.4%) patients, a microscopic residual tumor (R1) was found in 26 (24%) patients, and a macroscopic one was found in the remaining 3 patients. The majority of patients, however, were considered R1 due to pathological proof of either metastases in the higher mediastinal (R2) lymph nodes or of contralateral (N3) disease.

2.3. Statistical methods

The primary end points of the study were the occurrence of major postoperative complications (life-threatening complications required either intubation, cardioversion, emergency surgery, or transfer to an intensive care unit; major complications required therapy with an extension of the hospital stay), any postoperative deaths (any death occurring within 30 days, or after 30 days, if the

patient was continuously hospitalized after surgery), and survival.

The prognostic variables evaluated were: age, center, indication for resection (direct SVC invasion by the tumor, T, or by bulky N2 disease), induction treatment (any versus none), resection type (pneumonectomy and sleeve pneumonectomy versus lobar resection), type of SVC reconstruction (prosthesis versus running suture, vascular stapler resection, and patch replacement), pT status (T4 versus T1–T3), pN status (pN0 versus pN1 and pN2), and completeness of resection (R0 versus R1/R2). We decided to divide the period of observation (years of surgery) into two periods: the first period (1963–1990, $n = 46$) is considered the learning period, during which, beginning from experimental works, different clinical experiences were developed; the second period (1991–2000, $n = 63$), the last 10 years, references the period during which modern therapeutic strategies were applied to this extended surgery (i.e., induction treatment, etc.).

The chi-square test and the Fisher exact test were used to compare the distribution of patients, according to prognostic factors, by morbidity and mortality status. Logistic regression was used to analyze the occurrence of postoperative mortality and major complications, adjusting for prognostic variables. Survival curves were obtained via the Kaplan–Meier method and were compared amongst subgroups using the log rank test. Cox proportional regression models were used to estimate hazard ratios and 95% confidence interval (CI) adjustments for multiple variables. Hazard ratios were estimated taking into account events which had occurred in the first 60 months after surgery. A difference was considered statistically significant with a P-value ≤ 0.05. All statistical tests used were two-sided.

3. Results

There were no intraoperative deaths. Major postoperative complications developed in 33 (30%) patients. The postoperative mortality was 12% ($n = 13$). Pulmonary complications ($n = 20$, 60%) caused 92% ($n = 12$) of postoperative deaths; specifically, the causes of death were pulmonary edema ($n = 2$), postpneumonectomy pulmonary edema ($n = 3$), bronchial fistula ($n = 4$), lung abscess ($n = 2$), and embolism ($n = 1$). Five (4.5%) patients experienced early SVC thrombosis. These complications were treated with medical therapy alone in four cases and with surgery in the remaining. Early thrombosis developed in 3 patients in the prosthetic SVC replacement group (3/28, 11%) and in 2 patients in the running suture group (2/80, 2.5%).

Prosthesis infection developed after 2 (2/28, 7%) pulmonary complications (lung abscess and bronchial fistula). In the lung abscess case, the infection was cured by completion pneumonectomy and intrathoracic latissimus dorsi muscle myoplasty, without prosthesis removal. The patient was alive 4 years after operation without evidence of disease and with graft patency [19]. The overall median intensive care unit stay and hospital stay were 3 days (range: 0–42 days) and 16 days (range: 7–160 days), respectively.

3.1. Long-term results

In the group of patients with partial SVC resection, no late thrombosis was observed. In the group with prosthetic replacement, a graft patency study was done, in the majority of cases, using CT thoracic scan, but graft follow-up was only available for 16 patients. Four patients developed late graft thrombosis, but none of these patients presented with signs of SVC syndrome. Adjuvant chemotherapy was performed in 17 (15.6%) patients and radiotherapy was performed in 41 (37%) patients.

In the group of 109 patients, survival data were available for all but 1 patient, which had been lost at follow-up 3 months after the operation. At the completion of the study, 29 (26.8%) patients were censored. As of last contact with the patients (time of censoring), 22 were without evidence of disease, 3 were with disease, and in 4 patients, status was not specified. The median survival was 11 months (range: 0.13–127 months; 95% confidence interval: 8.5–17.9 months). The estimated 1-, 3- and 5-year survival rates were 49, 25 and 21%, respectively, for the overall series (Fig. 1); for patients operated on in the more recent period (1991–2000), the 5-year probability of survival was 28% (patients at risk at 1, 3 and 5 years = 27, 10 and 9, respectively). The majority of the patients in this study had systemic failure, but local control of the disease, in terms of the rate of local recurrence, was excellent.

None of the evaluated variables were associated with major complications when assessed individually. However, given that some treatment modalities were only introduced in recent years, we proceeded to assess the risk of major complications by years of surgery. Twenty-two of the 23 (95.6%) patients who received induction treatment were operated on during the period 1991–2000. In this period, the variable ''induction treatment'' was associated with an increased risk of developing major complications, with odds ratio (OR = 0.3;

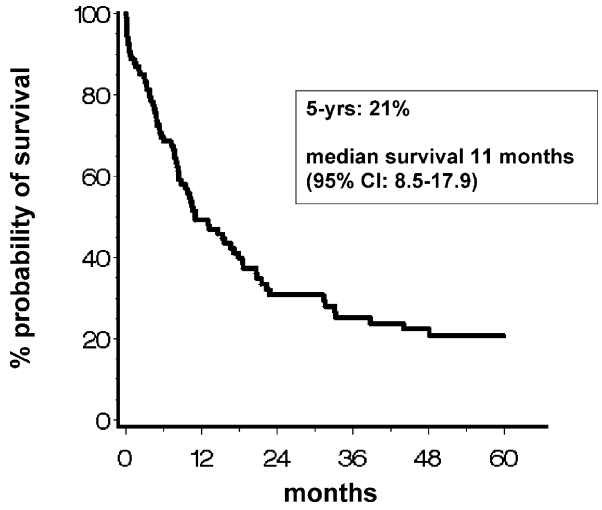

Fig. 1 Survival curve (Kaplan–Meier method) of patients who underwent resection of the SVC for NSCLC. The probability of survival at 1, 3 and 5 years were 49, 25 and 21%, respectively. Patients at risk at 12, 24, 36, 48 and 60 months were 44, 23, 18, 14 and 9, respectively. Median survival was 11 months (range: 0.13–127 months; 95% CI: 8.5–17.9 months).

95% CI = 0.1–0.98) approximately 70% lower if the patient did not receive induction treatment. This result became more pronounced ($P = 0.016$) when adjusted for all the other variables considered in the study. In patients treated in the recent period, a higher risk for major complications was observed in those patients who underwent prosthetic replacement after complete SVC resection as compared to patients who underwent partial SVC resection without prosthetic replacement ($P = 0.057$).

With the exception of years of surgery, none of the factors assessed were associated with postoperative death. However, the distribution of postoperative death in the two time periods studied revealed a greater number of patients dying in the earlier period (20.9% (1963–1990) versus 6.3% (1991–2000); Fisher's exact test, $P = 0.034$).

3.2. Survival

Considering the extended period of time covered by the study, we assessed survival by years of operation. An increased risk of death with decreasing years of surgery was observed (HR = 0.97; 95% CI = 0.94–1.00; $P = 0.052$; time as continuous), an approximate 3% increase per year. No variables were found to be significant in univariate analysis, in particular no difference in survival was observed in patients who underwent sleeve pneumonectomy compared to pneumonectomy (log rank test, $P = 0.8$).

Cox proportional-hazard regression showed that patients who underwent pneumonectomy compared to lobectomy showed a higher risk of death (HR = 2.9; 95% CI = 1.1–5.8; adjusted estimate $P = 0.0013$). Patients who underwent full SVC resection with prosthetic replacement compared to partial SVC resection also had a higher risk of death (HR = 2.2; 95% CI = 1.2–4; adjusted estimate $P = 0.014$) (Table 3).

In order to reduce the influence of heterogeneity of recruitment (long period, 40 years; different recruitment period for each center), which could introduce bias due to the inclusion of non-adjusted factors, an analysis of 64 patients operated on in the last 10 years (1991–2000) was performed. Comparison of the two time periods revealed a significant difference in survival (1963–1990, 5 years, 14%; 1991–2000, 5 years, 28%; $P = 0.044$). The prognostic variables considered were the same as in the previous analysis. The results of the multivariate analysis are summarized in Table 3. Type of resection (i.e., pneumonectomy) and type of SVC resection and reconstruction (i.e., full resection of the SVC with prosthetic replacement) still significantly increased the risk of death, thus confirming their value as prognostic factors.

4. Comment

The discussion regarding the oncological benefits of SVC resection in lung cancer patients has been a recurrent topic in literature [10–17] (Table 1). However, the low number of patients reported has not allowed any conclusive assessments regarding the real impact of such an extended surgery. The main ''open questions'' concern both the technical aspects, and their impact in terms of postoperative outcome, and the oncological benefits of such an extended surgery in curing this disease.

Regarding the technical aspects, in patients with limited SVC infiltration, the vessel can be partially resected en bloc with the neoplasm, after a tangential clamping of the SVC using a simple running suture to restore vascular continuity; an alternative, partial resection can be accomplished using a TA vascular stapler without previous clamping. The majority of the patients operated on in the present study (64%) underwent these resections. When the need to obtain border-free margins requires the resecting of major vessels, revascularization can be performed by interpositioning a patch. A limited number of patients were operated on using this technique because it is a more complicated and time-consuming procedure, requiring complete SVC clamping. An extra-anatomical venous shunt

Table 3 Multivariate analysis of survival using Cox regression

Variable	All patients			After 1991		
	HR	95% CI	*P*-value	HR	95% CI	*P*-value
Resection						
Pneumonectomy	2.96	1.5—5.8	0.0013	6.9	2.3—20.5	0.0005
Sleeve pneumonectomy	1.4	0.6—3.1	0.4	3	0.7—12.4	0.12
Lobectomy[a]						
Completeness of resection						
Residual tumor	1.28	0.7—2.4	0.43	2.1	0.8—5.5	0.14
Radical[a]						
Reconstruction						
Prosthesis	2.2	1.2—4	0.014	2.4	1.05—5.6	0.04
Other[a]						
Induction therapy						
Yes	1.14	0.5—2.6	0.76	0.85	0.29—2.5	0.8
No[a]						
pT						
T4	0.8	0.45—1.4	0.42	0.52	0.2—1.3	0.18
T1—T3[a]						
pN						
pN1/pN2	0.63	0.36—1.1	0.11	0.51	0.2—1.2	0.13
pN0[a]						
Age (continuous variable)	1.02	0.99—1.05	0.073	1.03	0.99—1.1	0.16
Years of surgery (continuous variable)	0.96	0.92—1	0.067	0.99	0.8—1.2	0.89
Center						
1	0.86	0.3—2.7	0.8	2.1	0.4—10	0.37
2	0.67	0.3—1.5	0.33	1.37	0.4—4.7	0.61
3	0.67	0.3—1.5	0.34	1.42	0.39—5.2	0.6
4[a]						

[a] Variable of reference.

has been proposed [10] to avoid cross-clamping effects, and this approach was used in three of our patients.

When invasion of the SVC involves more than 50% of its circumference, to achieve a complete resection, a prosthetic replacement is necessary. This is a more aggressive procedure for patients than partial SVC resection due to its technical aspects [18,20] and has rarely been used, based on the literature (about 40 patients in our review) (Table 1). We have already discussed both the technical and anesthesiological aspects of this surgery in our previous report [18].

Regarding postoperative SVC-related complications, the risk of developing early or late thrombosis probably depends on several factors. In partial SVC resection, early thrombosis is related to excessive vessel resection leading to stenosis. In the present study, 2.5% (2/80) of the patients in this group developed this complication; 1 patient was re-operated on using a saphenous vein patch early in the postoperative period due to the rapid onset of SVC syndrome, while the other was treated with just medical therapy alone. In the prosthesis group, 11% (3/28) of the patients experienced early thrombosis. All were medically cured. The causes for such an early complication in the prosthetic group might be due to the presence of several factors. First, persistent collateral venous bed before resection for an obstructed SVC, leading to reduced blood flow in the prosthesis, might facilitate early thrombosis. Second, the use of small lumen prostheses ($n < 10$) might be another cause of thrombosis.

In SVC surgery for NSCLC, the preferred approach is posterolateral thoracotomy (72.5%), as shown in the present study. However, lateral muscle sparing thoracotomy and sternotomy were also used in several patients. When prosthetic replacement of the SVC with anastomosis in the left innominate vein

is planned, a sternotomy or hemi-clamshell may be the better choice for exposing the vessel. In any case, the choice depends mainly on surgeon preference.

Regarding lung resection, pneumonectomies (with or without carinal resection) were performed in half of the cases, due to the fact that neoplasms often are very locally advanced. Lobar resection, with or without bronchoplastic procedures, are the remaining resections commonly associated with this extended vascular surgery.

In analyzing the factors which might influence postoperative outcome, induction treatment was highly significant in multivariate analysis, but interestingly, did not influence postoperative mortality. And even though the comparison between complete SVC resection with prosthetic replacement and partial SVC resection did not reach statistical significance, the value ($P = 0.057$) suggests that complete SVC resection could negatively influence postoperative outcome.

Regarding postoperative mortality, no prognostic factors were identified in multivariate analysis; however, the postoperative mortality differed significantly amongst the two surgery periods, identifying a decreased risk of death in the more recent years (1991—2000, 6.3%). These data probably reflect better patient selection in the last 10 years as well as an improvement in anesthesiological, intensive care unit and surgical management.

The most important results deriving from this study are those concerning long-term survival. The overall 5-year probability of survival was 21%, which is not negligible if we consider that a tumor involving the SVC is an advanced disease, usually considered unresectable. Furthermore, if we analyze the probability of survival based on the different time periods considered (1963—1990 versus 1991—2000), survival was significantly higher in the recent period (5 years, 28%).

Multivariate analysis showed that two factors affected survival (Table 3): the type of pulmonary resection, with identification of the high risk group among those patients who underwent pneumonectomy, and the type of SVC resection and reconstruction. Multivariate analysis performed on the group of patients operated on in the last 10 years (Table 3), using variables from the previous analysis, confirmed these results, indicating pneumonectomy and complete SVC resection as the worst prognostic factors. These differences are interesting, suggesting that these results are probably due to less extensive mediastinal invasion, thus indicating the necessity for a more conservative procedure.

In recent years, the results, in terms of postoperative outcome and long-term survival after this extended surgery, have undoubtedly improved. This is probably due to better patient selection, increased surgical experience after a learning period, and the use of modern anesthesiological and technical devices. Plus, induction treatments reducing tumoral mass might allow for a more conservative resection (lobectomy or sleeve resection instead of pneumonectomy, and partial SVC resection instead of complete resection), thus influencing, indirectly, the oncological results.

In conclusion, SVC resection for NSCLC is technically feasible, with postoperative morbidity influenced by the induction treatment and by the type of SVC resection, and with two variables influencing the risk of death: pneumonectomy and complete SVC resection.

Even though no other prognostic factors have been identified, we recommend strict criteria for patient selection. Cervical mediastinoscopy should be done in all patients in order to categorically exclude patients with positive higher (R2) mediastinal lymph nodes. Positive, but not bulky, R4 mediastinal lymph nodes at mediastinoscopy, after their exact relationship with the SVC-invading tumor (T4) has been taken into account, should not be considered an absolute contraindication to surgical resection after induction treatment. Patients with T1, T2, or T3 with pathological bulky N2 direct SVC invasion, on the other hand, should not be considered for resection. All candidates for resection should undergo new chemotherapy regimens before surgery, to reduce mediastinal invasion and possibly exclude from surgery those patients with rapidly evolving disease, thus allowing for more conservative SVC and pulmonary resections. Finally, taking into account the poor results, in terms of postoperative outcome and the survival of patients who underwent pneumonectomy (with or without carinal resection) and prosthetic replacement of the SVC, we recommend excluding from surgery those patients who, after induction treatment, still need pneumonectomy in association with a complete SVC resection and prosthetic replacement.

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