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Unilateral thoracoscopic reduction pneumoplasty for asymmetric emphysema[1]

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Abstract

Objective: We prospectively analyzed the surgical and functional results of unilateral thoracoscopic reduction pneumoplasty which we performed by choice in patients with asymmetric emphysema. **Methods**: Between October 1995 and June 1997, 119 emphysematous patients were examined and 34 were operated upon. Among these, 14 selected patients with asymmetric distribution of emphysema in the lungs underwent unilateral reduction pneumoplasty (ten right, and four left). There were 13 males and one female, with a mean age of 62 years. Eligibility criteria included bullous and non-bullous end-stage emphysema with severe limitation to daily activity. **Results**: No patient required conversion to thoracotomy. Mean operative time ranged between 70 and 240 min with a mean of 103 min. There was no postoperative mortality but five patients developed one or more complications: five prolonged air leaks (>7 days); two pulmonary infections; one empyema. No patient required postoperative mechanical ventilation. Median hospital stay was 8 days. At the 3-month follow-up the mean FEV1 increased from 0.8 l to 1.2 l ($P < 0.001$). Mean FVC increased from 2.6 l to 2.9 l ($P < 0.001$). The Medical Research Council dyspnea score decreased from a mean of 3.2 to 1.8 ($P < 0.001$). **Conclusions**: Asymmetric distribution is a frequent finding in patients with severe emphysema. Unilateral thoracoscopic reduction pneumoplasty may represent an ideal approach in this selected group of patients.

Keywords: Emphysema; Reduction pneumoplasty; Thoracoscopy

1. Introduction

Pulmonary emphysema is a major cause of morbidity and mortality in western countries. Forty-two percent of the patients develop important limitations in daily activities and most die 2 years after medical therapy has become ineffective [1]. The failure of medical therapy in severely-affected patients has prompted efforts to develop surgical treatment. Various surgical procedures have been proposed throughout the early and mid-1900s, including costochondrectomy [2], thoracoplasty [3], parietal pleurectomy [4], and tracheal stenting [5]. All of these procedures were rapidly abandoned because the results were unsatisfactory. On the other hand, the benefit deriving from excision of giant bullae occupying at least one-third of the hemithorax is well established [6]. In 1959, Brantingan [7] introduced a new concept entailing thoracotomic, multiple wedge resections of the most diseased lung regions in severe non-bullous emphysema to ameliorate the efficiency of the respiratory muscles, and to restore lung elastic recoil for reducing the early expiratory collapse of the small airways. However, the lack of an objective evaluation of the results and the consistent mortality rate led to the abandonment of the procedure. Until recently, lung transplantation was the only effective method to improve lung function in patients

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with end-stage emphysema. In 1995, Cooper [8] resumed the Brantingan concepts performing bilateral reduction pneumoplasty [9] through median sternotomy. More recently thoracoscopic reduction pneumoplasty has been performed either unilaterally [1,10,11] or bilaterally [12–14] resulting in satisfactory intermediate-term results. Although overall improvement after bilateral reduction pneumoplasty appears superior than after unilateral operation [10], the unilateral approach may have specific indications or may represent the first step of a staged bilateral procedure. In this study we analyze the results of uni lateral thoracoscopic reduction pneumoplasty which we performed by choice in patients with asymmetric emphysema.

2. Materials and methods

2.1. Patient population

Between October 1995 and June 1997, 119 patients with severe emphysema were evaluated for reduction pneumoplasty. Inclusion criteria are listed in Table 1. Patients with giant bullae occupying at least one-third of the hemithorax with relatively normal underlying lung were not included in this study. Among the 34 (29%) patients who were operated upon (11 bilaterally, and 23 unilaterally), 14 patients underwent unilateral thoracoscopic reduction pneumoplasty (UTRP) because of an asymmetric distribution of emphysema. The operation was performed on the right lung in ten patients and on the left lung in four patients. There were 13 men and one women, with a mean age of 62 ± 9 years. All patients were former smokers and one had also α_1-antitrypsin deficiency. All patients were receiving maximal bronchodilator therapy, with five patients also taking steroids regularly. Supplementary oxygen therapy was required by four patients.

Table 1

Inclusion criteria for reduction pneumoplasty

Heterogeneous, bullous and non-bullous emphysema with hyperinflation
Marked restriction in daily activities despite the most aggressive medical therapy
Severe obstructive ventilatory defect (FEV_1 <35%)
Age ≤ 75 years
Willingness to undertake risk of morbidity and mortality associated with reduction pneumoplasty
Pulmonary artery systolic pressure <55 mmHg
$PaCO_2$ <55 mmHg
ASA score ≤3
Oral corticosteroids at a dose <15 mg of prednisilone equivalent
Nutritional status within 70–130% of ideal body weight
Ability to participate in a vigorous pulmonary rehabilitation program
No coexisting medical problems that would significantly increase operative risk
No neoplastic disease with life expectancy of less than 2 years
Abstinence from cigarette smoking for at least 4 months
No previous thoracotomy or pleurodesis on side of proposed operation

A history of pulmonary tuberculosis was present in three patients, and one other patient had stable coronary disease. One patient was diabetic. Pulmonary hypertension with systolic pulmonary artery pressure between 30 and 45 mmHg was found in four patients. The study was approved by the Tor Vergata University Institutional Review Board for Biomedical Research. Informed consent was obtained from all patients, who were given the fundamental information on the procedure and the potential complications.

2.2. Pulmonary evaluation

Lung volumes were measured according to standard criteria using plethysmographic techniques, timed spirometry, and single-breath diffusing capacity for carbon monoxide (DLCO) (Sensor Medics 2400, Yorba Linda, CA). All values were compared with predictions and are expressed as the mean of three consecutive tests. All patients were considered to have fixed airflow limitation since the FEV_1 following two inhalations of aerosolized salbutamol improved by <20%. Exercise tolerance was assessed with a standard 6-min walk test (6MWT). The patients performed the walk on room air or supplemental oxygen to maintain oxyhemoglobin saturation >85%. 6MWT was carried out preoperatively and postoperatively at 3 months, 6 months and 1 year.

Dyspnea was rated according to the American Thoracic Society's Medical Research Council score [15].

Preoperatively all patients underwent fiberoptic bronchoscopy and bronchoalveolar lavage for culture and cytology examination. Prophylactic antibiotics were routinely started about 1 week before the operation.

2.3. Radiological evaluation

Radiological study included inspiratory and expiratory chest radiographs to evaluate the degree of thoracic distention, and high-resolution CT scan of the chest: thickness 1 mm, index 10 mm (Tomoscan SR 7000, Philips, Eindhoven, NL), to evaluate emphysema morphology. For this purpose six standard lung scans obtained from lung apex to base at end-inspiration (brachiocephalic trunk, aortic arch, main pulmonary artery, middle lobe bronchus, ventricular chambers, and 3 cm above the diaphragm) were independently examined by two expert radiologists. After the results were recorded, a consensus was obtained for the scans for which the result was unanimous, by a third radiologist's opinion. Emphysema was visually identified by areas of decreased density with loss of vascular lung structures. Moreover emphysema was defined as asymmetric when a marked difference in its distribution and/or the severity was recognized within the two lungs in at least two scans (Figs. 1 and 2).

Single photon emission computed tomography (SPECT) perfusion imaging (Sophycamera, Sophamedical, Paris, France) was carried out with a single-head gamma camera.

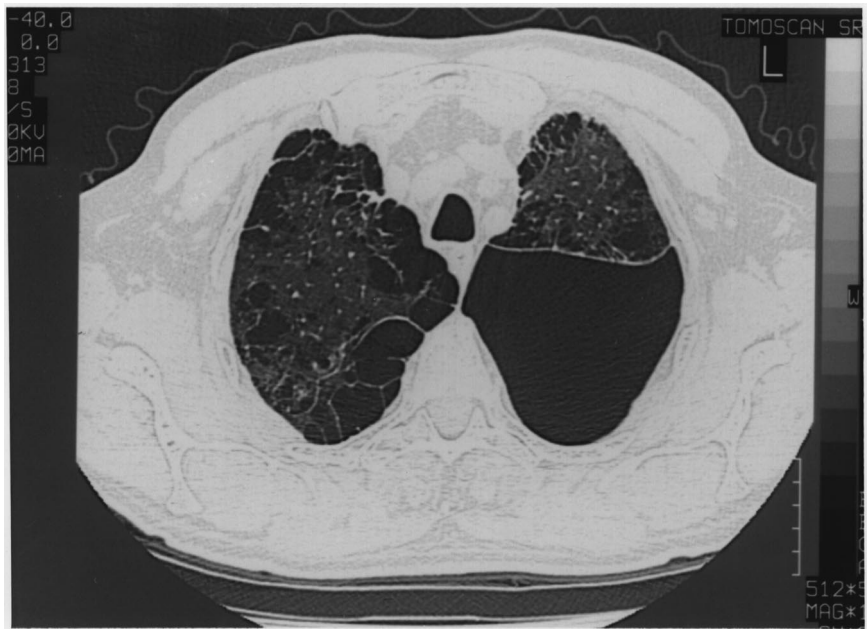

Fig. 1. Computed tomography of a patient with heterogeneous bullous and non-bullous emphysema. Asymmetric distribution is due to the presence of a large bulla in the apicodorsalis segment of the left upper lobe.

The transaxial data obtained by SPECT were re-processed to obtain a 3D rotating image for more accurate recognition of the target areas to be resected.

2.4. Cardiac evaluation

In addition to routine tests, echocardio-color Doppler (Hewlett–Packard Sonos 1000, Andover, MA), and right-heart catheterization were performed in all patients for the assessment of pulmonary artery pressures and right-heart function. Patients with a history of coronary disease underwent also cardiopulmonary stress testing on an electronically-braked cycle ergometer (Sensor Medics 2900, Yorba Linda, CA), and coronary angiography.

Preoperatively, all patients were encouraged to participate in a 6-week-based pulmonary rehabilitation program with the goals of optimizing exercise endurance (30 min continuous exercise) and pulmonary hygiene. During this

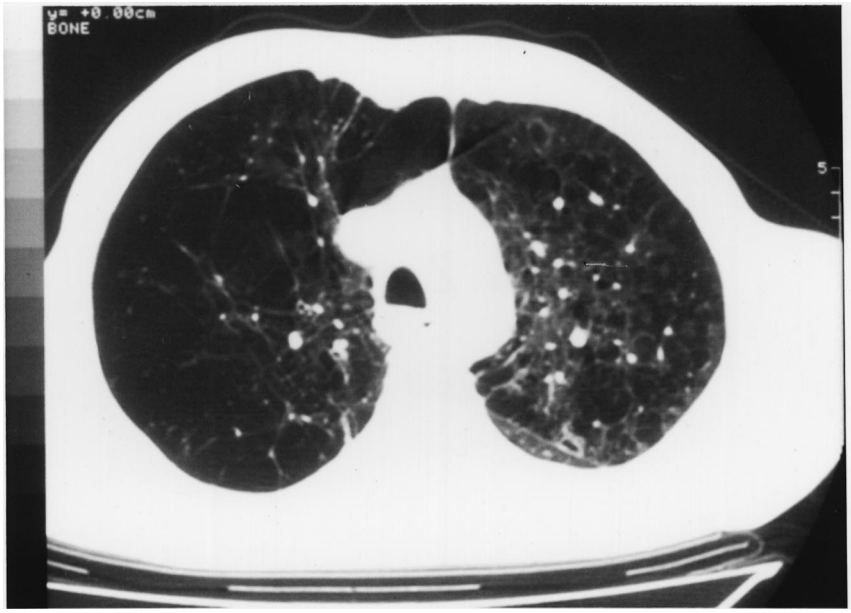

Fig. 2. Computed tomography of a patient with heterogeneous non-bullous emphysema. Asymmetric distribution is due to the more severe destruction and hyperinflation of the right upper lobe.

period conventional medical therapy utilizing inhaled and systemic bronchodilators was maximized. For those patients receiving steroids, an attempt was made to wean this medication to the lowest dose capable of ensuring stable lung function. Postoperatively, patients were required to re-enroll in an outpatient pulmonary rehabilitation program for an additional 6 weeks.

2.5. Surgical technique

A left-sided double-lumen endotracheal tube was placed for one-lung ventilation. The patient was placed in lateral decubitus prepared and draped as for thoracotomy. Four flexible trocars (Flexipath, Ethycon Endosurgery, Pomezia, Italy) were inserted: the camera port in the sixth intercostal space along the mid-axillary line, the operating ports in the fourth and seventh intercostal space along the anterior axillary line, and in the fourth intercostal space along the posterior axillary line. The procedure was performed using a 0° 10-mm rigid thoracoscope with a one-chip camera. The most destroyed portions of the lung as assessed by preoperative CT and SPECT scans and direct intraoperative inspection, were targeted for resection. Resection of the target areas was performed using endoscopic staplers (Endopath 45, Ethicon Endosurgery), possibly excising a single strip of lung parenchyma in order to reduce about 30% of the lung volume. Staple lines were buttressed with strips of bovine pericardium (Peristrips, Biovascular, Saint Paul, MN). During the procedure, the lung was periodically inflated to better estimate the extent of resection already accomplished. For predominantly upper-lobe disease the resection started at the base of the lingula or the middle lobe, and proceeded apically and then dorsally resulting in a 'hockey stick' excised specimen, to assure an adequate contour of the residual lung to fill the entire hemithorax. If prevalence of target areas was detected in the lower lobes we resected portions of the basilar segments and/or apical segment, and the inferior portion of the lingula or the middle lobe, for adequate rise and re-conforming of the diaphragm. To facilitate lung re-expansion pulmonary ligament was routinely sectioned. At the completion of the procedure, the resected specimens were removed through the most anterior trocar since the intercostal space is largest in that area. Neither pleural abrasion nor pleural tent was performed. Finally, two chest tubes were positioned with 10 cm/H_2O suction. Prophylactic minitracheotomy (Minitrach II, Seldinger, Portex, Hythe, Kent, UK) was performed in ten patients after the extubation.

The resected tissue was weighed immediately and its volume estimated. The tissue was than fixed, multiple sections were taken and finally stained with hematoxylin–eosin for routine light-microscopic evaluation.

2.6. Statistical analysis

Group descriptive statistics are presented as means ± SD. Paired or unpaired Student's *t*-test was used to compare data with normal distribution. The Wilcoxon test was used for paired data not normally distributed. The Fisher exact test was used to compare categoric variables, as appropriate. Results were considered significant if $P < 0.05$. Statistical analysis was performed with statistical software BMDP version 7.0 [16].

3. Results

3.1. Surgical results

During surgery, diffuse pleural adhesions were found in six patients, although in no patient was conversion to thoracotomy required. Mean operative time was 103 ± 40 min. A significant difference was found when comparing operative time in patients with or without pleural adhesions (149 ± 43 min vs. 83 ± 13 min, $P < 0.05$). All patients were immediately extubated at the end of the procedure and none required subsequent reintubation. Histopathologic diagnoses other than emphysema were: interstitial fibrosis in seven patients, non-specific granulomatous inflammation in two patients, and occult adenocarcinoma in one patient. There was no operative mortality whereas one or more complications developed in five patients (36%): five had a prolonged air leak, two pneumonias, and one empyema. Pleuro-pulmonary infections developed always after prolonged air leak. An air leak occurred more frequently among patients with adhesions compared with patients without adhesions (five out of six patients vs. zero out of eight patients, $P < 0.039$). Empyema was sustained by multidrug-resistant *Pseudomonas aeruginosa* and resolved on day 32. The median chest tube drainage time was 7 days, ranging from 4 to 32 days. The median hospital stay was 8 days, ranging from 6 to 32 days.

3.2. Functional results

All patients were evaluated postoperatively at 3 and 6 months and 11 patients were evaluated also at 12 months. Postoperative clinical and functional results are showed in Table 2. All evaluated parameters increased significantly at 3 months compared with preoperative values. In particular, maximal improvement was obtained at 3 months as regards the mean FEV_1 (50%), TLC (15%), RV (29%), FVC (11%), PaO_2 (6%), and $PaCO_2$ (2%). Maximal improvement of mean DLCO and dyspnea index (14% and 47%, respectively) was noted at 6 months whereas the 6MWT continued to improve even at the 12-month follow-up. At 3 months, three of the five patients who were taking prednisone preoperatively no longer needed it whereas three of the four patients who were oxygen dependent did not require supplemental oxygen any more.

Table 2
Comparison between preoperative and postoperative clinical and functional results

	Base-line	3 months	Change (%)	6 months	Change (%)	12 months	Change (%)	3–12 month change (%)
FEV_1 (l)	0.8 ± 0.1	1.2 ± 0.2	↑ 50*	1.2 ± 0.2	↑ 50	1.1 ± 0.1	↑ 37	↓ 13
TLC (l)	8.5 ± 0.6	7.2 ± 0.4	↑ 15*	7.3 ± 0.4	↓ 14	7.4 ± 0.4	↓ 13	↑ 2
RV (l)	5.1 ± 0.5	4.1 ± 0.5	↓ 20*	4.2 ± 0.5	↓ 18	4.3 ± 0.5	↓ 16	↑ 4
FVC (l)	2.6 ± 0.6	2.9 ± 0.7	↑ 11*	2.9 ± 0.7	↑ 11	2.8 ± 0.6	↑ 8	↓ 3
PaO_2 (mmHg)	69 ± 5.2	73 ± 4.6	↑ 6*	73 ± 4.7	↑ 6	72 ± 4.3	↑ 4	↓ 2
$PaCO_2$ (mmHg)	40 ± 1.5	39 ± 1.7	↓ 2*	39 ± 2.0	↓ 2	39 ± 1.7	↓ 2	–
DLCO (ml/min per mmHg)	14 ± 2.6	15 ± 1.6	↑ 7**	16 ± 2.1	↑ 14	15 ± 2.0	↑ 7	–
6MWT (m)	426 ± 34	519 ± 37	↑ 22*	532 ± 43	↑ 25	535 ± 43	↑ 26	↑ 4
DI	3.2 ± 0.6	1.8 ± 0.4	↓ 44*	1.7 ± 0.5	↓ 47	1.8 ± 0.5	↓ 44	–

Dyspnea index (DI) according to the MRC score. All values are expressed as the mean ± SD. Wilcoxon test: *$P < 0.001$, ** = $P < 0.05$.

4. Discussion

Reduction pneumoplasty is proving to be a promising therapeutic modality for the treatment of severe emphysema. The goals for this operation are improving pulmonary function, reducing or eliminating supplemental oxygen and steroid dependence, and relieving subjective dyspnea, with acceptable morbidity and mortality rates [10]. Although the exact mechanisms for respiratory improvement are still unclear, several explanation have been given: improved elastic recoil and opening of terminal bronchioles [7,17], improvement of chest wall and diaphragm mechanics [8], improvement of the ventilation perfusion mismatch [6,8], and reducing of the impediment to venous return [18].

Reduction pneumoplasty is being performed bilaterally by median sternotomy [19] or by thoracoscopy [12–14], and unilaterally by thoracotomy [19] or by thoracoscopy [1,10,11].

As a rule, a bilateral reduction pneumoplasty is expected to produce better results than a unilateral one [10]. However, some patients undergoing unilateral reduction pneumoplasty have a similar rate of improvement to those undergoing a bilateral operation [1]. Moreover, patients with end-stage emphysema are considerably fragile and some of them are poor risk for a bilateral approach. These considerations suggest that a rationale may be identified for either the unilateral and the bilateral approach.

McKenna et al. [10], in a retrospective, non-randomized study, compared the results achieved by unilateral or bilateral reduction pneumoplasty (BTRP). They found a higher 1-year mortality rate after UTRP (17%) than after BTRP (5%), whereas a greater overall improvement in FEV_1, oxygen and prednisone independence, and dyspnea index was provided by the bilateral approach. They concluded that the standard operation for patients with severe emphysema should be BTRP and that UTRP should be limited to patients with unilateral heterogeneous emphysema, or patients with contraindications for a bilateral operation.

Therefore, we believe that it might be important to define simple and reproducible morphologic criteria to preoperatively assess the severity, heterogeneity, and degree of asymmetry of emphysematous areas to aid the selection of candidates for unilateral or bilateral reduction pneumoplasty. Slone and Gierada [20] correlated emphysema morphology and functional outcome, proposing a complex scoring system which combines graded severity of hyperinflation, heterogeneity, and localization of emphysema. More recently, Weder et al. [21] proposed a simpler classification of emphysema identifying three main types in terms of degree of heterogeneity. Unfortunately, none of these classifications considered the degree of asymmetry in emphysema distribution.

We assigned each eligible patient to either a unilateral or a bilateral treatment taking into account the morphologic characteristics of their emphysema and we intentionally performed UTRP in patients with an asymmetric distribution of emphysema. Worthy of note, we have found that asymmetric emphysema is a frequent finding being recognized in 14 out of 34 operated patients. Asymmetric emphysema was also more frequently recognized in patients with heterogeneous bullous and non-bullous emphysema (Fig. 1). In fact we have found that bullae, which are classically defined as emphysematous spaces of more than 1-cm diameter in the inflated lung [22], very often coexist with diffuse emphysematous areas in end-stage disease. This finding diminishes the importance of a categorical distinction between these two entities.

We preferred the thoracoscopic approach since it provides an excellent view and access to all parts of the lungs, allowing precise dissection of adhesions even in the posterior and inferior aspects which are more difficult to deal with through median sternotomy [12,23]. In this series, no patient required conversion to thoracotomy, proving that adhesions can be managed thoracoscopically in the majority of patients. We also believe that palpating the lung parenchyma for a better identification of areas to be resected which is not possible with thoracoscopic surgery is unimportant,

because we mainly rely on computed tomography and perfusion scans to identify target areas.

In our study population, selected by stringent criteria, we had no early or late mortality. This result compares favorably with the 3.4% rate reported by Keenan et al. [1] and the 4% rate reported by Naunheim et al. [11], after UTRP.

Among non-fatal complications, air leakage requiring prolonged chest tube drainage occurs frequently [1,19]. For this reason, additional techniques such as the use of bovine pericardial strips to buttress the staple line, pleural tent [8,19], or pleural abrasion [24] have been advocated. However, none of these methods proved capable of eliminating this complication. In particular we do not use pleural abrasion because the occurrence of severe subcutaneous emphysema has been described in patients with air leak after laser bullectomy [24]. Cooper et al. [19], using both bovine pericardium and pleural tent reported a 46% rate of prolonged air leak in bilateral reduction pneumoplasty, whereas we had a 36% rate using pericardial strips only. As regards UTRP, our results compare favorably with the 54% rate reported by Keenan et al. [1], and are similar to the 30% rate reported by Naunheim et al. [11], both of whom did not use pericardial strips. It may be speculated that pericardial strips can reduce but not eliminate the occurrence of air leaks, which can develop at sites distant from the staple lines because of the increased tension developed during re-expansion of the residual lung. We have also found that air leak occurred more frequently in patients with diffuse adhesions in comparison with those without adhesions. This finding suggests that although endoscopic dissection of adhesions can be facilitated by the magnified imaging of video technology, an emphysematous lung can be easily damaged during the dissection maneuvers, resulting in additional air leaks.

Previous studies have shown that after reduction pneumoplasty, sustained functional and clinical improvement can be maintained for up to 12 months [13]. However, no data are yet available as regards the long-term outcome of this operation, nor whether a longer period of palliation will be achieved by simultaneous bilateral operations or by unilateral operation followed by contralateral treatment at the re-appearance of symptoms. At 3 months, we have found a significant improvement in functional and clinical parameters which remained sustained also at 6 months and 1 year. In particular, we have found a high 50% rate of improvement in FEV_1, which slightly decreased at 1 year. This rate of improvement is superior to that achieved with UTRP in non-selected patients [1,11], whereas it is in the range of that achieved with the bilateral treatment [19].

One explanation may be that in asymmetric emphysema, the functional impairment is mainly influenced by the more diseased and more hyperinflated lung, which hence constitute an ideal target for unilateral reduction pneumoplasty.

In conclusion, we believe that in the correct setting, UTRP is a safe and effective procedure to relieve dyspnea and improve lung function in patients with severe, bullous and non-bullous emphysema. The operation should not be considered an alternative to the bilateral procedure but rather an additional option for selected patients. Patients with asymmetric emphysema may represent ideal candidates for UTRP.

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Appendix A. Conference discussion

Dr O. Maiwand (*Middlesex, UK*): What is your criteria for the choice of patient? You showed the respiratory function test. What will be the minimum function in which you will accept the patient for surgery?

Dr Pompeo: Actually, I showed for a few seconds our inclusion criteria. The FEV1 less than 35% is our standard criteria for inclusion.

Dr Maiwand: Okay. Your FEV1, 0.8, you show that's there. So that's what you state.

Dr Pompeo: Yes.

Dr Maiwand: And forced vital capacity somewhere about 2?

Dr Pompeo: Yes. Anyway, our main criteria is as regards the FEV1.

Dr W. Weder (*Zurich, Switzerland*): What you stressed during your presentation, to include morphology in volume reduction surgery is very important. However, it is quite difficult to apply practical criteria. We recently published a simple clarification system for morphology based on CT-scans. Could you give us more detail based on which criteria did you judge if an emphysema type is asymmetric? Is it just the impression of the reviewer by reading the CT scan? What exactly are the criteria you use to consider an emphysema type asymmetric? In the conclusion you mentioned bullous emphysema as well. Did you include or exclude bullous types in this study? This is extremely important for the interpretation of your results.

Dr Pompeo: Our criteria for selection of patients for either unilateral or bilateral procedures is very simple. We didn't utilize a scoring system. We evaluate the radiologic morphology of our patients and in the simple classification we propose we consider emphysema as homogeneous or type 1 if no or minor heterogeneous distribution was recognized. If two segments at most are involved more seriously than the others, we classify this emphysema as intermediate or type 2. If the difference in theheterogeneity is regarding more than two segments, then we classify it as heterogeneous or type 3. Finally if a marked difference in heterogeneity or a more severe hyperinflation is recognized in one of the two lungs, then we classify that emphysema as aymmetric. The criteria is simple, it is not in any way evaluated with a scoring system.

Bullous emphysema is included in this series. As I said, we excluded only giant bullae surrounded by relatively normal parenchyma. We have found very frequently some degree of paraseptal, bullous emphysema. Particularly in association with centrilobular emphysema.

Mr R.R. Jeffrey (*Aberdeen, UK*): I would like to ask you about your pulmonary rehabilitation program. Did you have one and did your patients participate in it preoperatively and postoperatively, and what is your assessment of the importance of that rehabilitation program?

Dr Pompeo: Yes, we have a rehabilitation program. We start our rehabilitation program 4–6 weeks preoperatively and we continue the rehabilitation in an outpatient setting postoperatively, for 6 weeks.

Dr Benfield: Do you enroll all patients in your rehabilitation program?

Dr Pompeo: Yes, all patients.

Dr Benfield: Could you, clarify, how you as a surgeon enter into the selection process as compared to the pulmonologists? What is the relationship between you and the pulmonologists in selecting these patients for pneunoplasty?

Dr Pompeo: Well, this kind of surgery needs a good relationship with the pulmonologists in the selection process. As a matter of fact, most of these patients are sent to our center from pneumologists. We have good cooperation with our pneumologists, of course.

Dr Benfield: Let me ask the question a different way. Did you turn any patients down for operation that had been sent to you by the pulmonologists?

Dr Pompeo: We never had such an experience until now. All of the patients who entered our rehabilitation program and who were eligible for the operation were operated subsequently.

Dr Benfield: Thank you. As you know, in the United States our Health Care Financing Agency has declined to pay for this operation. I commented about this just recently at the other session. My question is whether in Italy have you had any limitations on allowing you to do this operation?

Dr Pompeo: No. We have no limitations because these operations are performed in a university hospital which is a public institution in Rome and the patient hasn't had to pay anything for this.

Dr L. Lacquet (*Nijmegen, The Netherlands*): If you have a conversion to thoracotomy for unilateral emphysema, what kind of thoracotomy are you using?

Dr Pompeo: We are using lateral thoracotomy.

Dr Lacquet: Lateral?

Dr Pompeo: Yes.

Dr Lacquet: And what was the result in that patient concerning lung function?

Dr Pompeo: Well, we had only one patient who was converted to thoracotomy. I know that this patient is doing well. But it is difficult to compare the whole group against only one patient. This is the problem.