Clinical Area: Living donor lung transplant (LDLT)

Keywords: Lobar transplantation, living donor, outcomes.


Study Type: Case series.

Study Aim: To report the outcome and complications, of bilateral lobar lung transplants, among recipients and their donors.

Outcomes

- **Primary:** one-year survival, incidence of acute rejection, postoperative morbidity.

Design

- **Number of subjects:** N=60 recipients
- **Method of subject selection (inclusion/exclusion criteria):** Meeting the criteria for standard cadaveric lung transplant at the University of Southern California. Living donor recipients were selected based on deterioration in the clinical condition with the expectation that a cadaveric donor will be not available in time. Exclusion criteria were not discussed.
- **Consecutive patients?** All patients who underwent bilateral lobar transplantation were included.
- **Description of study population:** 75% of the patients were adults, with a mean age of 27 years (range 18-47), and 25% were children with a mean age of 13 years (range 9-17). More than half (53%) were females and 47% were males. 50 (83%) of the patients had cystic fibrosis, 4 (6.7%) had primary pulmonary hypertension, 2 (33%) had postchemotherapy pulmonary fibrosis, one patient (1.7%) had bronchopulmonary dysplasia, and one had obliterative bronchiolitis. Of the 120 donors 98 (81.7%) were related and 22 (18.3%) were unrelated to the recipients.
- **Exposure/Intervention:** Potential related and unrelated donors were medically and psychologically evaluated, and screened in-depth. Suitable donors (two for each recipient) were further evaluated. Right and left lower lobectomies were performed and transplanted in the recipients. A noninduction immunosuppressive protocol with cyclosporine, azathioprine, and prednisone was used for most patients. Pneumocystis carinii prophylaxis was given to all patients for one year, and ganciclovir for 42 days followed by acyclovir for the first 6 months. The patients were then monitored for infections and rejections.
- **Source of outcome data (e.g. patient self-report, doctor report, lab results):** Routine follow-up evaluations, and pulmonary function tests. Transbronchial biopsies were performed when indicated.
- **Length of follow-up:** The mean follow-up was 16 months.
- **Completeness of follow-up:** Not discussed.

Validity

- **Is the study type appropriate for the question(s) being asked?** No, a prospective study with a control group will be more appropriate.
- **Were patients similar with respect to baseline characteristics?** No.
- **Was the intervention and other aspects of patient care similar for all patients (or for all patients in a defined subgroup)?** Yes.
- **Was the process of observation likely to affect the outcome?** No.
- **Did an objective observer assess outcomes and were outcome measurements consistent?** Not discussed.
- **Was follow-up duration appropriate?** Follow-up of the patients is ongoing.

Conclusions regarding validity of methods:
The study has the inherent limitations in a case series, including potential selection bias, confounding, and the lack of a control or comparison group.
Results:

**Recipient results:** N=60

<table>
<thead>
<tr>
<th>1-year survival rate</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All recipients (N=60)</td>
<td>43</td>
<td>(71.7 %)</td>
</tr>
<tr>
<td>Cystic fibrosis group (n=50)</td>
<td>36</td>
<td>(72.0 %)</td>
</tr>
<tr>
<td>Noncystic fibrosis group (n=10)</td>
<td>7</td>
<td>(70.0 %)</td>
</tr>
</tbody>
</table>

Mortality:

- Deaths: Overall 17 (28.3%)
  - In the first 2 months 13 (76.5 % of all deaths)
  - Due to infection 10 (58.8 % of all deaths)

Other causes of death were pulmonary embolism, multiorgan failure, chronic rejection, and nonspecific graft failure.

Morbidity:

- Infections (1.8 episodes per patient)
  - Pseudomonas 52% (of all infections)
  - Aspergillus 11% (of all infections)
  - Cytomegalovirus 11% (of all infections)

- Acute rejection (0.8 episode per patient)
  - Mild 98%
  - Unilateral 90%
  - Bilateral 10%

- Chronic rejection
  - Bronchiolitis obliterans 13% (8 recipients)

Pulmonary function tests (at 1 year follow-up (n=34)

- Average forced vital capacity (FVC) 73% predicted (range 50%-103%)
- Average forced exp. vol. in 1 sec (FEV₁) 74% predicted (range 53%-95%)

**Donor results:** N=120

| Needed surgical re-exploration* | n (%) | 4 (3.3 %) |
| Dressler syndrome (postpericardiotomy) | n (%) | 5 (4.2 %) |
| Persistent nonproductive cough (1-4 months) | n (%) | 5 (4.2 %) |

Postoperative pulmonary function tests (after 1 year)

| Average decrease in forced vital capacity (FVC) | 15% |
| Average decrease in FEV₁ | 14% |
| Average decrease in total lung capacity | 16% |

* For sterile empyema, intercostal arterial bleeding, persistent air leak, and thoracic hematomas.

**Authors’ Conclusions**

The authors concluded, “Despite the constant concerns regarding the risk to the living donors, our results have demonstrated the safety of the procedure with resulting organ availability that has been life saving in severely ill patients who will either die or become unsuitable recipients before a cadaveric organ becomes available.”

**Reviewer’s Conclusions**

This case series shows that 71.7 % of the recipients survived the living donor transplantation at one year. Three fourths of the deaths occurred in the first two months, 60% of which were due to infections.

The study limitations, including small sample size, potential selection bias, and confounding, in the addition to the lack of a comparison group, need to be taken in account before drawing any conclusions based on the results.