CARDIAC AND PULMONARY REPLACEMENT

EXPERIENCE WITH LIVING-DONOR LOBAR TRANSPLANTATION FOR INDICATIONS OTHER THAN CYSTIC FIBROSIS

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Objective: Since development of a living donor bilateral lobar transplantation protocol for patients with cystic fibrosis, our indications have expanded to include recipients with other diagnoses. **Methods:** We report on our experience in eight patients with primary pulmonary hypertension, postchemotherapy pulmonary fibrosis, bronchopulmonary dysplasia, idiopathic pulmonary fibrosis, and obliterative bronchiolitis. The average age of the eight patients was 19.1 years (range 9 to 40). The mean preoperative carbon dioxide tension for the four patients who did not have primary pulmonary hypertension was 92 mm Hg (range 64 to 120 mm Hg), and the two patients with pulmonary fibrosis were intubated (one on high-frequency jet ventilation). Each recipient received a right lower lobe ($n = 7$) or middle lobe ($n = 1$) and a left lower lobe ($n = 8$) from a total of 16 donors representing various combinations of the recipient's family ($n = 15$) and an unrelated friend ($n = 1$). **Results:** With an average follow-up of 1 year the overall survival is 75%. For the five patients followed up for at least 1 year, mean forced vital capacity was 80.6%, forced expiratory volume in 1 second was 75.6%, mid-forced expiratory flow was 64%, and diffusing lung capacity corrected for alveolar volume was 73% of predicted. For those patients with primary pulmonary hypertension, preoperative hemodynamics revealed mean pressures as follows: blood pressure 84.8 mm Hg, right atrial pressure 7.8 mm Hg, pulmonary artery pressure 71.3 mm Hg, pulmonary capillary wedge pressure 9.5 mm Hg, cardiac index 2.9 L/min per square meter, and pulmonary vascular resistance index 22.8 Wood units. Postoperative hemodynamics revealed a mean blood pressure of 84.3 mm Hg, right atrial pressure of 2.7 mm Hg, pulmonary artery pressure of 16 mm Hg, pulmonary capillary wedge pressure of 7.3 mm Hg, cardiac index of 4.2 L/min per square meter, and pulmonary vascular resistance index of 1.9 Wood units. **Conclusions:** Early results of living-donor bilateral lobar transplantation for diseases other than cystic fibrosis have resulted in satisfactory survival and pulmonary function. Additionally, patients with severe primary pulmonary hypertension have had dramatic normalization of their hemodynamics despite the limited amount of lung tissue transplanted. We believe that the data from this small cohort experience compares favorably with our larger series with cystic fibrosis and supports an expanded role for living-donor lobar transplantation in patients with alternate indications. (J Thorac Cardiovasc Surg 1997; 114:917-22)

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Since the first attempts at clinical lung transplantation more than three decades ago, dramatic improvements in surgical technique, organ preservation, prevention and treatment of acute rejection, and management of infection have occurred. As the indications and number of referrals for lung transplantation have grown, the availability of donor organs has failed to significantly increase. As a consequence of this supply and demand mismatch, an increasing number of patients have died while on the recipient waiting list. With this in mind, our group investigated the concept of clinical living-donor lobar transplantation.¹ The majority of our experience in this field has involved patients with cystic fibrosis. To date, we have performed 42 bilateral lobar transplants in this population with a 1-year survival of 73.8%. Given these results in an extremely challenging group of recipients with *Pseudomonas* and *Aspergillus* in addition to all of the nonpulmonary complications of cystic fibrosis, we expanded our indications to include potential recipients with other diagnoses. We report on our early experience with our first eight patients receiving living-donor bilateral lobar transplants for indications other than cystic fibrosis.

Patients and methods

Recipient selection. From November 1993 to March 1997, eight bilateral living-donor transplants were performed in patients with diagnoses other than cystic fibrosis. The indications (Table I) included primary pulmonary hypertension, postchemotherapy pulmonary fibrosis, bronchopulmonary dysplasia, idiopathic pulmonary fibrosis, and obliterative bronchiolitis (presumed to be from a viral origin). Three of the patients were adults, with a mean age of 30.3 years (range 19 to 40 years), and five were children, with a mean age of 12.4 years (range 9 to 15 years). This cohort included only one male patient (idiopathic pulmonary fibrosis). The patients all had severe progressive deterioration in clinical status, with or without a specific acute decline, and an expectation that a cadaveric allograft would not be available in time. Of the eight patients, three pediatric patients with end-stage primary pulmonary hypertension were referred from Japan, where cadaveric lung transplantation is not an option as a result of absence of brain death legislation. For the remaining five patients, the average time accumulated on the cadaveric waiting list was 18 weeks (range 1 to 78 weeks) before they underwent living-donor lobar transplantation.

The patients all required long-term supplemental oxygen, and the two patients with pulmonary fibrosis were ventilator-dependent receiving 100% inspired oxygen, of whom one was using a high-frequency jet ventilator. For the four patients without primary pulmonary hypertension, the average preoperative carbon dioxide tension was 92 mm Hg (range 64 to 120 mm Hg) and three patients

were steroid-dependent. All four patients with primary pulmonary hypertension had systemic or near-systemic pulmonary artery pressures, massively dilated right atrial and ventricular chambers, severe tricuspid regurgitation, and syncopal episodes despite long-term epoprostenol (prostacyclin) therapy. One of the patients with primary pulmonary hypertension was on high-dose intravenous inotropic therapy for right ventricular support and had a cardiac arrest immediately before the transplant operation. All eight patients were either wheelchair- and bed-bound or hospital-bound before transplantation (Table II). The patients had no irreversible end-organ damage other than their pulmonary disease. Institutional Review Board approval from the University of Southern California and Childrens Hospital Los Angeles was initially obtained before considering a patient for the procedure. Currently, we do not require institutional review board approval as a result of the acceptance of this procedure by the transplant community. All patients underwent the appropriate pretransplant serologic and physiologic workup and satisfied the usual criteria for cadaveric lung transplantation at our institution, as previously described.² As with other organ transplant procedures, especially those in which a pediatric population is involved, the presence of a stable outpatient support structure with functional coping mechanisms is mandatory.

Donor selection. The 16 living donors selected for the eight recipients represented various combinations of either the recipient's family (mothers, $n = 5$; fathers, $n = 5$; brothers, $n = 2$; sisters, $n = 2$; and cousin, $n = 1$) or an unrelated friend ($n = 1$). Both psychosocial and physiologic factors were extensively assessed. All potential donors were screened by an independent committee including a psychiatrist and social worker to safeguard against coercion, as well as by the transplant team to ensure donor comprehension of the procedure, risks, and outcomes. As previously described, the donor evaluation included arterial blood gas analysis, complete spirometry, ventilation/perfusion scanning, chest roentgenogram, chest computed tomography, echocardiography, exercise treadmill stress testing (for male donors older than 45 years of age), and routine serologic and viral screening.² Histocompatibility antigen (HLA) typing was performed for the recipient and chosen donors but was not used to guide donor selection.

The lobes donated were a right lower lobe ($n = 7$) or right middle lobe ($n = 1$) from one donor and the left lower lobe from the other donor ($n = 8$). The choice of which donor is used for either the right or left side and whether the right lower lobe (or rarely the middle lobe) is used is decided on the basis of the aforementioned testing and size matching considerations. The middle lobe is generally no longer considered and the standard procedure involves use of the right and left lower lobes. If an otherwise acceptable donor has a prior history of infection, trauma, or thoracic surgery unilaterally, then the contralateral side is chosen. If all aspects are equal, then the larger donor is usually selected for donation of the right lower lobe. The average donor age was 39.4 years with a mean donor height of 168 cm and a mean donor weight of 73 kg. In comparison, the mean recipient height was 152 cm and the mean weight was 40 kg (Table III).

Table I. Primary diagnoses

Diagnoses	Patients (n = 8)	Age (yr)
Pulmonary hypertension	4	11, 12, 15, 15
Idiopathic pulmonary fibrosis	1	40
Postchemotherapy pulmonary fibrosis	1	32
Bronchopulmonary dysplasia	1	19
Obliterative bronchiolitis	1	9

Operative procedures. The surgical and logistic aspects of the right and left donor lobectomy, the donor lobe back-table preservation technique, and the recipient bilateral pneumonectomy and bilateral lobar implantation have been previously described by our group.^{1,3,4}

Recipient postoperative management and immunosuppression. The immediate perioperative and postoperative management and immunosuppressive protocol (including our modified chest tube management) is also similar to our prior description in the population with cystic fibrosis.⁴ The patient remains intubated with a single-lumen endotracheal tube for 72 hours with a positive end-expiratory pressure of 10 cm H₂O. This prolonged ventilatory support is provided in an attempt to minimize atelectasis and maintain optimal expansion of the lobes. In addition, as the entire cardiac output is now flowing through two relatively undersized lobes, the hope is that this ventilatory management will decrease pulmonary edema and reperfusion injury. Specific differences in management in this group not having cystic fibrosis include an increased use of intravenous inotropic agents for right ventricular support in the patients with significant preoperative primary pulmonary hypertension. Empiric or culture-guided use of broad-spectrum antibiotics is less frequent in this group than in the cystic fibrosis group, who nearly universally harbor pathogenic bacterial or fungal species, or both. A noninduction immunosuppressive protocol with cyclosporine (INN: ciclosporin) or tacrolimus, azathioprine, and corticosteroids is used. More recently, mycophenolate mofetil has been used instead of azathioprine. Prednisone is tapered to achieve a dose of 0.5 mg/kg per day by the end of the first postoperative month. The dose is decreased every subsequent month by 0.1 mg/kg until the patient has reached a maintenance dose of 0.1 mg to 0.15 mg/kg per day. Cytomegalovirus (CMV) prophylaxis is given to all patients receiving a CMV-positive donor lobe, regardless of preoperative recipient status. Our current protocol is intravenous ganciclovir at 6 mg/kg per day for 2 weeks followed by oral ganciclovir 3 gm/day for the first 6 months. Prophylaxis for *Pneumocystis carinii* consists of trimethoprim-sulfamethoxazole (320/1600 mg) three times a week for the first year. As an outpatient, pulmonary function testing and chest roentgenography are performed with each clinic visit. Bronchoscopy with or without transbronchial biopsy is performed only when clinically indicated by symptoms, radiography, or a decrease in spirometric results.

Table II. Preoperative data and severity of illness

In hospital	4/8 (50%)
Preoperative steroid therapy	3/8 (38%)
Ventilator dependent	2/8 (25%)
High-frequency jet ventilation	1/8 (12.5%)
Mean PCO ₂ (non-PPH patients)	92 mm Hg (range 64-120)
NYHA class IV	8/8 (100%)

PCO₂, Carbon dioxide tension; PPH, primary pulmonary hypertension; NYHA, New York Heart Association.

Results

With an average follow-up of 1 year (range 1 to 30 months for all patients), survival probability was 0.75 with a standard error of 0.15 according to Kaplan-Meier analysis (WinSTAT for Windows 3.1). The two deaths (both at 1 month after the operation) occurred in the patient with idiopathic pulmonary fibrosis as a result of *Aspergillus* pneumonia and in the patient with obliterative bronchiolitis with nonspecific bilateral graft failure of unclear origin (culture negative, rejection free, with dense infiltration of polymorphonuclear cells). All six of the remaining patients are highly functional with no limitations on their activities. Two mild rejection episodes have occurred, classified as grade A2 according to the International Society for Heart and Lung Transplantation grading system, in the six patients. Both episodes responded to an augmentation in corticosteroid dosing. Of note, the average number of HLA matches between recipient and donors was 2.75 (range 0 to 6) and mismatches was 2.73 (range 0 to 6). There has been only one infection (in the six surviving patients) necessitating intravenous antimicrobial therapy involving CMV viremia in one of the patients after treatment for the aforementioned rejection episode. This responded completely to intravenous ganciclovir therapy.

Postoperative spirometry revealed a gradual progressive improvement in pulmonary function that tends to plateau by postoperative months 9 to 12. For the five patients followed up at least 1 year, mean forced vital capacity is 80.6% of predicted, mean forced expiratory volume in 1 second is 75.6% of predicted, mean mid-forced expiratory flow is 64% of predicted, and mean diffusing lung capacity corrected for alveolar volume is 73% of predicted (Table IV). For the four patients with primary pulmonary hypertension, postoperative right heart catheterization revealed normal pressures and pulmonary vascular resistance. Preoperative (within 3 months of transplantation) and postoperative hemo-

Table III. Recipient and donor demographics

	Mean	Range
Recipient (<i>n</i> = 8)		
Adult (<i>n</i> = 3)		
Age (yr)	30.3	19-40
Pediatric (<i>n</i> = 5)		
Age (yr)	12.4	9-15
Height (cm)	152	135-170
Weight (kg)	40	30-65
Donors (<i>n</i> = 16)		
Age (yr)	39.4	21-49
Height (cm)	168	150-185
Weight (kg)	73	46-97

Table IV. Postoperative pulmonary spirometry

	Mean (% predicted)	Range (% predicted)
FVC	80.6	52-97
FEV ₁	75.6	54-93
FEF _{25/75}	64.0	47-97
DLCO/VA	73.0	58-85

FVC, Forced vital capacity; FEV₁, forced expiratory volume in 1 second; FEF_{25/75}, Mid-forced expiratory flow; DLCO/VA, diffusing lung capacity corrected for alveolar volume.

dynamics are shown in Table V. Right atrial and ventricular chamber size and tricuspid valve regurgitation normalized in all four patients. All six intermediate and long-term survivors are in New York Heart Association functional class I.

Among the 16 donors, there were two complications in the postoperative period. One donor of a right lower lobe had a persistent air leak, defined as greater than 10 days, which was managed conservatively with continuous suction for 14 days. Another donor of a left lower lobe required surgical reexploration on the first postoperative day for evacuation of a hematoma after removal of a chest tube resulted in intercostal venous bleeding. Both donors otherwise did well with no additional morbidity. For those donors with at least 1 year's follow-up (*n* = 10), compared with baseline values, spirometry revealed a mean decrease in forced vital capacity of 15%, in forced expiratory volume in 1 second of 13%, and in total lung capacity of 16%. All 16 donors have resumed their normal activity and lifestyles.

Discussion

As a consequence of the steady progress that has been achieved in lung transplantation, the discrepancy between donor availability and the recipient

Table V. Right heart catheterization results (*n* = 4 patients)

	Preoperative		Postoperative	
	Mean	Range	Mean	Range
BP (mm Hg)	84.8	68-98	84.3	62-98
RA (mm Hg)	7.8	2-14	2.7	0-8
PA (mm Hg)	71.3	60-85	16.0	11-18
PCWP (mm Hg)	9.5	7-11	7.3	5-12
CI (L/min/m ²)	2.9	1.9-3.4	4.2	3.2-5.5
SVRI (Wood units/BSA)	28.6	16.9-44.2	21.6	17.4-24.1
PVRI (Wood units/BSA)	22.8	16.2-32.1	1.9	1.1-2.7

BP, Systemic blood pressure; RA, right atrial pressure; PA, pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure; CI, cardiac index; SVRI, systemic vascular resistance index; PVRI, pulmonary vascular resistance index; BSA, body surface area.

waiting list continues to increase. Although the field of living-donor lobar transplantation is still relatively new, our experience in this aspect of pulmonary transplantation has not only resulted in an increase in the number of available allografts but, more important, has made them available in an expedient fashion. This has been life-saving for those potential recipients who are in rapidly deteriorating condition and will either become unsuitable candidates or die before an organ becomes available. In our region, the mean waiting time for cadaveric double lung transplantation is 12 months for pediatric patients and 20 months for adult patients. The majority of our experience in the field of living-donor lobar transplantation has involved recipients with end-stage cystic fibrosis. Our prior work in that extremely challenging patient population has demonstrated the safety and reproducibility of the procedure, with recipient outcomes comparable with those with conventional cadaveric double lung transplantation.^{4,6} To date, our experience with bilateral living-donor lobar transplants in patients with cystic fibrosis has resulted in a 1-year actuarial survival of 73.8%. This is despite the severity of illness of this group and the urgent nature of the transplant for most of the recipients.

In an attempt to expand the indications for this procedure to include patients with diagnoses other than cystic fibrosis, we now report on our early experience with eight patients with end-stage pulmonary disease from different causes. The cohort consisted of pediatric and adult recipients with primary pulmonary hypertension, postchemotherapy pulmonary fibrosis, bronchopulmonary dysplasia, idiopathic pulmonary fibrosis, and obliterative bronchiolitis. Three of those patients were moribund going into the operating

room. Each recipient received two lobes from various combinations of their family members or, in one case, from an unrelated friend. With two deaths from infectious causes, the 1-year survival was 75%. All six remaining survivors have had excellent functional outcome with a relatively low rejection and infection rate at 1-year follow-up. Postoperative spirometry has revealed excellent pulmonary function. The four patients with primary pulmonary hypertension all had end-stage disease with significant right heart failure, tricuspid regurgitation, and markedly dilated right-sided chambers, despite maximal medical therapy including long-term epoprostenol (prostacyclin). After transplantation, cardiac size and function and hemodynamics all completely normalized. Similar to the postoperative hemodynamics seen in our cystic fibrosis population, the normal right heart catheterization results confirm the capability of two pulmonary lobes to handle the entire cardiac output. This is particularly important if patients with underlying diseases resulting in severe pulmonary hypertension are considered as candidates in view of their markedly reduced preoperative right ventricular function. The spirometric and hemodynamic results reflect the clinical picture of these recipients who have returned to an unrestricted, active lifestyle.

The complications seen in the cohort of donors continues to be relatively mild and have occurred with an incidence comparable with that observed in our larger series. With more than 100 lobectomies performed in both related and unrelated living donors, the short- and long-term morbidity has been consistently low. We continue to follow these data (as well as quality of life surveys) extremely closely because we strongly believe that donor outcome is as important as, if not more important than, recipient outcome.

The data from this small cohort experience in patients with end-stage pulmonary disease from causes other than cystic fibrosis compare favorably with our larger series with cystic fibrosis. We believe this report combined with our overall experience supports an expanded role for living-donor lobar transplantation in patients with alternate indications.

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Discussion

Dr. G. Alec Patterson (St. Louis, Mo.). Dr. Starnes and his group deserves credit for introducing and expanding the role of living-related donor transplantation for patients with lung diseases amenable to transplantation who will not survive long enough to obtain a cadaveric donor.

We know that the mortality rate for patients with cystic fibrosis on transplant waiting lists is approximately 30% in some centers. We also know that patients with pulmonary fibrosis and pulmonary hypertension may have an even higher mortality rate on the waiting list. Therefore, I believe that living-related donor transplantation does represent a reasonable option for selected patients if results can be achieved that equal cadaveric transplantation.

I have a number of observations and questions which I would like to address to Dr. Starnes regarding this initial experience. The mortality rate of 25% is higher than that of standard transplantation in experienced programs. I suspect that this relates to recipient selection rather than to technical details of the operation. I would like your comments.

Donor follow-up is critical in this procedure. How do you obtain follow-up information on these donors, particularly from those donors whose lobes were transplanted into recipients who died in the perioperative period?

Finally, suitable donor lungs are obviously difficult to identify, yet in the Los Angeles area, despite the presence of active heart transplant programs, it seems to me that there is a very small number of cadaveric lung transplants being performed. Can you comment on the number of transplants performed using standard cadaveric donor lungs from your own region. Could you also speculate on whether the active living-related lung transplant program somehow diminishes the enthusiasm of regional organ procurement organizations to procure suitable cadaveric lungs?

Dr. Starnes. Dr. Patterson, thank you very much for those comments. Your contributions to the field have been enormous, and I really take the opportunity to answer your questions with some insight into what you have contributed.

The mortality rate of 25% is higher than in a large

cadaveric series of papers, but I think there are two problems. First, our "n" is small. With two deaths in a group of eight, the mortality rate is 25% immediately. The preoperative evaluation showed that these patients were critically ill. They were dying. Some of our patients who have the opportunity to wait at home for a cadaveric donor often are in better condition. These patient selection issues probably increased our mortality rate.

We monitor our donors very carefully. We do a survey at 1 year and we do a survey again at 2 years. The obvious question asked is, "Would you do it again?" The response to that has been overwhelmingly about 95% "yes." The 5% that said that they would have to think about it or absolutely they would not do it again are those individuals that had donated a lobe to a nonsurvivor. We have found that we have had no long-term complications that have affected the quality of life in the donors. They are all back at work and doing the things that they were able to do before the operation. In terms of outcomes, we have not had a negative problem.

Your points regarding the suitability of donor lungs and cadaveric lungs are well taken. The Los Angeles area is huge, and we get too few cadaveric lungs from it. I do not think that the impact of our program has biased the number of cadaveric donor organs that become available, however. Some of our issues are that we have large county hospitals serving a lot of John Does, and we cannot find family members to allow us to go forward with organ procurement. Now that our two organ procurement organizations are working in conjunction, I hope to be able to improve that and increase the number of donors in our area.

Dr. Douglas J. Mathisen (*Boston, Mass.*). Dr. Starnes, would you comment on the HLA status of this group? How does this compare with the cystic fibrosis population? Do you think the viral infections are different from the bacterial infections that patients with cystic fibrosis have in terms of suitability for transplantation?

Dr. Starnes. HLA matching in particular we have looked at and detailed. What we would anticipate is a fairly standard haploid match, particularly if it was coming from parents. In point of fact, the number of matches turned out to be about 2.7, and the number of mismatches about 2.7. If you evaluated the rejecting lobe versus the nonrejecting lobe, the HLA matching did not seem to play

an important role, except in an occasional brother or sister, in whom we have had a five- and six-antigen match where it obviously did play a role. Anything less than a four-antigen match did not seem to affect the outcome in terms of rejection.

Some differences arise in comparing viral illness versus bacterial illness, particularly in the pediatric age group. Some of these children come in with organisms, such as the adenoviral and parainfluenza organisms, for which we do not have effective therapy. We have actually canceled transplants because of a nasal swab and a preliminary report of the viruses that were growing. I cannot remember cancelling a cystic fibrosis case because of a bacteria or flora once the patient was on our list. I do think there are some differences there.

Dr. Stefano Nazari (*Pavia, Italy*). Have you had any bronchial healing complications? If so, is there any difference in the incidence of this complication between the adult and the pediatric patient?

Dr. Starnes. Of the total experience of 52 patients, we have had one bronchial complication. It was a stenosis that we have treated with balloon dilation. We have not had to use a stent. Living-donor organs are somewhat different from cadaveric organs because we are taking a lobe, and the bronchus and the collaterals to that bronchus are in much closer proximity to the lung tissue. Obviously, by definition, the length of the bronchial stump in the lobar transplant is very short. That probably as much as anything has decreased our incidence of bronchial healing complications.

Dr. David J. Sugarbaker (*Boston, Mass.*). In terms of your surveillance, because of the two immunologic make-ups of the donor lobes, are you required to obtain a transbronchial biopsy specimen from each lobe at the time?

Dr. Starnes. Yes. What we have found is that the lobe that rejects initially tends to be the lobe that rejects in the future, but we still survey both sides.

Dr. Sugarbaker. Has that increased your complication rate from transbronchial biopsies in the follow-up period?

Dr. Starnes. It has not, but we do not do routine biopsies. We base our biopsies on spirometry data. Also, we have noted that the tendency for bleeding after transbronchial biopsies in the lobar group is a little higher, I guess because there is more blood flow through the lobe.