

NEW YORK-PRESBYTERIAN TRANSPLANT

Affiliated with COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS AND SURGEONS and WEILL CORNELL MEDICAL COLLEGE

Fall 2007

Kidney Transplant: Physicians Perfect Laparoscopy

The laparoscopic technique for harvesting grafts has dramatically expanded the availability of live kidney donations for transplantation. This approach has rapidly been adapted as a standard of care worldwide because of its considerable advantages, but transplant surgeons at NewYork-Presbyterian Hospital were pioneers in this procedure and continue to perfect the protocol.

"The dramatic increase in live-donor kidney transplants parallels the development of laparoscopic techniques. In the United States, more than 80% of all live kidney donations are now performed laparoscopically, and it has meant that far more patients with failing kidneys are receiving potentially lifesaving transplants," observed Lloyd E. Ratner, MD, who participated in the very first laparoscopic harvesting of a donor kidney in 1995 and has since instructed hundreds of surgeons on how to perform the procedure at centers around the world.

"In animal models, we are now looking at minimally invasive procedures for kidney grafts in the recipient. The early work is promising and may be leading to clinical applications," he said. According to Dr. Ratner, recipients would derive the same types of benefits, particularly rapid recovery, that donors now derive from procedures performed laparoscopically.

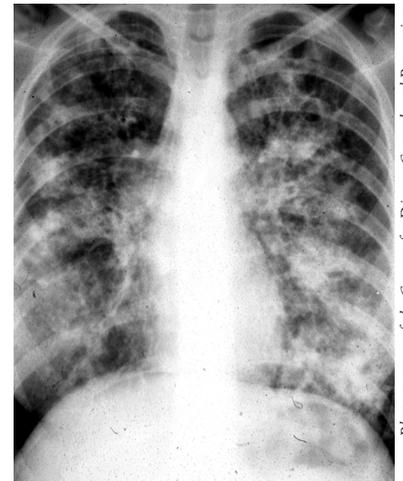
Joseph J. Del Pizzo, MD, started his work in minimally invasive live-donor kidney transplants at the University of Maryland, soon after Dr. Ratner initiated the procedure. Dr. Del Pizzo noted that

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Selection Criteria Expand for Cystic Fibrosis Lung Transplant

NewYork-Presbyterian Hospital has taken a leadership role in perfecting techniques and patient selection criteria for lung transplantation in patients with cystic fibrosis (CF). As a result, the Hospital is home to the largest CF lung transplant program in New York City. Leveraging this experience, the Hospital has now expanded the program to include patients under the age of 18 years. Although current management strategies reasonably control the disease into adulthood in most pediatric patients, lung transplantation may offer extended survival in pediatric patients with advancing disease who have severe and irreversible airflow obstruction.

"Obviously, the goal is to delay transplant as long as possible, but it is important to have the option of transplantation for any individual with advanced CF," noted Selim Arcasoy, MD, who worked as a co-author of a recent update of the international guidelines for selection of lung transplant candidates (*J Heart Lung Transplant* 2006;25:745-755). Dr. Arcasoy added that, as part of the expanded program, there will be no age limit, and children will be considered for transplantation as early as necessary.



An image of the lungs of a child with cystic fibrosis (CF). In NewYork-Presbyterian Hospital's newly expanded lung transplant program, there will be no age limit, and children with CF will be considered for transplantation as early as necessary.

Photo courtesy of the Centers for Disease Control and Prevention.

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Transplant Statistics

- In 2006, the NewYork-Presbyterian Hospital Transplant program performed more transplants than any other center in the U.S. (United Network for Organ Sharing [UNOS]).
- In 2006, the Hospital's Heart and Kidney programs both ranked #1 for individual organs; Lung Transplant ranked #7 and Liver Transplant ranked #6 (UNOS).
- NewYork-Presbyterian/Weill Cornell's Kidney program and NewYork-Presbyterian/Columbia's Lung program showed statistically higher 1-year patient and graft survival rates compared with other transplant centers. Both programs are ranked in the top 5% in the country (Scientific Registry for Transplant Recipients).

UPDATES

Dermatology Program Combats Post-transplant Skin Cancer

Most transplant recipients develop skin cancer as a result of a combination of risk factors including skin pigmentation, history of sun exposure, and the need for treatment with immunosuppressant medications. Within 20 years of transplantation, up to 70% of patients will develop at least 1 skin cancer, and skin cancer in immunosuppressed organ transplant recipients often behaves aggressively and can be a significant cause of decreased quality of life and even death.

Transplant recipients have a 65-fold higher risk of developing squamous cell carcinomas, a 10-fold higher risk of basal cell carcinomas, and a 3-fold higher risk of melanoma than the general population. Additionally, skin cancers often grow faster and are more likely to metastasize in transplant recipients. For these reasons, it is crucial to reduce the risk of skin cancer in organ transplant recipients.

In 2006, to help address the problem of skin cancer in this population, NewYork-Presbyterian Hospital established an organ transplant dermatology program to provide a comprehensive approach that includes screening for skin cancer both before and after transplantation. Additionally, patients receive education about skin cancer prevention and how cancerous and precancerous skin lesions

are treated. This is the first clinic of its kind to be established in New York State.

As a national leader in organ transplantation, NewYork-Presbyterian is a logical site for this program. The Hospital performs more heart transplantations than any other hospital in the United States. Additional transplants performed at NewYork-Presbyterian include kidney, lung, liver, and pancreas.

Working with Giuseppe Militello, MD, transplant care coordinator Leisy Strachan, and dermatologic surgeon Désirée Ratner, MD, Heather Rogers, MD, established the clinic in response to a clearly unmet medical need.

Dr. Rogers is a second-year resident in the Department of Dermatology at NewYork-Presbyterian and will be chief resident next year. When she began seeing transplant patients in the dermatology clinic, she was very concerned about how little patients knew about their increased risk for skin cancer after organ transplantation.

According to Dr. Rogers, now that patients are surviving longer following transplants as a result of better medical care, the development of skin cancer—usually beginning 3 to 4 years post-transplant—is occurring with greater frequency. “You shouldn’t survive a heart transplant and then die of skin cancer,”

remarked Dr. Rogers, who also pointed out that once squamous cell carcinoma metastasizes in an organ transplant recipient, the 3-year survival rate is less than 60%.

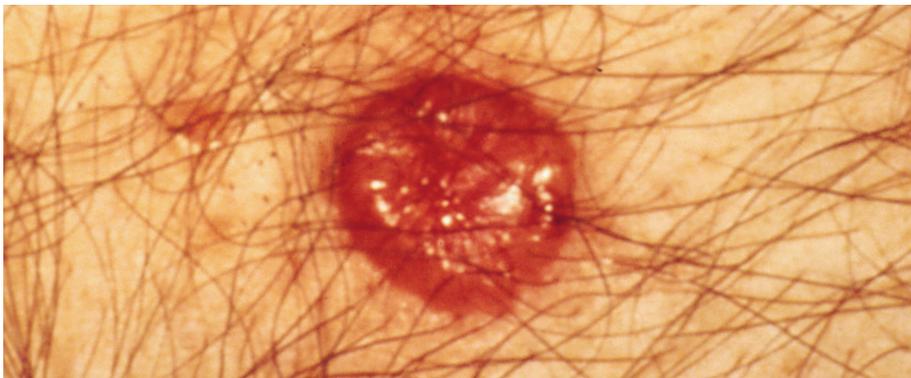
Goals of the program include educating transplant patients proactively about their increased risk for developing skin cancer; implementing preventive measures to diminish their risk of developing skin cancer; ensuring early recognition and treatment of skin cancers; and facilitating cooperation between dermatologists and the transplant teams in caring for patients with potentially life-threatening skin cancers.

In addition to providing regular follow-up assessments for organ transplant recipients, the clinic is designed to be an integral part of the pre-transplant evaluation. Total skin examinations are performed, and if necessary, patients are treated prior to the initiation of immunosuppressive therapy. John Carucci, MD, PhD, a dermatologic surgeon at NewYork-Presbyterian Hospital/Weill Cornell Medical Center, agrees that screening before transplantation is optimal. “The ideal time would be in the pre-transplant work-up to identify those patients who are at risk,” he remarked.

The risk of skin cancer is assessed at the clinic based on age, sun exposure, skin pigmentation, history of human papillomavirus infection, and the type of transplant to be performed. Different types of transplants are associated with different risks for skin cancer. Heart transplant patients are at highest risk because they typically require the highest doses of immunosuppressive medicines. Kidney transplant patients have the next highest risk, then liver transplant patients.

Patients are counseled regarding avoiding sun exposure, performing monthly skin self-examinations, and scheduling regular follow-up visits to the clinic to examine anything that is worrisome. The clinic’s purpose is not only to educate transplant recipients to help them better protect themselves from the sun and become more knowledgeable about skin cancer, but also to implement treatments that could decrease the likelihood of developing skin cancer in the future. “The goal is to diagnose and treat patients rapidly

Photo courtesy of the Centers for Disease Control and Prevention.



Basal cell carcinoma. Data indicate that transplant patients have a 10-fold higher risk for developing the disease than the general population.

NewYork-Presbyterian Hospital established an organ transplant dermatology program to provide a comprehensive approach that includes screening for skin cancer both before and after transplantation.

because skin cancers in this population progress so quickly,” said Dr. Rogers.

The clinic refers patients requiring surgery to specialists in dermatologic surgery, such as Dr. Ratner or Dr. Carucci, who perform Mohs micrographic surgery, which is a state-of-the-art technique that completely defines and removes skin tumors while preserving normal tissue and is usually followed by immediate reconstruction. “I’m seeing a good number of transplant recipients for skin cancers. Unfortunately, they get more frequent skin cancers, mostly squamous cell carcinomas,” said Dr. Carucci.

With regard to dermatology screening for skin cancer, Dr. Carucci emphasized, “It is incredibly important for these patients, as it is for anyone, but it is very important for transplant recipients.” He believes that general awareness of skin cancer has greatly increased in the past 10 years, but more education about skin cancer risk and prevention is still needed, particularly for younger people.

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Multimodality Approach Improves Outcomes in Hepatocellular Carcinoma

With nationally and internationally recognized authorities in established modalities as well as experimental techniques, the treatment team for hepatocellular carcinoma and hilar cholangiocarcinoma at the Center for Liver Disease and Transplantation at NewYork-Presbyterian Hospital/Columbia University Medical Center is setting new standards for patient outcomes—including long-term survival—in resection, adjuvant therapies, and transplantation.

“It is natural for cancer centers to focus their attention toward what they do best at their center, but when you have a team with expertise on the full array of options, you can work together to do what is best for each patient,” observed Robert S. Brown, Jr, MD, MPH. “This type of expertise also permits thinking that is outside of the box. In addition, with the team approach, it is simple to switch between modalities as the clinical situation changes.”

Patients with liver and biliary tree cancers come to the Center through referrals from hepatologists, surgeons, oncologists, or other specialists; however, once they are

referred, the case is automatically introduced into review by the multidisciplinary team that meets several times per week. Because of this collaboration, patients not only benefit from a group of experts agreeing on an optimal strategy from the perspective of very different disciplines, but there is also attention to the long-term implications of therapy. In liver cancer, successful downsizing of the tumor through adjunctive chemotherapy, radiation, or resection may mean a change in direction, such as liver transplant, in which the goal becomes cure rather than disease control.

“We have been able to consider transplant far outside of the traditional boundaries because the multimodality approach allows us to increase the proportion of liver cancer patients who are candidates for transplant,” reported John F. Renz, MD, PhD. According to Dr. Renz, in unresectable but localized liver cancer, transplant may be the only way to prevent recurrence.

Among the innovative transplant programs currently being pursued at NewYork-Presbyterian/Columbia is one

“We have been able to consider transplant far outside of the traditional boundaries because the multimodality approach allows us to increase the proportion of liver cancer patients who are candidates for transplant.”

—John F. Renz, MD, PhD

involving the treatment of hilar cholangiocarcinoma. Adapting an approach first pioneered at the Mayo Clinic, the protocol involves a regimen of chemoradiation to eliminate any systemic malignant cells, followed by transplant, which removes the primary tumor. The approach is experimental but promising, and it is expected to not only extend overall survival; it should also prevent late recurrence.

Transplant success at NewYork-Presbyterian/Columbia is not just a function of transplant skill. Drs. Brown and Renz credited the work of oncologists on the team, particularly Abby B. Siegel, MD. Dr. Siegel is involved in the design of numerous clinical trials with agents aimed at debulking cancers, which can render patients transplant candidates. Recently, she has been particularly active in studying anti-angiogenic agents, such as bevacizumab, which help deprive tumors of their blood supply.

“If you can provide a systemic therapy that ultimately permits the patient to undergo transplant, this is potentially life-saving. Five-year survival in some series of patients with unresectable localized disease that have undergone transplantation has been 75% to 80%,” Dr. Siegel observed. “We have been the primary study site or a participating study site in several trials with agents that act at the molecular level, which can mean shrinkage of tumor with relatively modest side effects relative to traditional chemotherapy agents.”

Dr. Siegel has recently become interested in evidence that Caucasians with liver

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Table. Analysis of Curative or Palliative Therapy Used to Treat HCC: United States Surveillance, Epidemiology, and End Results (SEER) Registry

	Patients, %
Curative Therapy, Total	13
Resection	8.2
Local ablation	4.1
Transplant	0.9
Palliative Therapy, Total	61
TACE	4
Other palliative therapy	57
No specific therapy, total	26

HCC, hepatocellular carcinoma; TACE, transcatheter arterial chemoembolisation
El-Serag HB, Siegel AB, Davila JA, et al. J Hepatol. 2006;44:158-166.

Results Lead Hospital To Expand Multiple-Organ Transplant Program

Researchers at NewYork-Presbyterian Hospital/Columbia University Medical Center are studying methods for improving outcomes in multiple-organ transplant procedures, including heart–kidney and liver–kidney transplantations.

“Because we have such a large heart and liver program and our kidney program is substantial, we probably have more experience than anywhere in the country in doing these combined transplants, and we have ample opportunity for research,” said Lloyd Ratner, MD, who collaborates with Yoshifumi Naka, Surgical Director of the Heart Transplant program, and Donna Mancini, MD, Medical Director of the Heart Transplant program.

Dr. Ratner and his colleagues are comparing the outcomes achieved when heart or liver transplantation is simultaneously combined with kidney transplantation with the outcomes obtained when kidney transplantation is performed after heart or liver transplantation. Thus far, the outcomes appear to be better with simultaneous procedures.

“We aren’t sure why, however,” he said. Dr. Ratner and his team believe that a 2-organ transplant may decrease the risk for rejection. Another theory is that a patient who is followed by 2 teams of transplant surgeons simultaneously may have better access to care than a patient who is followed by 1 team at a time, as is the case for patients undergoing subsequent transplants, according to Dr. Ratner. This type of research, especially that involving liver–kidney transplantation, is important because the policy for liver allocation, according to the United Network for Organ Sharing (UNOS) Model for End-Stage Liver Disease (MELD), implemented in 2002, ensures that patients with relatively poor kidney function receive a liver first.

“The expectation is that the need for simultaneous liver–kidney transplantation will increase,” said Dr. Ratner.

Overall, among the most important new developments applicable to all types of organ transplant procedures is the ability to detect the rejection of donor organs

via a blood test of molecular gene expression rather than a muscle biopsy. About 7 years ago, this technique was evaluated in patients undergoing heart transplantation, and the diagnostic blood test is now commercially available. About 4 years ago, NewYork-Presbyterian/Columbia researchers started investigating the use of this diagnostic technique in lung transplantation, and the liver and kidney teams are now discussing it, too.

Other researchers at NewYork-Presbyterian/Columbia, led by Mark Russo, MD, have evaluated UNOS data for heart–kidney transplants. Dr. Russo’s team has examined whether patients with marginal kidney function who received a

for a single organ. Data to date indicate that because outcomes will be better in some recipients of multiple organs, the transplantation of multiple organs makes both medical and fiscal sense.

In addition to heart–kidney and liver–kidney procedures, physicians at NewYork-Presbyterian/Columbia have performed 4 heart–liver transplants—2 simultaneous procedures with organs from the same donor and 2 sequential procedures. These transplants comprise fewer than 1% of surgeries in the entire heart transplant group at the Hospital, which is the largest in the country.

“Heart–liver transplants are very specialized surgeries that can only be done in large centers such as ours,” said Mario Deng, MD. Collaboration among specialties is key, he added. The procedures require the input of cardiologists, anes-

Among the most important new developments applicable to all types of organ transplant procedures is the ability to detect the rejection of donor organs via a blood test of molecular gene expression rather than a muscle biopsy.... NewYork-Presbyterian/Columbia researchers started investigating the use of this diagnostic technique in lung transplantation.

combined heart–kidney transplant fared better than those who received a heart transplant and then were followed to see how their kidneys functioned after heart transplantation. Determining whether a patient’s kidney problems are intrinsic or secondary to heart disease is difficult, according to Jonathan Chen, MD, a study investigator. Still, the researchers found that patients with chronic kidney disease had a survival advantage with a combined transplant. Heart transplant patients who must undergo hemodialysis or continuous venovenous hemofiltration require the placement of indwelling catheters, which can be a source of infection, leading to complications and death.

The research at NewYork-Presbyterian/Columbia also touches on the ethical issue of whether a patient should receive more than 1 organ while other patients remain on the UNOS waiting list

thesiologists, and hepatologists, in addition to the skills of the transplant team.

Liver–small bowel transplants are also quite specialized, particularly in children, according to Dominique Jan, MD. One of the keys to a successful procedure is to coordinate pre-transplant management. The results of intestinal transplantation are generally better if the recipient’s overall health is good, he explained. Another consideration in pediatric patients is that space may be limited. Because the pediatric transplant recipient is receiving organs that are healthier and bigger than the native organs, more room is needed for them than may be available.

“With placement of these donor organs, you sometimes can’t close the abdominal wall,” noted Dr. Jan. When the plastic and reconstructive surgery team performs an abdominal wall

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Multi-organ

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transplant, using muscle and skin to enlarge the abdominal wall, space is obtained for the new organs and results may be improved.

Another important development at NewYork-Presbyterian/Columbia is the rejuvenation of the heart–lung transplantation program, said Dr. Chen. Combined heart–lung transplantation was enthusiastically received in the early 1990s, he explained. However, patients given this combination of organs did very poorly, he said, mostly because of lung complications. “There was almost a moratorium on them,” he said. “NewYork-Presbyterian Hospital performed their last heart–lung transplant in 1998.”

Since that time, thoracic surgeon Josh Sonett, MD, and pulmonologist Selim Arcasoy, MD, have helped to greatly improve the outcomes of lung transplantation at the Hospital, reducing associated morbidity and making heart–lung transplantation an option, according to Dr. Chen. Only 5 other centers in the United States offer this combined procedure.

“For kids in the New York area, this is really important because they used to get shipped out to Pittsburgh and St. Louis for surgery, and their families had to relocate,” said Dr. Chen. “Now there’s an option along the East Coast corridor.”

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Liver

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cancer are more likely than other racial groups to undergo transplant. Drawn from the United States Surveillance, Epidemiology, and End Results (SEER) registry, the data suggest that overall outcome could be improved by looking for opportunities to increase liver transplant in patient populations that now have low

rates (Table, page 4). This is less likely to be the product of denying liver transplant in specific groups than more complex issues, such as delayed diagnosis that reduces the number of candidates for transplant. Addressing obstacles to transplant may have important ramifications for survival.

“Because we serve a large Hispanic population, we have been trying hard to understand and eliminate any barriers to transplant in this and other historically underserved populations,” Dr. Siegel reported. There is a particular opportunity for improving this record in a system in which the multimodality approach to care is exercised in every patient. Dr. Brown also emphasized the importance of providing the same high standard of care to every patient.

“The Hospital is a one-stop exposure to specialists from multiple fields, allowing every option to be fully explored before the best approach is selected,” Dr. Brown noted. “With advances in many fields being pursued simultaneously, this is the way care should be offered.”

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“If you can provide a systemic therapy that ultimately permits the patient to undergo transplant, this is potentially lifesaving.”

—Abby B. Siegel, MD

Lung

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The indications for transplantation in patients under the age of 18 with CF are the same as they are in older individuals, according to Dr. Arcasoy. Pediatric patients who are considered for transplant typically have irreversible disease that has rendered them dependent on supplemental oxygen. Other signs of advancing disease, such as frequent exacerbations, high blood levels of carbon dioxide, and pulmonary hypertension, are also usually present. CF is the reason for transplant in approximately 20% of the lung transplants performed

reputation, and his name reached the mainstream media when he operated on former United States President Bill Clinton for a lung complication following his coronary bypass surgery. He has long been involved in a variety of innovative work, not just in lung transplantation, but also in a broad array of pulmonary diseases. In CF, for example, he has been involved in placement of stents in the lung to treat obstructed pulmonary function in pediatric patients.

Additionally, the transplant program has been very active in studies of the pathophysiology of graft rejection, including early detection of genetic signals of an impending rejection episode. Their efforts to provide sufficient

scored according to severity of their lung disease, so that those with the highest scores move to the head of the line. Although recipients and donors are matched by age so that those patients with CF younger than age 12, 12 to 17 years old, and 18 years or older receive organs from matched age groups, the new allocation system has permitted a greater number of very sick CF patients to receive an organ. However, patients younger than age 12 are still prioritized based on waiting time as in the old allocation system for adults, and this has to be considered during listing decisions for transplantation with children.

“Fortunately, there is a limited need for lung transplantation in pediatric CF

“Fortunately, there is a limited need for lung transplantation in pediatric CF patients due to the progress in medical management. However, there are cases where this is the best option for extending life, and we have been encouraged that outcomes in younger patients appear to be as good as those observed in adults.”

—Selim Arcasoy, MD

at NewYork-Presbyterian/Columbia University Medical Center. Of the 39 transplants performed in CF patients since 2001, 2 have been in individuals under the age of 18, and more are anticipated. Outcomes so far have been similar in children and adults.

“Our program has generated very good outcomes data in follow-up that now exceeds 5 years in CF patients,” Dr. Arcasoy reported. “The 1-year survival for lung transplants overall has been 96%, and the 3-year survival is 90%. In contrast, the national data from UNOS [United Network for Organ Sharing] is currently reporting 1-year survival of 83% and 3-year survival of 67%.” A factor likely contributing to the high rates of survival in the NewYork-Presbyterian/Columbia program is that Dr. Arcasoy and his colleague Joshua Sonett, MD, are involved in a variety of research projects that are moving the field forward and inform their clinical practices. Dr. Sonett’s skills in lung transplant surgery have won him an international

immunosuppression to suppress rejection episodes while minimizing the complications of immunosuppressive agents are critical to extending graft and patient survival.

Because of the challenges of transplantation for patients, Dr. Arcasoy emphasized the importance of early referral of patients with advancing CF, whether they are adults or children. He suggested that transplant might be most effective when it is considered and introduced in the context of ongoing care.

“It is best if we can consult with patients long before lung transplantation is necessary,” he said. “It not only provides time to perform tests on a timely basis, but also to prepare the patient both physically and psychologically for transplant if it becomes necessary. Patient education is an important component of a successful transplant.”

The allocation of donor grafts was modified in 2005. Previously, patients moved up the list in the order that they were inscribed, but now patients are

patients due to the progress in medical management,” Dr. Arcasoy noted. “However, there are cases where this is the best option for extending life, and we have been encouraged that outcomes in younger patients appear to be as good as those observed in adults.”

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Kidney

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although the technical demands of the laparoscopic procedure are greater than those for an open live-donor transplant, the benefits not only extend to the graft donors but to others on the waiting list for a donor organ.

"If you increase the number of donors, everyone benefits, including those who move up on the waiting list for a cadaveric organ," he said. "With the open procedure, there are a lot of disincentives even for the motivated donor, including significant risk of morbidity and a substantial recovery time. In the past, donors often have to put their whole life on hold for a couple of months."

According to the United States Organ Procurement and Transplantation Network (OPTN), there are currently 71,600 patients on the waiting list for a kidney transplant. The majority of these individuals are those who have been unable to provide their own living donor and are now waiting for suitable cadaveric organs. Based on survival, living donor organs are preferable. Each step toward reducing the risks and morbidity for donors is likely to increase the number of patients who are able to locate suitable volunteers.

Importantly, when the procedure is performed laparoscopically, complication

rates are reduced with no change in graft survival, according to follow-up that now extends to 10 years in some patients. Asked about the quality of the grafts, Sandip Kapur, MD, reported that "the quality of the grafts is at least as good," and more live donors means better preoperative planning.

"From my perspective, the minimally invasive procedure has been a major step forward," added Dr. Kapur, who works with surgeons in planning the harvesting of donor grafts in order to facilitate the transfer. "By reducing the recovery time, it increases the number of individuals who are willing to be donors, and it permits some individuals who would not have been considered good candidates for the stress of an open procedure, such as older individuals, to donate an organ. There really is no substantial downside."

In an open procedure, typical hospital stays were 10 days and sufficient recovery allowing patients to return to normal daily activities could be 3 months or longer. When the live donor transplant is performed laparoscopically, the patient goes home the next day and may only need 2 or 3 weeks before returning to normal activities.

The national conversion rate is about 5%; at NewYork-Presbyterian/Weill Cornell, the conversion rate is less than 1%, according to Dr. Del Pizzo. The same can be said for the work at NewYork-Presbyterian/Columbia University Medical Center.

"It is true that the laparoscopic procedures are more difficult to perform than open procedures from a technical perspective, but these can be converted to open procedures if necessary," Dr. Del Pizzo said.

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Fall 2007

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