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Comparison of Open and Laparoscopic Live Donor Nephrectomy

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Objective
This study compares an initial group of patients undergoing laparoscopic live donor nephrectomy to a group of patients undergoing open donor nephrectomy to assess the efficacy, morbidity, and patient recovery after the laparoscopic technique.

Summary Background Data
Recent data have shown the technical feasibility of harvesting live renal allografts using a laparoscopic approach. However, comparison of donor recovery, morbidity, and short-term graft function to open donor nephrectomy has not been performed previously.

Methods
An initial series of patients undergoing laparoscopic live donor nephrectomy were compared to historic control subjects undergoing open donor nephrectomy. The groups were matched for age, gender, race, and comorbidity. Graft function, intraoperative variables, and clinical outcome of the two groups were compared.

Results
Laparoscopic donor nephrectomy was attempted in 70 patients and completed successfully in 94% of cases. Graft survival was 97% *versus* 98% ($p = 0.6191$), and immediate graft function occurred in 97% *versus* 100% in the laparoscopic and open groups, respectively ($p = 0.4961$). Blood loss, length of stay, parenteral narcotic requirements, resumption of diet, and return to normal activity were significantly less in the laparoscopic group. Mean warm ischemia time was 3 minutes after laparoscopic harvest. Morbidity was 14% in the laparoscopic group and 35% in the open group. There was no mortality in either group.

Conclusions
Laparoscopic live donor nephrectomy can be performed with morbidity and mortality comparable to open donor nephrectomy, with substantial improvements in patient recovery after the laparoscopic approach. Initial graft survival and function rates are equal to those of open donor nephrectomy, but longer follow-up is necessary to confirm these observations.

One method of addressing the growing shortage of organs for kidney transplantation is the increased use of living kidney donors. Nearly all of the 250 transplant centers in the United States perform live donor kidney transplants. Live donors accounted for 3209 (29%) of 10,892 kidney transplants reported to the United Network for Organ Sharing in 1995.[1,2] At the current time, nephrectomy via a retroperitoneal flank approach is the most common method of live donor renal allograft harvest. The procedure is safe and efficacious, usually resulting in the harvest of a kidney in optimal condition with minimal warm ischemia. Mortality is approximately 0.03%, but long-term morbidity may be substantial, ranging from 15%–20% or higher.[3,4]

Although the extraperitoneal flank incision results in lower morbidity than a midline transperitoneal approach, wound complications including infection and hernia formation occur in approximately 9% of patients with a flank approach.[2] Pneumothorax requiring pleural space drainage occurs in approximately 8% of patients. Chronic wound ''diastasis'' or bulging and chronic incisional pain have been reported in up to 25% of patients, and return to normal activity may not occur for as long as 6 to 8 weeks after surgery.[3,4] These limitations of extraperitoneal flank nephrectomy, combined with the success of other laparoscopic solid organ surgery such as laparoscopic splenectomy and adrenalectomy,[5,6] provide the rationale for the development of minimally invasive donor nephrectomy.

Potential benefits of laparoscopic donor nephrectomy include less postoperative pain, shorter hospitalization, less incisional morbidity, more rapid return-to-normal activity, and improved cosmesis.[7] However, the biggest potential advantage of the laparoscopic approach is that the sum of these improvements in patient recovery may result in increased acceptance of the donor operation and expand the pool of potential kidney donors. This is especially true in areas in which cadaveric kidneys are not widely available.

Laparoscopic live donor nephrectomy has been performed at the University of Maryland Medical System (UMMS) since March 1996. This article compares the initial UMMS experience with laparoscopic live donor nephrectomy to a cohort of age-matched control subjects undergoing traditional donor nephrectomy with a flank incision to determine whether early graft survival, intraoperative variables, and postoperative recovery are similar between open and laparoscopic donor nephrectomy.

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PATIENTS AND METHODS

Patient Selection

Live donor nephrectomy was performed in 76 patients at the UMMS from March 1996 through March 1997. Six patients (8%) were excluded from consideration for laparoscopy. Reasons for exclusion were morbid obesity (two patients), patient preference, renal artery aneurysm, unavailability of a laparoscopic surgeon, and the presence of a pelvic mass requiring operative evaluation (one patient each). Seventy patients underwent laparoscopic live donor nephrectomy. Laparoscopic donors were compared to a cohort of 65 patients undergoing open donor nephrectomy at UMMS from January 1994 through March 1997. The two groups were matched for age, gender, race, and comorbidity. Patient data were obtained from a combination of a prospective longitudinal database, medical record review, and personal and telephone interviews. Graft function and survival were compared using Fisher's exact test. Intraoperative and postoperative recovery data consisting of continuous variables were compared using analysis of covariance. Multiple logistic regression was used to compute covariate-adjusted odds ratios to compare binary variables. All significant results remained significant when adjusted for multiplicities.[8] All statistical analysis was performed in SAS (Statistical Analysis Software; SAS Institute Inc, Cary, NC). Values of $p < 0.05$ were considered statistically significant.

All patients evaluated for live donor nephrectomy were considered for the laparoscopic approach. Absolute contraindications to either open or laparoscopic donor nephrectomy included absence of two functional kidneys, ABO incompatibility, pregnancy, certain infectious diseases (hepatitis B or C, human immunodeficiency virus), significant renal arterial occlusive disease, renal parenchymal diseases such as malignancy or polycystic kidney disease, uncorrectable coagulopathy, and horseshoe kidney. Relative contraindications to laparoscopic donor nephrectomy include underlying medical conditions (extremes of age, hypertension, diabetes mellitus, nephrolithiasis), inability to tolerate general anesthesia or pneumoperitoneum, prior left colonic or splenic surgery, retroperitoneal inflammatory processes (diverticulitis, retroperitoneal fibrosis), morbid obesity, and ascites. Laparoscopic donor nephrectomy was performed on the left kidney in all cases to maximize the length of renal vein available to the transplant surgeon.

Potential candidates for donor nephrectomy underwent a standard preoperative evaluation by the transplant division.[1] The presence of two functional kidneys and the assessment of vascular anatomy were determined by high-resolution computed tomographic angiography. Standard arteriography was performed if computed tomographic angiography was equivocal or renal artery occlusive disease was suspected.

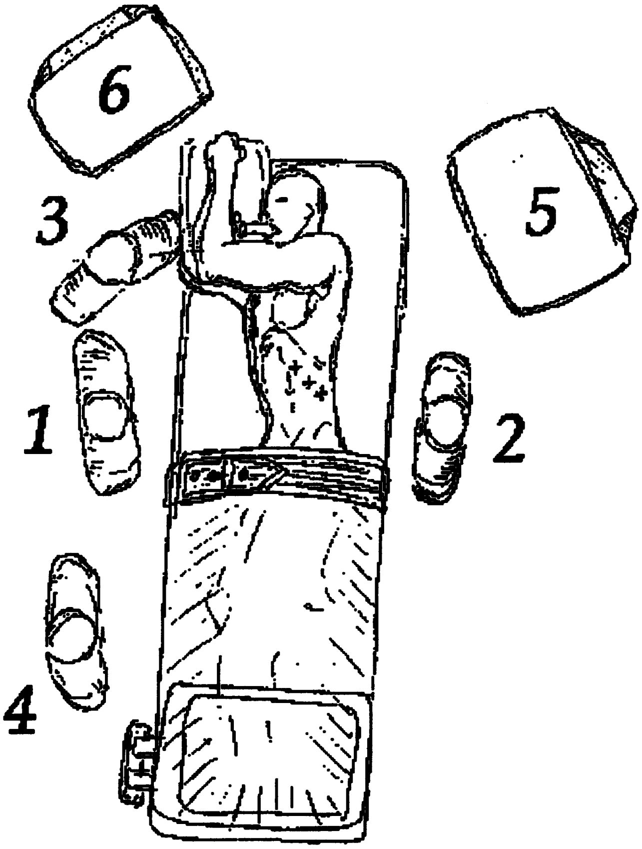

Figure 1. (1) Operating surgeon; (2) first assistant; (3) camera operator; (4) scrub person; (5) primary monitor; (6) secondary monitor.

Operative Technique

Laparoscopic live donor left nephrectomy is performed with the patient under general endotracheal anesthesia and in the right decubitus position. The patient is draped to allow access for a standard left flank incision as well as the midline, permitting extraction of the kidney through a short midline incision and conversion to urgent laparotomy if necessary. The operating table is flexed at its midpoint and a kidney rest elevated to maximize left flank surface area. Orogastric suction, bladder catheterization, antibiotic prophylaxis, and antithrombic compression devices are used routinely. No bowel preparation is used.

Two monitors are placed at the head of the table, just as for other upper abdominal laparoscopic procedures. The operating surgeon stands at the patient's right with the camera operator cephalad and the scrub nurse caudad. The first assistant stands across the table on the patient's left (Fig. 1).

A 15-mmHg carbon dioxide pneumoperitoneum is created using a closed technique with Verres needle insertion in the left subcostal region. A total of four operating ports (three 12 mm and one 5 mm) are used for the dissection (Fig. 2). A 15-mm operating port is placed later during the procedure through a 6- to 7-cm midline incision to aid in extraction of the kidney. The camera is placed in the uppermost subcostal port, and two dissection ports are located along the left costal margin. A 5-mm retraction port is located in the posterior axillary line near the tip of the 11th or 12th rib.

The operative procedure is conducted in the following order: mobilization of the left colon and spleen, dissection of the renal vein, dissection of the renal artery, dissection of the ureter, mobilization of the kidney (opening of the renal fascia and division of perinephric fat), creation of the extraction incision and deployment of the extraction bag, and renal extraction. Renal extraction is accomplished by systemic anticoagulation followed by division of the ureter, renal artery, and renal vein, in that order. A linear laparoscopic stapler with a vascular cartridge is used for division of the renal vessels (United States Surgical Corporation, Norwalk, CT).

Adequate urine output is ensured by vigorous hydration to optimize preload. Osmotic diuresis is induced with 25 g mannitol given in two divided doses, one at the beginning of the vascular dissection and one before renal extraction. Vasospasm of the renal artery is minimized by routine topical administration of papaverine during the arterial dissection.

The extraction process is begun with a 6-cm midline umbilical incision through the abdominal wall fascia without violating the peritoneum. A 15-mm operating port is placed through the extraction incision, and a large plastic extraction sac is inserted and deployed over the liver, in preparation to receive the kidney. The patient is anticoagulated with 100 units/kg intravenous heparin sodium. The distal ureter is clipped and divided. After division of the renal artery and vein, the kidney is placed into the extraction sac and delivered through the midline wound. The allograft is immersed immediately in iced saline solution and transferred to an adjoining operating suite, where

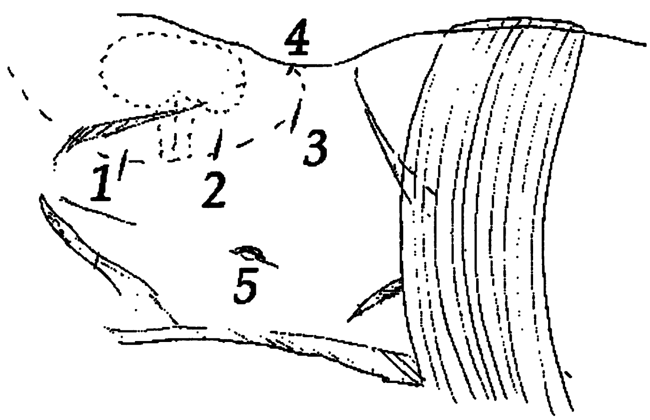

Figure 2. (1) Camera port (12 mm); (2) left hand working port (12 mm); (3) right hand working port (12 mm); (4) posterior assistant's retraction port (5 mm); (5) extraction incision (6 cm).

Table 1. PATIENT DEMOGRAPHICS AND OPERATIVE DATA

Number of patients	70
Sex	
Male	26 (37%)
Female	44 (63%)
Age (yr)(range)	37.9 (19–67)
Weight (kg)(range)	78.1 (51–127)
Conversion to laparotomy	4 (5.7%)
Warm ischemia time (min)(range)	3.0 (1.9–6.9)
Reoperation	1 (1.4%)

it is perfused and prepared for transplantation. The anticoagulation is reversed with 100-mg protamine sulfate, and the retroperitoneum, spleen, and vascular staple lines are inspected carefully for hemostasis. The abdominal wounds are closed at the fascial and skin levels, and the procedure is concluded.

RESULTS

Laparoscopic live donor nephrectomy was attempted in 70 patients and completed successfully in 66 cases (94%). In one case, a successful laparoscopic procurement was performed, but the kidney was not transplanted because of discovery of an incidental 1-cm renal cell carcinoma not identified by computed tomography or laparoscopy. Sixty-five patients ultimately received kidneys from laparoscopic donors. Four patients (6%) required conversion to laparotomy, three for vascular injury and one for a combination of morbid obesity and inability to sustain pneumoperitoneum. Vascular injuries included renal artery injury during transection of the vessel in one case and external iliac artery injury during division of the ureter in another; both patients required urgent laparotomy and recovered uneventfully. The third vascular injury was avulsion of a small branch from the posterior aspect of the renal vein. Hemorrhage was controlled easily, but elective conversion to laparotomy was undertaken because the injury could not be repaired easily using laparoscopic means. One patient (1.4%) required reoperation for postoperative hemorrhage from a splenic injury. Laparotomy and splenorrhaphy were performed and the patient recovered without incident. Patient demographics are listed in Table 1.

Graft survival has been maintained in 67 (97%) of 69 transplanted kidneys with a mean follow-up of 7 months (range, 2–12 months). Graft failure occurred in one patient 2 months after transplantation after a severe rejection episode necessitating transplant nephrectomy. Another patient had gangrenous cholecystitis and septicemia develop 6 weeks after transplantation and ultimately died. No evidence of acute tubular necrosis was present on duplex flow scan or renal biopsy in either case. Immediate graft function occurred in 67 (97%) of 69 patients, and delayed graft function occurred in two patients (3%). Delayed graft function occurred in one allograft after uneventful laparoscopic harvest and in the morbidly obese patient converted to laparotomy. Warm ischemia time was <3 minutes in both cases. Both grafts recovered function within 10 days of surgery. Graft survival and function after open nephrectomy are compared to the laparoscopic group in Table 2.

Table 2. GRAFT FUNCTION AND SURVIVAL

	Number of Patients	Graft Survival [n (%)]	Delayed Graft Function [n (%)]
Laparoscopic	69	67 (97)	2 (3)
Open	65	64 (98)	1 (2)
p value		0.6191	0.4961

Intraoperative variables and early postoperative recovery data are listed in Table 3. Mean intraoperative blood loss in the laparoscopic group was 30% of the open group (122 *vs.* 408 mL). Resumption of diet for the laparoscopic group occurred in 32% of the time necessary for the open group for liquids (16.3 *vs.* 51 hours) and 51% for solid food (40 *vs.* 77.7 hours). Duration of parenteral narcotic use in the laparoscopic group averaged 48% of that in the open group (28.6 hours *vs.* 60.1 hours), and length of stay in the laparoscopic group was 49% of the open group (2.2 *vs.* 4.5 days).

Return to normal activity was estimated by the length of time necessary to resume normal housework, drive an automobile, and return to usual preoperative employment (Table 4). Laparoscopic donors returned to housework in 33% of the time necessary for the open group. In the laparoscopic group, driving occurred in 35% of the time and return to employment occurred in 31% of the time for the open group. Return to employment in the open group was skewed by three patients with prolonged recov-

Table 3. INTRAOPERATIVE DATA AND EARLY POSTOPERATIVE RECOVERY

	Laparoscopic	Open	p Value
Operating room time (min)	226.3	212.8	0.1658
Estimated blood loss (mL)	122.3	408.0	0.0001
Diet (hr)			
Liquids	16.3	51.0	0.0001
Solids	40.0	77.7	0.0001
Parenteral narcotic use (hr)	28.6	60.1	0.0001
Length of stay (days)	2.2	4.5	0.0001

Table 4. POSTOPERATIVE RECOVERY: RETURN TO NORMAL ACTIVITY

	Laparoscopic	Open	p Value
Housework (days)	8.8	26.9	0.0001
Driving (days)	11.1	31.6	0.0001
Employment (days)	15.9	51.5	0.0001

ery due to chronic incisional pain; exclusion of these patients results in a mean of 45.5 days for return to employment.

Perioperative morbidity occurred in ten patients (14%) in the laparoscopic group (Table 5). Hemorrhage requiring blood transfusion occurred in four patients, including the patient with renal artery injury. One patient with postoperative hypoxia had a preoperative history of chronic obstructive pulmonary disease. No evidence of pneumonia, pulmonary embolism, or fluid overload was present in either case; the patients were presumed to have severe atelectasis. The patient with postoperative congestive heart failure had a history of old myocardial infarct and unsuspected mitral valve insufficiency. Complications after open donor nephrectomy are listed in Table 6. There were no statistically significant differences in complication rates after open and laparoscopic donor nephrectomy (odds ratio = 4.1). There was no mortality in either the laparoscopic or open donor group.

DISCUSSION

Donor nephrectomy is unique among major surgical procedures, because it exposes an otherwise healthy patient to the risks of major surgery entirely for the benefit of another person. For laparoscopic live donor nephrectomy to become a viable option for procuring kidneys for renal transplantation, several conditions must be met. Most important, the laparoscopic donor should suffer no additional or unique morbidity when compared to the open donor. In addition, kidneys harvested using laparoscopic techniques must have graft survival and function rates equivalent to those obtained by the "gold standard" of open nephrectomy using an extraperitoneal flank approach. Finally, the laparoscopic approach should convey some advantage to the patient such as less pain, shorter hospital stay, and earlier return to normal activity.

Table 5. PERIOPERATIVE MORBIDITY: LAPAROSCOPIC DONOR NEPHRECTOMY

	Number (%) of Patients
Hemorrhage	4 (6)
Hypoxia	2 (3)
Renal artery injury	1 (1.4)
External iliac artery injury	1 (1.4)
Urinary retention	1 (1.4)
Congestive heart failure	1 (1.4)
Total	10 (14)

Table 6. PERIOPERATIVE MORBIDITY: OPEN DONOR NEPHRECTOMY

	Number (%) of Patients
Pneumothorax	14 (22)
Hemorrhage	7 (11)
Fever	6 (9)
Persistent incisional pain	5 (8)
Ileus/vomiting	4 (6)
Wound hernia/seroma	4 (6)
Urinary retention	4 (6)
Dyspnea	2 (3)

Several patients had more than a single complication.

Preliminary graft survival rates (97%) after laparoscopic procurement compare favorably with both recent historic control subject rates at our institution as well as the latest data reported by the United Network for Organ Sharing. There is no difference in graft survival between the laparoscopic cohort and open donors at UMMS over the past 3 years. Through October 1995, 1-year United Network for Organ Sharing graft survival rates after living donor renal transplants ranged from 89% to 95%, depending on the histocompatibility of the donor and recipient.[2] Graft failures after laparoscopic donor nephrectomy in this series occurred as a result of overwhelming sepsis and severe rejection. In both cases, the transplanted kidneys functioned immediately, and there is no evidence to suggest laparoscopic procurement as a factor leading to graft failure. Longer follow-up is necessary to determine the true incidence of graft survival after laparoscopic donor nephrectomy.

The incidence of delayed graft function in this series was 3% (two patients). The incidence of acute tubular necrosis after traditional living related kidney donation ranges from 1% to 6%.[1,2,9] Delayed graft function–acute tubular necrosis after renal transplantation is presumed to be an ischemic event. Although neither allograft experienced prolonged warm ischemia, one donor had a technically difficult procedure because of obesity, which may have resulted in excessive manipulation and vasospasm, and the recipient in the second case experienced an episode of significant hypotension in the immediate postoperative period, which may have contributed to acute tubular necrosis. Both kidneys recovered and continue to function well.

Laparoscopic donor nephrectomy resulted in impressive improvements in patient outcome when compared to open donor nephrectomy. Operative times were comparable to those of open donors, a finding not seen in other recent comparisons of open and laparoscopic nephrectomy.[10,11] Resumption of diet, parenteral narcotic use, and length of stay averaged <50% of the times for the open procedure. These benefits extended into the convalescent phase of the recovery with laparoscopic donors returning to housework, driving, and preoperative employment in 34% to 38% of the time necessary for their open counterparts. Length of stay after open donor nephrectomy ranges from 5 to 17.6 days in recent series, with the most typical stay being 5.6 to 7.9 days.[1,3,4,9,12–15] Few recent data are available regarding convalescence after flank donor nephrectomy; one recent series of 29 cases reported ''return to usual activities'' at 2.25 months and ''time to full recovery'' of 9.46 months.[10] The rapid in-hospital recovery and shorter convalescence associated with laparoscopic donor nephrectomy have been verified by two other recent series comparing laparoscopic nephrectomy for benign disease to transperitoneal and extraperitoneal flank nephrectomy.[10,11]

The ultimate goal of laparoscopic live donor nephrectomy is to increase the number of living related kidney transplants. By improving the patient's early postoperative recovery and minimizing the time needed to return to normal activity and gainful employment, it is hoped that willingness to donate organs will be increased. Our initial experience at UMMS suggests this may be the case. Since the inception of the laparoscopic donor program in March 1996, the number of patients evaluated for the kidney transplant waiting list has increased by 40% and the number of screening cross-matches performed for potential live donors has increased by 37%. The number of actual living donor harvests increased by 85% from the year preceding the study period (41 cases in 1995 *vs.* 76 cases in 1996).

Despite the initial success and patient satisfaction associated with laparoscopic live donor nephrectomy, the technical difficulty of the procedure cannot be overestimated. Laparoscopic donor nephrectomy differs from virtually all other laparoscopic procedures in three important respects. First, the kidney must be procured in absolutely pristine condition; no amount of parenchymal damage is permissible during the dissection or extraction. Second, the procedure not only involves a delicate major vascular dissection, but full anticoagulation is required during the most critical step, division of the renal vessels. Third, extraction must be rapid and atraumatic to minimize warm ischemia to the donor kidney. Thorough knowledge of the basic surgical tenets of living donor renal procurement, commonly encountered vascular anomalies (34% of patients in this series had vascular anatomy other than a single artery and vein), and operative skills in advanced laparoscopy are necessary. At the current time, these requirements dictate that two surgeons (a donor surgeon and a laparoscopist) will be needed in most instances.

The technical difficulty and long learning curve of laparoscopic live donor nephrectomy are illustrated by the complications in this series. Both major vascular injuries (one renal artery and one external iliac artery) were avoidable errors in operative technique related to relative inexperience with advanced laparoscopic procedures on the part of the operating surgeon. Three of the four patients requiring transfusion had splenic injury as a result of excessive traction or inadequate mobilization of the organ during laparoscopic dissection. One patient ultimately required laparotomy and splenorrhaphy to control bleeding. There was no significant difference in morbidity between the open and laparoscopic groups in this series. The total laparoscopic morbidity of 14% compares favorably to other large series of open donor nephrectomy, in which total morbidity ranges from 10% to 20%.[3,4,9,12–15] No unique types of morbidity appear to arise from the laparoscopic technique. Notably absent from the laparoscopic group in this series are wound complications (*e.g.*, infection, hernia, chronic pain), pneumothorax, and deep venous thrombosis and pulmonary embolism.

There are some technical limitations and unanswered questions regarding laparoscopic live donor nephrectomy. The procedure is quite challenging in very obese patients, a group that could most benefit from the laparoscopic approach by avoidance of a large incision. Methods for laparoscopic vascular dissection and hemostasis remain relatively crude, although laparoscopic vascular instrumentation is in development. Warm ischemia time is longer than for open donor nephrectomy, although it is not entirely clear what constitutes an acceptable limit. Most series of open donor nephrectomy do not quote times for warm ischemia. Mean warm ischemia for the laparoscopic patients in this series was 3 minutes. Although the mean time was reduced to 2.25 minutes for the last 20 cases in the series, it is unlikely that warm ischemia will drop much below 2 minutes using current techniques. Finally, the effects of procuring a renal allograft in the altered physiologic environment of positive-pressure pneumoperitoneum are not known. Studies currently are in progress at UMMS to examine the effect of these variables on graft function and donor outcome.

Laparoscopic live donor nephrectomy is technically feasible and can be performed with morbidity and mortality rates comparable to those of open donor nephrectomy, with substantial improvements in patient recovery after the laparoscopic approach. The procedure is very challenging from a technical standpoint. Initial graft survival and function rates appear to be similar to open donor nephrectomy, but longer follow-up is necessary to confirm these observations. If these rates persist, laparoscopic donor nephrectomy may improve willingness to donate kidneys and expand the potential pool of organ donors.

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Discussion

DR. ARNOLD G. DIETHELM (Birmingham, Alabama): This is an interesting approach to a proven operation. The operation of open nephrectomy, as it is described, was first done in 1954, as most people know, and we have continued that approach in Birmingham. We have had 1400 open donor nephrectomies performed in 29 years for living related donor transplantation. We have used the same procedure in every instance. We have not had a mortality, and we have had some morbidity. And I will come back to that in a minute.

Now, if you think of this subject, it is really a new approach to an old theme, a new approach to a old operation. What are the absolute minimum accomplishments that have to occur in this operation? One, it has to be safe. And there is no margin of error for anything less than a safe operation in a well patient. Second is that the kidney must be usable. It must be a good kidney. That is not a given. And third, and perhaps not as important as the first two, is the morbidity. The authors today have shown us that in their experience the morbidity is less when you use the laparoscopic approach compared with the open approach.

I have some concerns about the laparoscopic technique, and perhaps it is because I am used to a single way for nearly 30 years. I am not sure at all that the laparoscopic technique will increase organ donation in our community.

When you talk to a donor, they fall into two categories. One group is enthusiastic, they are positive, they have thought it out, and you can't deter them. But you certainly spend time explaining the details. The other one is apprehensive, sometimes finds many complaints about the hospital, and so forth. And that is the individual you had best put some time in with, because he or she probably is not anxious to be a donor.

Now, there is one last point. And this, I think, is the most important. Organ donation from a living donor is not a given. That person is a volunteer. The potential risk to that person is obvious to everyone. To indicate that a slight improvement in morbidity and a slight improvement in mortality is highly beneficial probably is not important to the average donor.

So I am not at all critical of the excellent results that we have heard today from Dr. Flowers and his colleagues, but I would be cautious about exporting this operation to everyone. And I am not the least bit convinced that it will increase or diminish the reluctance of some people to act as donors.

And finally, we should never forget that the donor is really a volunteer.

DR. FRANK C. SPENCER (New York, New York): To reemphasize Dr. Diethelm's comments, his experiences with 1400 donors with no mortality defines a very clear baseline for alternate approaches.

DR. JOHN HUNTER (Atlanta, Georgia): This superb paper and the one presented by Dr. Gagner the other day prove that Dr. Barker's fears that the best work is going to the specialty societies may be unfounded. I have listened to a lot of papers on laparoscopy this year and I think that the two presented here at this meeting represent the cream of the crop.

There has been a recent echo of the initial sentiment that laparoscopic surgery was allowed to grow wildly without controlled randomized trials. I think this paper demonstrates the difficulties of performing such trials in laparoscopic surgery.

Once the phase 1 trial of safety and the phase 2 trial of efficacy are complete, and if that phase 2 trial is performed by a skilled laparoscopic surgeon such as Dr. Flowers, it becomes difficult to get any patient to volunteer for the phase 3 prospective randomized trial. When a benefit of a procedure is so clear to the patient that they are not willing to undergo randomization, should we be proceeding with prospective randomized trials? A rhetorical question only.

Three questions, two of them methodological. Are the two groups you compared really identical? Some patients were excluded from laparoscopic surgery because they were poor-risk patients. In the historic control groups were similar poor-risk difficult patients excluded from data analysis? Second, data selection was prospective in the laparoscopic group and retrospective in the historic controls. My question is, were the data in the chart or in the record of these historic controls sufficiently