

References

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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

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

complete that one didn't have to go back and requery the patients? I would question the validity of data that was obtained many months or years later.

Lastly, I have a very important technical point, because the data showed that the kidneys were removed in 2 to 3 minutes. Having struggled for more than 15 minutes to get a spleen into a bag, I can tell you that it is no easy feat to get anything into a bag that fast. I would like to get Dr. Flowers to tell us how he got the kidneys out of the patients within 2 minutes to decrease the warm ischemia time.

DR. FRANK C. SPENCER (New York, New York): Dr. Flowers, my only question is about the one or two vessels that were bleeding. Were the vessels inadvertently incised, or did the clips fail? As you mentioned, a principal concern with the laparoscopic approach is the potential hazard from working with the large renal artery and vein.

DR. AINSLIE G. R. SHEIL (Sydney, Australia): I would like to query the authors as to whether they would advise others to take this up. Obviously, in their skilled hands, they have been able to accomplish something clearly dramatic. They do emphasize the difficulty of the technique and, as is Dr. Diethelm, I am concerned that others attempting to follow their path might run into considerable difficulties. Could we have comments on this, please?

DR. JAMES F. BURDICK (Baltimore, Maryland): I certainly would like to congratulate the Maryland group on their excellent results and then make a couple of comments, and I have a question.

My colleagues from Johns Hopkins, Dr. Ratner and Dr. Kavoussi, pioneered this and first reported it, and, actually, with Dr. Sheil, are now on occasion giving a course. We do feel that it is appropriate to export it to other centers. But I would certainly underscore Dr. Diethelm's reservations in terms of the fact that patients should be advised that this is new and we don't have the experience in the country or in the world as yet to push patients in this direction.

However, I think it is overwhelmingly evident to people observing this approach that it has a high likelihood of increasing the number of people who would be willing to be organ donors.

My question is, one of the concerns is maintaining good hemodynamics in the kidney, and I wonder if there has been any concern or thought about the degree to which the pneumoperitoneum may decrease venous return to the kidney and actually impair the physiologic situation just a bit. In our hands this does not seem an important problem, but it remains a concern in the early development of this particular technique.

DR. THOMAS R. GADACZ (Augusta, Georgia): To achieve your low mortality and morbidity, are there certain patients who

were excluded from a laparoscopic approach and had an open nephrectomy?

DR. JOHN L. FLOWERS (Closing Discussion): I would like to thank all the discussants, first Dr. Diethelm for his insightful comments. I would like to reiterate—first of all, we did not mention during the discussion that there was no mortality in either group. I actually did not put that on any of the slides.

I believe, just as you do, that basically we are not trying to fix something that isn't broken here. I think the open donor operation is an excellent procedure that clearly has stood the test of time and produces a very good kidney. Our primary reason for pushing this forward is that in our population we have a number of patients who need to return to work and family very rapidly. We think that this is probably not an operation for everyone, and the big advantage is in that earlier return to work. Safety and the production of a useful kidney are definitely our primary concerns.

Dr. Hunter asked how our data was collected. Unfortunately, these were historic controls. We used a combination of chart review and personal telephone interviews with all of the patients who were in the control group. Unfortunately, we were not able to match them for weight. That proved to be too much of a difficulty because we reached a point where we couldn't obtain accurate information past a certain time period.

Dr. Spencer asked about bleeding vessels. The renal artery injury occurred for those, virtually all of us, who use staplers. Sometimes you have that little piece of tissue that is left behind after the staple line has transected the vessel. In this particular case the proximal end of the vessel, or the stump of the renal artery, was transected rather than the soft tissue remaining. And in the external iliac artery the injury occurred as a result of past pointing with the scissors during division of the ureter.

Dr. Sheil mentioned about whether other people should be doing this. I also would like to reiterate that it was Drs. Kavoussi and Rattner who initially performed and developed this procedure. We have certainly benefited from their experience and I would be remiss without mentioning them. We have had a number of groups come through our institution to watch us do this operation. And when they leave they either are shaking their heads or going, "Wow, this is great, let's see how soon we can set this up." I believe that this must be approached very cautiously, because at the present time I don't know how many people there are with sufficient skill to do a major vascular dissection and expose the aorta. Certainly more groups are leaning in this direction.

Dr. Gadacz has asked about the hemodynamics in the kidney. This is also a concern of ours because we have observed that unless the patients are fluid-loaded before the procedure relatively aggressively one can see relative oliguria soon after transplantation. We are beginning to embark on a study to measure exactly what the reduction in renal flow is and what the interstitial dynamics are, because really this is an altered physiologic environment for procurement of the kidney that is one of positive pressure.