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LONG-TERM FOLLOWUP AFTER LAPAROSCOPIC RADICAL NEPHRECTOMY

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ABSTRACT

Purpose: Laparoscopic radical nephrectomy has been shown to be less morbid than traditional open radical nephrectomy. The long-term oncological effectiveness of laparoscopic radical nephrectomy remains to be established.

Materials and Methods: At 3 centers patients undergoing laparoscopic radical nephrectomy before November 1, 1996 with pathologically confirmed renal cell carcinoma were identified. A representative group of patients undergoing open radical nephrectomy for clinical T1, T2 lesions was also identified. Staging, operative details and postoperative course were reviewed. Followup consisted of review of clinical, laboratory and radiological records. Kaplan-Meier analysis was performed.

Results: The study included 64 patients treated with laparoscopic and 69 treated with open radical nephrectomy with respective average ages of 60.6 and 61.3 years at surgery. On preoperative imaging open lesions were larger (6.2 cm., range 2.5 to 15) than laparoscopic radical nephrectomy lesions (4.3 cm., range 2 to 10, $p < 0.001$). Pathology reports revealed no difference in specimen weight (425 and 495 gm., $p = 0.146$) or average Fuhrman grade (1.88 and 1.78, $p = 0.476$) between laparoscopic and open radical nephrectomy, respectively. Median followup was 54 months (range 0 to 94) for laparoscopic and 69 months (range 8 to 114) for open radical nephrectomy. Kaplan-Meier analysis with log rank comparison revealed 5-year recurrence-free survival of 92% and 91% for laparoscopic and open radical nephrectomy, respectively ($p = 0.583$). At 5 years cancer specific survival was 98% and 92% ($p = 0.124$), and nonspecific survival was 81% and 89% ($p = 0.260$) for laparoscopic and open radical nephrectomy, respectively.

Conclusions: Laparoscopic radical nephrectomy confers long-term oncological effectiveness equivalent to traditional open radical nephrectomy.

KEY WORDS: laparoscopy; nephrectomy; carcinoma, renal cell

The initial laparoscopic total nephrectomy (that is en bloc removal of the kidney, the majority of Gerota's fascia and pararenal fat while leaving the adrenal gland intact) was performed at Washington University in June 1990.[1] Since then the laparoscopic approach for extirpation of renal cell carcinoma has been adopted and modified at numerous centers worldwide, and has been expanded to include radical nephrectomy (that is en bloc removal of the kidney and adrenal along with Gerota's fascia and pararenal fat).[2–7] Comparisons between laparoscopic and traditional open total/radical nephrectomy have consistently demonstrated advantages to the laparoscopic approach in all indexes of perioperative morbidity, including estimated blood loss, postoperative narcotic requirements, length of hospitalization and duration of convalescence (table 1).[2–6]

While the immediate benefits of laparoscopic radical nephrectomy are clearly established, the crucial question that remains to be answered is whether the oncological effectiveness of this minimally invasive approach is adequate. To date, followup after laparoscopic radical nephrectomy has been limited to 36 months or less in a small number of patients (table 2). To assess this issue fully, the experience from 3 institutions at which laparoscopic radical nephrectomy was performed on a large-scale basis is compared to a contemporaneous experience with traditional open radical nephrectomy for similar clinical stage disease. To our knowledge this is the first report to assess the oncological effectiveness of laparoscopic radical nephrectomy at 5 years in a large cohort of patients.

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***Editor's Note*: This article is the third of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 1454 and 1455.**

METHODS

Patients undergoing laparoscopic total/radical nephrectomy or open total/radical nephrectomy for clinically localized renal cell carcinoma before January 1996 were identified at 3 centers in Nagoya, Japan, Saskatoon, Canada and St. Louis, Missouri. At each center all patients undergoing laparoscopic total/radical nephrectomy for pathologically confirmed renal cell carcinoma were included in the analysis and an equivalent number of patients undergoing open total/radical nephrectomy for pathologically confirmed renal cell carcinoma were included for comparison. A total of 64 patients treated with laparoscopic total/radical nephrectomy and 69 treated with open total radical nephrectomy were identified for analysis.

TABLE 1. *Perioperative aspects of laparoscopic radical nephrectomy*

References	No. Pts.	Mean Operating Room Time (hrs.)	Mean Specimen Wt. (gm.)	Mean Size Mass (cm.)	Mean Estimated Blood Loss (ml.)	Narcotics (mg. morphine sulfate equivalent)	Mean Length of Stay (days)	Mean Time to Normal Activities (wks.)
Dunn et al:[2]								
Laparoscopic	60	5.5	452	5.3	172	28	3.4	3.6
Open	33	2.8	666	7.4	451	78	5.2	8.1
Ono et al:[3]								
Laparoscopic	60	5.2	279		255	14		3.3
Open	40	3.3	339		512	22		8.1
Barrett et al:[4]								
Laparoscopic	66	2.9	402	4.5			4.4	
Janetschek et al:[7]								
Laparoscopic	73	2.4		3.8	170		7.2	
Abbou et al:[6]								
Laparoscopic	29	2.4		4.1	100		4.8	
Open	29	2		5.7	284		9.7	
Gill et al:[5]								
Laparoscopic	34	3.1	605	5	97	14	1.4	4
Open	34	3.1	638	6.1	370	295	5.8	10

TABLE 2. *Reports of oncological followup of cT1, T2 tumors after laparoscopic and open total/radical nephrectomy*

References	No. Pts.	Mean Followup (mos.)	No. Ca Recurrence	No. Ca Specific Mortality
Dunn et al:[2]				
Laparoscopic	44	25	3	2
Open	30	27.5	3	0
Ono et al:[3]				
Laparoscopic	60	24	2	0
Open	40	28.5	2	1

Laparoscopic total/radical nephrectomy was performed usually by a transperitoneal route (52 cases) and rarely by a retroperitoneal approach (12 cases). Operative technique has been previously published in reports from each center.[2–4] The adrenal gland was taken en bloc with the kidney in 43 cases (that is radical nephrectomy) and left in situ (that is total nephrectomy) in the remainder. The mobilized specimen was removed intact in 39 of 64 cases and was morcellated in an impermeable sack and removed via a 12 mm. port site in the remaining 25 cases.

Charts were reviewed to ascertain preoperative staging, operative details, pathological diagnosis and perioperative course. Details of postoperative followup were gathered with specific inclusion of clinical evaluation, cross-sectional imaging and laboratory data. Cross-sectional abdominal imaging is not standard of care in Canada, and so was not routinely performed. Local failure was defined as recurrent disease within the surgical site. Distant failure was defined as any evidence of metastatic disease outside of the renal fossa, including visceral, bone or cutaneous metastases. Immediate cause of death was obtained from the death certificate. Autopsies were not routinely performed.

Statistical analysis was performed with commercially available software. Continuous variables were compared with Student's t test and categorical variables were assessed with chi-square test. Kaplan-Meier survival analysis was performed.

RESULTS

Patient demographics are presented in table 3. The laparoscopic group consisted of 64 patients while 69 patients were included in the open group. Patient age and American Society of Anesthesiologists score were equivalent between groups. Operative blood loss was significantly less ($p = 0.016$) and operative time was significantly longer ($p < 0.001$) for the laparoscopic versus the open group. Length of hospitalization was significantly shorter for the laparoscopic group ($p < 0.001$).

Tumor size was significantly larger for the open group than the laparoscopic group at 6.2 cm. versus 4.3 cm., respectively ($p < 0.001$). However, specimen weight was not significantly different between groups ($p = 0.146$). When mass size was categorized relative to 4 and 7 cm. criteria, the laparoscopic group had more lesions smaller than 4 cm. and fewer lesions larger than 7 cm. relative to the open group (table 3). The number of lesions between 4 and 7 cm. was similar between groups. Distribution of Fuhrman grades was remarkably similar between groups (table 3).

TABLE 3. *Patient characteristics*

	Laparoscopic	Open	p Value
No. pts.	64	69	
Mean age	61.1	61.1	0.740
Mean American Society of Anesthesiologists score	1.95	1.75	0.584
Mean estimated blood loss (cc)	219	354	0.016
Mean operating room time (mins.)	287	128	0.000
Mean length of stay*	4.8	7.4	0.000
Mean mass size (cm.):	4.3	6.2	0.000
No. less than 4	34	14	
No. 4–7	20	27	
No. greater than 7	9	24	
Mean specimen wt. (gm.)	425	495	0.146
No. Fuhrman grade:			
1	17	20	
2	31	33	
3	6	7	
4	0	2	

* Does not include Japanese data.

Data regarding recurrences and deaths for open and laparoscopic nephrectomy are presented in table 4. Local recurrence after open radical nephrectomy occurred in just 1 patient. The patient had a 15 cm. Fuhrman grade 3 papillary carcinoma with recurrence detected 8.2 years postoperatively and was still alive at last followup of 9 years. Similarly, 1 patient in the laparoscopic group had local recurrence 1 year after resection of a 9 cm. Fuhrman grade 4 clear cell carcinoma. At 10 months following resection of the recurrence, he has no evidence of disease. Patients were also evaluated based on clinical T1 disease status (table 5). Distant recurrence of renal cell carcinoma was detected in 10 patients an

TABLE 4. *Deaths and recurrences*

Surgery Date	Mean Pt. Age	Mean Mass (cm.)	Mean Specimen Wt. (gm.)	Histological Diagnosis	Fuhrman Grade	Mean Postop. Followup (yrs.)	Mean Time to Recurrence (yrs.)	Recurrence Site	Cause of Death
Open radical nephrectomy									
Death from renal cell Ca:									
4/3/92	75.1	4.7	370	Clear cell	3	0.7	0.4	Lung, bone	Renal cell Ca
2/12/93	71.4	7.5	568	Granular		3.4	0.9	Lung	Renal cell Ca
10/21/93	58.0	6.5	531	Clear cell	1	5.4	5.1	Lung	Renal cell Ca
1/17/94	66.3	10.0	654	Clear cell	2	4.6	4.3	Lung	Renal cell Ca
4/13/94	68.0	13.0	1150	Clear cell	1	2.0	0.6	Bone	Renal cell Ca
10/20/94	81.1	3.0	370	Mixed	2	0.8	0.6	Lung, liver, bone	Renal cell Ca
Renal cell Ca recurrence:									
7/18/90	59.6	6.0	431	Clear cell		9.5	9.3	Lung	
2/1/91	45.8	8.0	568	Clear cell	2	9.0	8.1	Lung	
9/14/94	59.2	7.4	630	Clear cell	3	5.0	2.1	Brain, liver, bone	
7/30/90	52.4	15.0	1572	Papillary	3	9.0	8.2	Local	
Nonrenal cell Ca death:									
8/3/92	82.4	6.0	1150	Not stated	2	3.0			Coronary artery disease
6/3/93	74.5	6.9		Not stated	3	3.7			Cerebrovascular accident
Laparoscopic radical nephrectomy									
Death from renal cell Ca:									
9/23/92	60.1	5.0	436	Clear cell	3	4.3	3.5	Lung	Renal cell Ca
Renal cell Ca recurrence:									
4/27/93	72.0	3.2	160	Clear cell	2	7.0	4.7	Lung	
7/20/95	73.1	3.0	208	Clear cell	3	2.0	1.4	Bone	Pneumonia
9/11/95	61.3	9.0	393	Clear cell	3	1.4	1.0	Local	
Nonrenal cell Ca death:									
2/22/94	72.3	3.0		Papillary	1	1.9			Cerebrovascular accident
6/8/94	60.4	3.0	264	Granular	4	3.0			Coronary artery disease
8/23/94	78.3	5.3		Clear cell	2	0.0			Renal failure
8/29/94	79.8	5.0	265	Clear cell	1	3.7			Cerebrovascular accident
9/26/94	87.2	8.8	227	Granular		0.7			Coronary artery disease
12/22/94	83.5	6.2	278	Clear cell		0.2			Diabetes
7/18/95	65.7	3.5	654	Clear cell	1	4.2			Ovarian Ca
10/6/95	74.0	3.0	230	Clear cell	1	3.8			Coronary artery disease
12/20/95	49.7	4.0	451	Clear cell	1	2.1			Liver failure

TABLE 5. *Kaplan-Meier analysis of 5-year survival*

Mass Size (cm.)	Laparoscopic	Open	p Value
Mean followup			
All	4.49	5.77	0.000*
Less than 7	4.65	5.89	0.002*
7 or greater	3.82	5.69	0.017*
Overall survival			
All	81%	89%	0.260†
Less than 7	82%	92%	0.272†
7 or greater	89%	86%	0.883†
Recurrence-free survival			
All	92%	91%	0.583†
Less than 7	92%	95%	0.951†
7 or greater	87%	83%	0.804†
Cancer specific survival			
All	98%	92%	0.124†
Less than 7	97%	95%	0.303†
7 or greater	100%	87%	0.383†

* Student's t test.
† Log rank test.

average of 3.5 years after open total/radical nephrectomy. Among the patients with recurrence after open nephrectomy the average lesion size was 7.3 cm. (range 3 to 13). Distant recurrence was noted in 3 patients at an average of 4.5 years after laparoscopic radical nephrectomy. The original size of the mass among these 3 patients ranged from 3 to 5 cm. Of the 10 and 3 patients with distant recurrence 6 and 1 died of disease after an average of 0.8 year.

Noncancer related deaths occurred in 2 patients after open and in 9 after laparoscopic total/radical nephrectomy. In the laparoscopic group 5 patients died of heart disease or stroke and 1 each died of azotemia, diabetes, liver failure and ovarian cancer. Among these patients only 1 died 2 weeks postoperatively due to renal failure. In the open surgery group 1 patient died of coronary artery disease and 1 died after a cerebrovascular accident.

The 5-year survival was calculated by the Kaplan-Meier method with an average followup of 4.5 years in the laparoscopic and 5.8 years in the open surgical groups. Kaplan-Meier curves for patients free of tumor recurrence, overall survival and cancer specific survival are presented in figures 1 to 3, respectively. Overall survival was not significantly different at 81% and 89%, ($p = 0.26$) recurrence-free survival was 92% and 91% ($p = 0.583$) and cancer specific survival was not significantly different at 98% and 92% ($p = 0.124$) for the laparoscopic and open surgical groups, respectively. The 5-year survival was subdivided into T1 and T2 lesions using the newly developed criterion of T1 tumors being 7 cm. or less, and again, no differences between groups were significant (table 5).

DISCUSSION

Localized renal cell carcinoma remains a surgical disease and as such the effectiveness of the extirpative procedure is paramount. In this retrospective, multicenter review it is demonstrated that 5-year survival after laparoscopic total/radical nephrectomy is equivalent to that after traditional open surgery. While there are inherent weaknesses with any retrospective review, there are several unique aspects regarding the laparoscopic cases in this report. These cases comprise the total experience of the initial 3 centers to adopt laparoscopic total/radical nephrectomy on a large scale and as such the initial 10–20 learning curve cases also were reviewed. All patients in the study had clinically localized disease and pathologically confirmed renal cell carcinoma. All participating centers have been examining their experience in an ongoing manner and regularly publishing their results as they have accrued during the last several years.

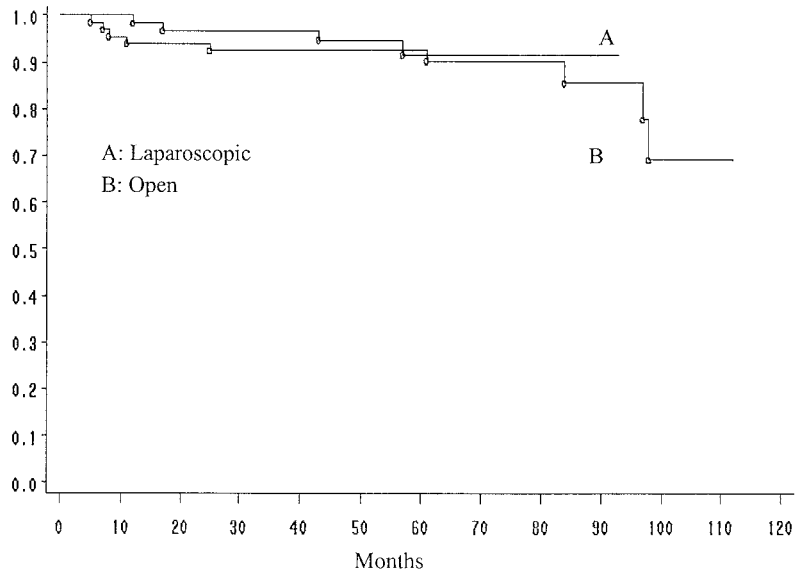

FIG. 1. Kaplan-Meier curve for proportions free of tumor recurrences

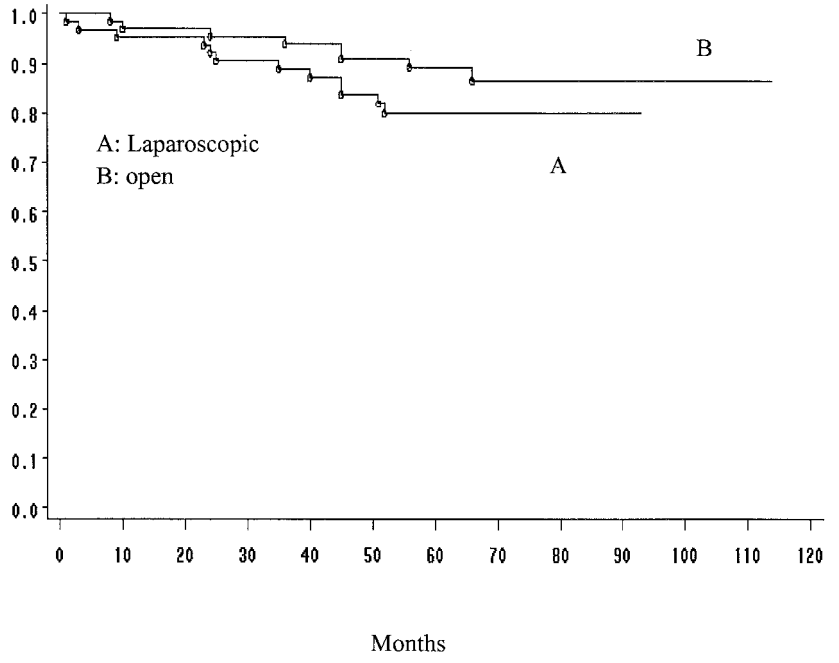

FIG. 2. Kaplan-Meier survival curve for all causes of death

An open total/radical nephrectomy group from each of the centers was included for comparison. This group consisted of patients with preoperative characteristics that potentially could have been treated with a laparoscopic procedure. There is obviously some selection bias in both groups. In Saskatoon, after initial forays into laparoscopy were found to be successful, all total/radical nephrectomies were performed laparoscopically. The investigators at that center accrued their comparison open population from patients who underwent surgery before complete adoption of laparoscopic surgery, which resulted in a longer followup period for the open than laparoscopic groups in the Saskatoon population. However, in Nagoya and St. Louis the open population was contemporary as other surgeons at both places continued to perform open total/radical nephrectomies. Also, it should be noted that lesion size was a factor in the direction of patients towards laparoscopic or open resection. In Japan laparoscopic total/radical nephrectomy was not offered to patients with lesions greater than 5 cm. until October 1996 and in St. Louis the initial approach was to avoid tumors larger than 7 cm. This selection bias resulted in the smaller lesion size in the laparoscopic group.

Oncological effectiveness of total/radical nephrectomy can be evaluated on the basis of 4 criteria. First, the tumor bearing kidney must be removed without any transgression of the borders of the tumor itself. As such, for T1 and T2 disease the kidney must be completely mobilized along with Gerota's fascia and surrounding pararenal fat. Removal of the adrenal depends on the site and size of the tumor and the presence of any abnormality in the adrenal gland on preoperative computerized tomography (CT). If the adrenal appears to be uninvolved by the renal tumor and the renal tumor itself is not in the upper pole, then it is reasonable to spare the ipsilateral adrenal gland. In this case Gerota's fascia is entered superiorly and the adrenal gland is separated from the perirenal fat and preserved. The specimen

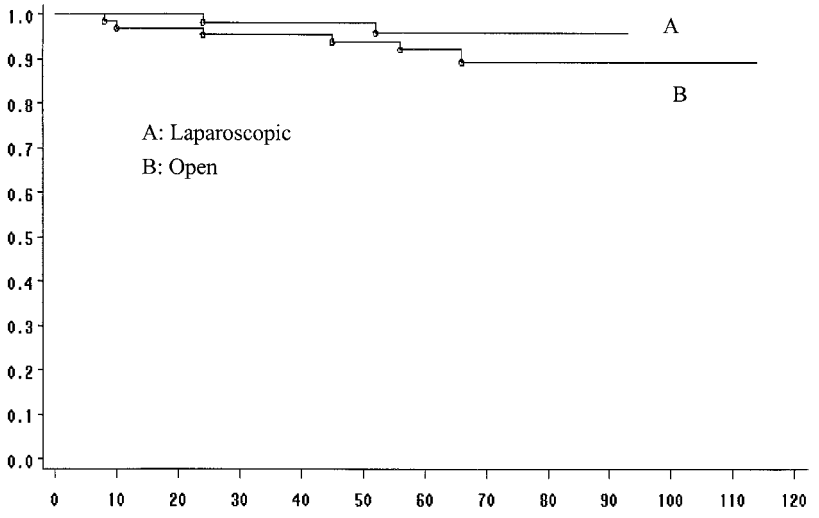

FIG. 3. Kaplan-Meier survival curve for cancer specific death

needs to be removed from the patient without any contamination of the surrounding tissues. In our study specimen weights were not statistically significantly different between groups but they tended to be slightly smaller for the laparoscopic group. In the Washington University series, even taking into consideration a 20% reduction in specimen weight due to morcellation, the average specimen still weighed approximately 100 gm. less than its open counterpart. However, tumor size in general was smaller in the laparoscopic group (54% less than 4 cm. and only 14% for T2) versus the open group (only 22% less than 4 cm. and 37% for T2).

The second criterion of oncological effectiveness is incidence of local recurrence. There was just 1 case of local recurrence each in the laparoscopic and open groups, and in both the lesion was large (laparoscopic 9 cm. and open 15 cm.) and of high grade. The Canadian group reported 1 case of local recurrence following laparoscopy after 1995 which is not included in this study.[4] The patient had an 8.7 cm. tumor that was pathologically T3 and high grade (Fuhrman 3). The Japanese group has yet to detect a local recurrence in their experience before and after 1995.[8]

Concerns have been expressed over possible port site seeding or intraperitoneal extension when the specimen is morcellated. To date, there has been a solitary report of a port site recurrence detected 25 months postoperatively by the Canadian group.[9] The patient had a 14.6 cm. grade 4 lesion in a port site. While the original specimen was morcellated, the seeding was not in the port site used for morcellation. There have been no case reports of intraperitoneal seeding following morcellation. Also, morcellation results in loss of pathological staging but in its defense tumor grade and the presence of vascular invasion are accurately determined. The value of pathological staging, given the accuracy of present day CT and absence of adjuvant therapy for renal cell cancer, is of questionable importance.

The third criterion of oncological effectiveness is distant recurrence, which was noted in 3 patients in the laparoscopic and 9 in the open surgical group. Of the distal failures 4 occurred after 5 years in the open surgical group and as such actuarial 5-year recurrence-free survival was not statistically different between the laparoscopic and open groups. Of interest, the 5-year laparoscopic survival documented in our study is similar to the "projected" 5-year survival from a large multicenter study of 157 patients undergoing laparoscopic nephrectomy for renal cell cancer but with an average follow-up of only 19.2 months.[10]

The ultimate criterion of oncological surgery is patient survival. Overall 5-year survival after laparoscopic nephrectomy (81%) was statistically equivalent to that seen following traditional open surgery (89%). Of note, more patients died of noncancer related causes after laparoscopic than after open surgery, including 1 death within 6 weeks of surgery.

Cancer specific 5-year survival was similar between the laparoscopic (98%) and open (92%) surgical groups, overall or for T1 and T2 disease specifically. In our study laparoscopic and open cancer specific survival was 97% and 95% for T1Nx and T1N0, respectively, and 100% for laparoscopic T2Nx and 87% for open T2N0. Of note, the laparoscopic group was predominantly staged clinically and not pathologically, as almost half of the specimens were morcellated. In earlier studies at our institution we found that clinical CT staging has a 9% to 20% under staging error, thereby biasing outcome results against the laparoscopic approach. However, these scans were from the early 1990s and are not representative of current thin section CT with the capability of 3-dimensional reconstruction, which allows for more accurate clinical tumor staging.

Our results are consistent with existing reports of survival after traditional total/radical nephrectomy (table 6). A recent large retrospective review at University of California Los Angeles on 5-year cancer specific survival after open total/radical nephrectomy for T1N0 and T2N0 (1997 TNM guidelines) revealed rates of 91% and 74%.[11] However, when the lymph node status was not determined the respective cancer specific survival decreased to 83% and 57%, respectively. Similarly, Javidan et al examined a large group of patients

TABLE 6. *Reports of 5-year cancer specific survival after traditional open radical nephrectomy*

References	Mass Size (cm.)	No. Pts.	% 5-yr. Cancer Specific Survival
Butler et al[13]	Less than 4	42	97
Lee et al[14]	Less than 4	183	95
Guinan et al[16]	Less than 7.5	83	94
Tsui et al[11]:	Less than 7 (T1N0M0), greater than 7 (T1N0M0), less than 7 (T1Nx), 7 or greater (T2Nx)	185, 57, 227, 101	91, 74, 83, 57
Javidan et al[12]	Less than 7 (T1N0), 7 or greater (T2N0)	205, 53	95, 88

with T1N0 and T2N0 lesions and found that 5-year cancer specific survival was slightly higher in the T1N0 group at 95% versus 88% for T2N0.[12] Our laparoscopic results are also consistent with recent reports of 95% to 97% cancer specific survival after total nephrectomy for tumors less than 4 cm. which occurred in more than half of our patients.[13, 14]

In contrast with traditional open total/radical nephrectomy, the laparoscopic procedure remains a technique in evolution. Already variations on a pure laparoscopic approach with specimen morcellation or intact retrieval are being reported. Small series of patients treated with a purely retroperitoneal approach with intact removal are just now being reported.[5, 6] Also, the introduction of hand assisted total/radical nephrectomy has become popular. This method greatly simplifies the transperitoneal approach and may allow more urologists to use a laparoscopic approach.[15] However, neither of these approaches has been in existence long enough to consider long-term outcomes. While it would appear that these approaches should be equally efficacious to an unassisted transperitoneal laparoscopic approach, long-term 5-year data need to be generated.

CONCLUSIONS

Prior reports on laparoscopic nephrectomy for renal cell cancer have documented its feasibility, adequacy of the specimen and immediate patient benefits with regard to shorter hospital stay, more rapid convalescence, decreased pain and less disfigurement. However, until now a major concern has been whether the long-term efficacy of this procedure would match the results of standard open nephrectomy. Based on 5-year followup data, laparoscopic total/radical nephrectomy has been demonstrated to have oncological effectiveness equivalent to traditional open surgery. Today at our institution and others laparoscopic total/radical nephrectomy has become first line therapy for all T1 and many T2 (that is 7 to 13 cm.) renal tumors.

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