Transplant International

Transplant International ISSN 0934-0874

ORIGINAL ARTICLE

A single center comparison of long-term outcomes of renal allografts procured laparoscopically versus historic controls procured by the open approach

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Keywords
clinical kidney transplantation, live donors, outcome, surgery, techniques.

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Received: 11 March 2008
Accepted: 4 April 2008

doi:10.1111/j.1432-2277.2008.00687.x

Summary

We have previously reported that renal allografts procured by the laparoscopic live donor nephrectomy (lapNx) demonstrate worse early renal outcomes but noninferior 1-year renal function as compared to those procured by the standard open nephrectomy (openNx). We undertook this study to examine whether the apparent early dysfunction will impair long-term renal allograft survival. We retrospectively updated the status of the first 132 consecutive adult left lapNx recipients at our center and the preceding 99 adult openNx recipients. With a mean follow-up of 5.8 ± 2.0 years in lapNx and 8.7 ± 3.3 years in openNx, we found that death-censored renal allograft survival was identical on univariate and multivariate analysis. Patient survival was worse (log rank *P*-value = 0.048) in lapNx, but this finding did not persist in multivariate analysis. Combined graft-patient survival as well as 1-year mean serum creatinine levels were similar on univariate and multivariate analyses. We conclude that, despite having suffered early renal dysfunction, the lapNx cohort of renal allograft recipients enjoys similar long-term renal allograft survival as compared to openNx.

Introduction

Laparoscopic live donor nephrectomy (lapNx) has improved short-term donor outcomes and cosmetic acceptance after live kidney donation as compared to the standard open live donor nephrectomy (openNx) [1–5], and it has lessened disincentives to donation for many potential donors [6–10]. Increasing recourse to the lapNx procedure is likely to have been an important factor in the marked increase in the pace of living kidney donation over the past decade. While the efforts to optimize the donor outcomes and organ supply are laudable and important, the transplant community must ensure that this is not achieved at the expense of worse recipient outcomes. The organ recovered by this procurement technique, which is less invasive and generally considered to be more technically challenging than the open live donor nephrectomy, must be delivered to the recipient in acceptable condition. Still though, there are currently insufficient data from randomized trials comparing recipient renal outcomes after lapNx as compared to openNx [11–15]. Although most groups that have retrospectively examined recipient renal outcomes have reported excellent and/or equivalent early outcomes as compared to the open approach [5,16–38], a few groups have shown that renal allografts procured laparoscopically from living donors have higher rates of early graft dysfunction than those procured by the open technique [39–42]. Thus far, however, no study to our knowledge has shown worse renal outcomes over the long term, suggesting that the

live donor renal allografts recover even if they suffer procurement-related insults. Nevertheless, concern that early renal insults – even if not severe – may adversely impact long-term outcomes is justified because of the relatively short duration of follow-up in prior studies and because of the extensive literature that show that early dysfunction in deceased donor renal allografts is associated with worse allograft survival [43–45].

We previously reported a retrospective review [39] of our first 132 recipients of lapNx done at our center between March 1996 and November 1997 compared with 99 historic controls done by openNx between October 1993 and March 1996, with a mean duration of follow-up of 0.78 years for lapNx and 2.5 years for openNx. We found that more patients required dialysis during the first postoperative week in lapNx as compared with openNx (5.3% vs. 0%, respectively) and that early mean serum creatinines were higher in lapNx, with 1-week serum creatinine (SCr) at 2.8 ± 0.3 and 1.8 ± 0.2 mg/dl, respectively ($P = 0.005$) and 1-month SCr at 2.0 ± 0.1 and 1.6 ± 0.1 mg/dl, respectively ($P = 0.05$). Subsequent renal function outcomes as estimated by SCr at 3, 6, and 12 months were not inferior in lapNx.

On account of the concern that the apparent early renal insults associated with the laparoscopic nephrectomy procurement may lead to impaired long-term graft function that was not yet apparent in our earlier analysis [39], we undertook this study to examine whether longer-term renal and patient outcomes in this group of lapNx recipients are worse than those in openNx.

Materials and methods

This report is a retrospective cohort study, which provides extended long-term outcome data on a previously described lapNx cohort and historic control group. Our lapNx cohort included the first 132 consecutive adult recipients of left lapNx (performed between March 1996 and November 1997). The openNx cohort, our historic control group, consisted of the 99 consecutive recipients whose renal allografts were procured by open approach immediately prior to our center's conversion to the laparoscopic technique as the procedure of choice (performed between October 1993 and March 1996).

After obtaining approval from our center's Institutional Review Board, graft and patient survival status information on subjects were updated by querying our center's computerized clinical database. Additionally, to ensure that graft losses were not missed, we further investigated the transplant clinic records and hospital records for those subjects whose most recent serum creatinine was above 2.5 mg/dl. Failure of renal allograft was defined as return to dialysis or repeat kidney transplantation. Also, because the longest durations of follow-up among the lapNx group (9.5 years) were less than that of openNx, survival analyses beyond the end of available follow-up in lapNx lacked controls and were essentially meaningless. Therefore, we truncated graft and patient survival analyses at an even 10 years by censoring all survivors at this time.

Continuous variables were reported as mean ± standard deviation (unless otherwise specified) and were compared using Student's *t*-tests. Categorical variables were reported as absolute number of patients and/or percentage of the group studied and were compared using chi squared tests. Adjustments for multiple covariates were made using linear regression for continuous outcomes. The assumption of linearity of the relationship was examined with component plus residue plotting for continuous variables and by comparing the subgroup residuals for binary covariates. Patient and graft survival were analyzed using Kaplan–Meier techniques, compared with log-rank tests, and adjusted for potential confounders using Cox proportional hazard regression. The proportionality assumptions were tested using Schoenfeld tests and log-minus-log survival plots. Values of $P < 0.05$ were considered statistically significant. Potential confounding variables were chosen *a priori* for inclusion in the multivariate analysis if data were available in the database on a sufficient number of subjects (>95%) and if an independent effect on the outcomes was felt likely by the study team, even if a statistically significant effect was not demonstrated in univariate analysis. For allograft survival and allograft renal function outcomes, we included the following covariates in the multivariate models: recipient age, recipient gender, recipient African American race, donor age, donor gender, donor African American race, pretransplant diabetes mellitus (DM), use of antilymphocyte antibody induction, use of tacrolimus in initial immunosuppression (IS) regimen, use of mycophenolate mofetil (MMF) in initial IS regimen, zero human leukocyte antigen (HLA) mismatch, and donor-estimated GFR by abbreviated MDRD Study equation [46]. For patient survival outcomes, we included the following covariates in the multivariate models: recipient age, recipient gender, recipient African American race, pretransplant DM, use of antilymphocyte antibody induction, and zero HLA mismatch. SPSS Version 8.0 (SPSS, Inc., Chicago, IL, USA) and STATA SE 9.1 (Stata Corporation, College Station, TX, USA) software were used for statistical analyses. No specific funding sources were used in the completion of this study.

Results

The reader is referred to our initial report for details of baseline demographic and clinical parameters. To summa-

rize, the two groups were similar in most respects, except that the lapNx group was slightly older, had a slightly more disparate DR match, was less likely to receive antilymphocyte antibody induction, and was much more likely to receive MMF rather than azathioprine as the initial maintenance IS regimens. As a result of the sequential nature of the cohorts, the duration of follow-up was shorter in the lapNx cohort as compared to the preceding openNx control group (5.8 ± 2.0 years vs. 8.7 ± 3.3 years, respectively. $P < 0.001$). Because we were one of the few centers performing lapNx at that time, several of the lapNx recipients came to our center from other regions of the country and then returned to a local transplant center for subsequent care. For this reason, more patients in the lapNx cohort were lost to follow-up at our center: eight of 132 (6.1%) of lapNx versus two of 97 (2.1%) of openNx were censored by 1 year for lack of follow-up.

The death-censored renal allograft survival of the two groups and the crude 1-year and 5-year graft survivals (with dead subjects not included in the denominator) were similar, as shown in Fig. 1. Likewise, the combined graft-patient survival (with death with function being considered graft loss) and the crude 1-year and 5-year graft survivals (with dead patients included in denominator) were similar, as shown in Fig. 2. Laparoscopic method of procurement remained nonpredictive of death-censored graft survival (RR 1.79 for lapNx as compared to openNx, 95% CI 0.79–4.08, *P*-value 0.16) and combined graft-patient survival (RR 1.23 for lapNx as compared to openNx, 95% CI 0.62–2.42, *P*-value 0.55) in our multivariate model.

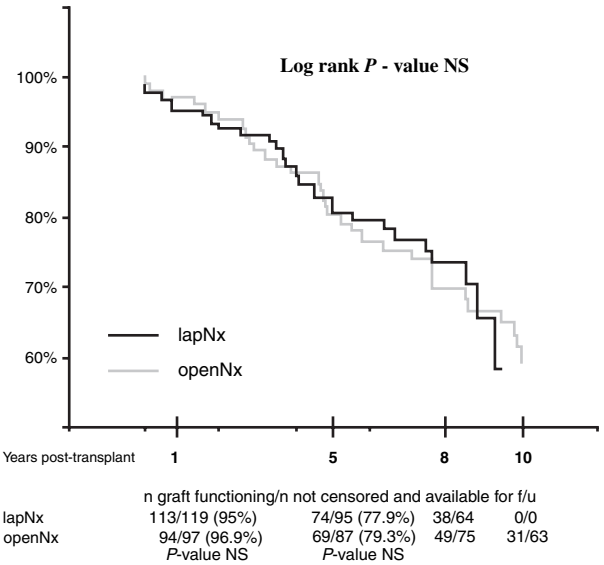

Figure 1 Death-censored renal allograft survival up to one decade post-transplantation.

As shown in Fig. 3, patient survival as well as 1-year and 5-year patient survival were worse in the lapNx cohort on unadjusted analyses. However, laparoscopic method of procurement was not predictive of mortality in our multivariate model, and the details of the univariate and multivariate Cox proportional hazard models for patient survival are provided in Table 1. The causes of 25 deaths in the lapNx cohort were 10 unknown, 8 cardiac, 2 stroke, 1 cancer, and 4 infections. The causes of 21

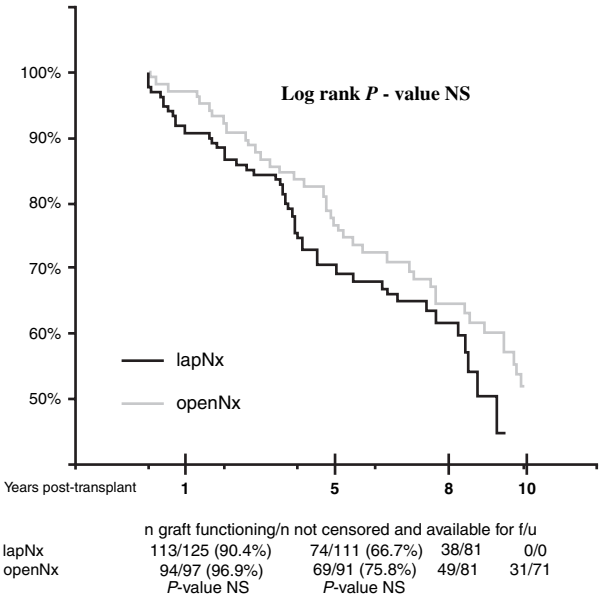

Figure 2 Combined renal allograft-patient survival up to one decade post-transplantation.

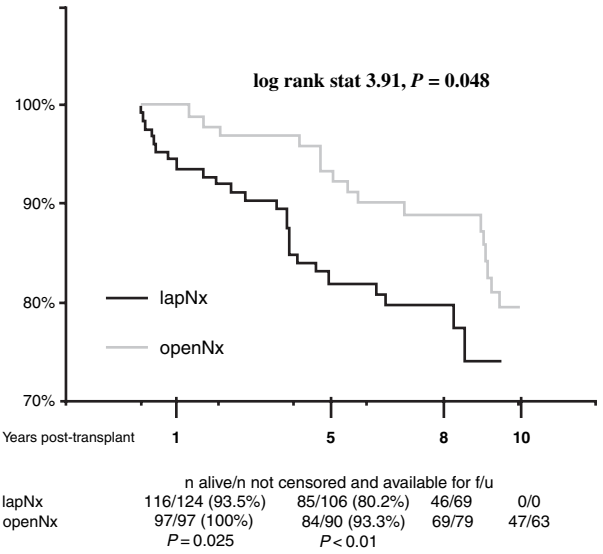

Figure 3 Patient survival up to one decade post-transplantation.

Table 1. Univariate and multivariate models of patient survival using Cox proportional hazards analysis.

	Univariate model		Multivariate model	
Patient survival	RR (95% CI)	*P*-value	RR (95% CI)	*P*-value
LapNx	1.87 (0.95–3.66)	0.066	1.09 (0.46–2.47)	0.88
Recipient age (per decade)	1.26 (0.97–1.64)	0.089	1.20 (0.92–1.56)	0.18
Recipient African American	1.30 (0.69–2.45)	0.42	1.45 (0.75–2.80)	0.26
Recipient male	1.06 (0.56–2.00)	0.87	0.95 (0.49–1.85)	0.88
Antilymphocyte induction	0.57 (0.29–1.10)	0.095	0.43 (0.18–0.99)	0.047
Zero HLA mismatch	0.34 (0.082–1.41)	0.14	0.27 (0.058–1.21)	0.087
Pretransplant DM	0.51 (0.22–1.15)	0.11	0.58 (0.25–1.34)	0.21

deaths in the openNx cohort were 15 unknown, 3 cardiac, 1 stroke, and 2 cancer.

Finally, we compared the 1-year mean serum creatinine for the groups and found that they were similar (1.57 ± 0.64 in lapNx and 1.65 ± 0.51 mg/dl in openNx; *P*-value NS; $n = 107$ for lapNx and $n = 88$ for openNx). The lack of difference between the groups persisted in multivariate analysis also (*P*-value NS).

Discussion

This current study shows that our center's early cohort of recipients of laparoscopically procured live donor renal allografts – who had demonstrated relatively impaired early graft function – had similar 1-year renal allograft function and similar long-term renal survival as compared to the preceding historic control cohort of recipients of live donor renal allografts procured by the standard open nephrectomy. This conclusion is supported by the similar 1-year mean serum creatinine and by the death-censored graft survival curves of the two cohorts that are by general appearance and statistically nearly identical.

These reassuring findings suggest that a living donor's kidney is so healthy that it can recover from the relatively minor ischemic and mechanical injuries that could be sustained during a laparoscopic procurement. Supporting this view is the current literature's lack of evidence of worse long-term recipient outcomes after lapNx, including UNOS data from the early years of lapNx (1998–2001) that did not demonstrate any indication that type of donor surgery affected graft survival rates [47]. Also consistent with the recoverability of the living donor renal allografts after early insults are the findings of a recent study of by Brennan *et al.* [48] that compared those living donor allografts that had experienced delayed graft function or slow graft function (serum creatinine ≥ 3.0 mg/dl at POD#5) to those without early graft dysfunction and found no statistically significant differences in 1-year creatinine clearances or in graft outcome after a mean follow-up of 31 months.

On the other hand our current study has important limitations. Although this study does provide some reassurance that the lapNx is effective and safe, the results of our retrospective comparative analysis are by no means definitive. The study and control cohorts were performed in different eras; and differences in baseline risks, standards of medical care, and immunosuppression regimens confound the comparisons and severely limit the conclusions that can be made from this historic cohort-controlled, retrospective study. In fact, when adjustments are made for potential confounders, a substantial but statistically insignificant graft survival disadvantage in the lapNx cohort was found, with an adjusted relative risk of death-censored graft survival of 1.79. Furthermore, it is important to note that our data did not exclude the possibility of dramatically worse graft survival in this group, as demonstrated by the 95% confidence interval of relative risk extending up to 4.08. Therefore, type II error is a significant possibility in that it is still possible that the lapNx may have imparted a significant graft survival disadvantage but that we had too few subjects to demonstrate it. It remains plausible that injury sustained during lapNx could initiate a chain of events that ultimately impairs long-term graft survival but that may not have been clinically apparent in the relatively crude medium-term outcomes assessed in earlier studies (such as serum creatinines up to 1 year) and that may have not been statistically apparent in the relatively small cohorts in this current study. Renal ischemia is known to increase MHC class II expression [49,50]; and it is possible that mechanical injury and warm ischemia could increase immunogenicity and initiate a gradual progression to chronic allograft nephropathy via an injury-inflammation-immune recognition mechanism. Supporting this concern is the strong evidence that delayed graft function or slow graft function may increase risk of subsequent rejection after deceased donor or living donor kidney transplanta-

tion [51–55]. Additionally, if the early renal injury is significant enough to cause nephron dropout, then it is possible that this may lead to a vicious cycle of single nephron hyperfunction and progressive hyperfiltration injury with eventual glomerulosclerosis and slowly progressive chronic renal dysfunction. In fact, national data support concern that early dysfunction in the setting of living donor kidney transplantation has major lasting effects on graft outcomes: according to the OPTN/SRTR 2005 Annual Report, the 1-year graft survival is 65% if dialysis is needed within the first post-transplant week as compared to 97%, if not [45].

Our study also demonstrated that patient survival was worse in the lapNx cohort using unadjusted Kaplan–Meier analysis, and this is of significant concern. However, we feel that this finding is more likely on account of a change in practice patterns over the years of the study, which resulted in a lapNx cohort that had an increased baseline mortality risk as compared to openNx; and this assessment is supported by the finding that the apparent deleterious effect of lapNx on patient survival was abolished when we incorporated other potentially confounding variables into our multivariate analysis. Still, the finding that none of the baseline factors individually appeared to be strongly predictive of survival on univariate or multivariate analysis (see Table 1) indicates that the finding of eradication of survival differences on multivariate analysis eludes simple explanation and is more likely because of a combination of multiple inconspicuous factors. It should also be noted that if the procurement procedure were to negatively impact patient survival, then one would expect that this would be mediated by earlier graft failures or via more intensive immunosuppression resulting from a higher risk of rejection (by mechanisms discussed above). The findings of this study of similar allograft survival argues against the former scenario, and the finding in our earlier study [39] that the rejection-free survival was not worse in the lapNx cohort argues against the latter.

In conclusion, our follow-up study on this intensively analyzed early cohort of lapNx recipients at a single center that pioneered the procedure suggests – but certainly does not definitively prove – that long-term renal allograft function and survival after procurement by lapNx are similar to those after procurement by openNx. Although the lapNx cohort had a higher unadjusted mortality rate, we suspect that this is on account of factors other than those related to mode of organ procurement. Sufficiently large randomized controlled trials could more definitively assess the effect of procurement technique on important recipient outcomes. Yet, given the popularity of lapNx with donors and the strong market forces favoring the use of the LapNx procedure, it is unlikely that such study on a large scale will be done. Larger long-term observational studies can also provide important guidance on this issue.

Authorship

JMN: designed research project, collected data, analyzed data, wrote manuscript. SCJ: collected data, designed research project, assisted in writing manuscript. AH: analyzed data, assisted in writing manuscript. MWP: assisted in writing manuscript. MRW: designed research project, analyzed data, assisted in writing manuscript. SLS: analyzed data, assisted in writing manuscript. HAH: collected data, assisted in writing manuscript. MC: analyzed data, assisted in writing manuscript.

Grant funding

None.

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