

Increasing Live Donor Kidney Transplantation: A Randomized Controlled Trial of a Home-Based Educational Intervention

J. R. Rodrigue^{a,*}, D. L. Cornell^b, J. K. Lin^c,
B. Kaplan^d and R. J. Howard^e

^aThe Transplant Center and the Department of Psychiatry, Beth Israel Deaconess Medical Center, 110 Francis Street, LMOB – 7th Floor, Boston, Massachusetts

^bLifeQuest Organ Recovery Services, 720 S.W. 2nd Avenue, Suite 570, Gainesville, Florida

^cMD Anderson Cancer Center, 1400 S. Orange Ave., MP 780, Orlando, Florida

^dDepartments of Medicine and Pharmacology, University of Illinois at Chicago, 840 South Wood Street, CN 483, Chicago, Illinois

^eDepartment of Surgery, Box 100286, University of Florida, Gainesville, Florida

*Corresponding author: James R. Rodrigue, jrrodrig@bidmc.harvard.edu

With the shortage of deceased donor kidneys and the superior clinical outcomes possible with live donor kidney transplantation (LDKT), more patients should seriously consider LDKT. However, little is known about how best to educate patients and their family members about LDKT. We evaluated the effectiveness of a home-based (HB) educational program in increasing LDKT. Patients were randomized to clinic-based (CB) education alone (CB, n = 69) or CB plus HB education (CB+HB, n = 63). Compared to CB, more patients in the CB+HB group had living donor inquiries (63.8% vs. 82.5%, p = 0.019) and evaluations (34.8% vs. 60.3%, p = 0.005) and LDKTs (30.4% vs. 52.4%, p = 0.013). Assignment to the CB+HB group, White race, more LDKT knowledge, higher willingness to discuss LDKT with others, and fewer LDKT concerns were predictors of having LDKT (p-values < 0.05). Both groups demonstrated an increase in LDKT knowledge after the CB education, but CB+HB led to an additional increase in LDKT knowledge (p < 0.0001) and in willingness to discuss LDKT with others (p < 0.0001), and a decrease in LDKT concerns (p < 0.0001). Results indicate that an HB outreach program is more effective in increasing LDKT rates than CB education alone.

Key words: Clinical trial, donor education, kidney transplantation, living donation

Received 25 August 2006, revised 19 September 2006 and accepted for publication 2 October 2006

Introduction

While waiting list registrations and waiting time for deceased donor kidney transplantation both continue to rapidly expand, evidence suggests that even if kidneys were procured from all possible eligible deceased donors there would not be enough kidneys available to meet the demand (1). Live donor kidney transplantation (LDKT) is an important option for patients because it is associated with superior graft and patient survival outcomes, and it pre-empts the need for or reduces the duration of dialysis treatments (2–5). In addition, LDKT is more cost-effective than long-term dialysis and deceased donor transplantation (6,7), and living kidney donation increases the overall pool of available organs.

In the last 10 years, the number of LDKTs in the United States has increased dramatically and now accounts for 41% of all kidney transplants (8). Widespread use of laparoscopic techniques, less reliance on a perfect human leukocyte antigen match between donor and recipient, expanded selection criteria for acceptable living donor candidates (e.g. obesity, well-controlled hypertension), and use of a live donor nurse coordinator may explain, in part, higher LDKT rates. Despite these impressive gains in LDKT, even higher LDKT rates could be realized by enhancing educational efforts, removing disincentives, and addressing patients' concerns and fears. For instance, recent research has shown that patient reluctance to approach others about living donation, lack of knowledge about living donation and LDKT risks and benefits, misinformation about who can be a living donor, mistrust of the healthcare system, concerns about harming the donor's health and excessive guilt are commonly identified as barriers to pursuing LDKT (9–13).

Transplant programs often provide patients with living donation and LDKT information in the context of transplant clinic visits, combining informal discussions with members of the transplant team, written brochures, videotapes/DVDs and formal seminars. While certainly beneficial and cost-effective, this clinic-based (CB) educational approach may be limited by a number of factors. First, usually it includes only the patient and those individuals who accompany the patient to clinic. Second, it may not address patients' primary concerns (i.e. imposing on others, uncertainty about how to discuss living donation with

others, misinformation about donor eligibility criteria, donor outcomes, etc.). Third, it relies on the patient to have a high level of health literacy and to disseminate information about living donation to others. Finally, information about living donation may not be delivered in a culturally sensitive manner. The precise number of potential living donors who are never evaluated because of these factors is unknown, but is potentially high. Therefore, there is a need to develop and evaluate LDKT educational programs that are disseminated in a way that overcomes these potential limitations.

There are no published randomized controlled trials of educational interventions to determine what approach is most effective in increasing LDKT rates. Drawing upon socioecological and family system models (14), we developed a home-based (HB) educational intervention designed to provide patients and their support system with information regarding living kidney donation and LDKT. We hypothesized that an interactive educational program that targets both patients and their larger support network in a familiar, easily accessible environment would allow for a more effective dissemination of living donation and LDKT information than what could be achieved during routine transplant clinic appointments. Herein, we report the results of a randomized clinical trial comparing the effects of this HB educational intervention versus CB education alone on living donor inquiries and evaluations, LDKT rates, the number of potential donors educated and patients' LDKT knowledge, willingness and concerns.

Materials and Methods

Participants

During a 36-month enrollment period, patients were recruited from the outpatient kidney transplant clinic at Shands Hospital at the University of Florida. Inclusion criteria included: medical approval for transplant listing; ≥ 21 years of age; lived within 90 miles of the transplant center; and residential telephone or cell phone service. Patients were excluded if they had very limited ability to read, speak or understand English. Informed consent was obtained according to procedures approved by the Institutional Review Board at the University of Florida.

Study design

This study was a single-center, prospective design in which patients were randomized into two groups: CB education alone and CB education plus HB education (CB+HB). Because 48% of patients on the waiting list at the study site were African American, we oversampled for African Americans and stratified randomization by race (White, African American) in order to best balance the two intervention groups. Primary outcomes included the proportion of patients with living donor inquiries, living donor evaluations and LDKT. Secondary outcomes included the number of potential donors educated per patient and patients' LDKT knowledge, willingness to discuss LDKT with others, and concerns about LDKT. Knowledge, willingness and concerns were assessed at baseline and immediately after CB education for all patients, and after the home visit for CB+HB patients.

Primary outcomes

Primary outcomes included the proportion of patients with living donor inquiries, living donor evaluations and LDKT. A donor inquiry was defined as

any verbal or written expression (e.g. return of a health history questionnaire) of possible donor interest received by one of the kidney transplant coordinators on behalf of an enrolled patient. A donor evaluation was defined as an initiation of the donor workup that is part of the transplant center's clinical pathway. Finally, we recorded whether patients had received a deceased donor kidney transplant or had died.

Secondary outcomes

The number of family members and friends who participated in the CB education and who attended the home visit was recorded. Patients' LDKT knowledge, willingness to discuss LDKT with others and LDKT concerns were assessed using questionnaires designed by the research team on the basis of prior research and clinical experiences of the research team. LDKT knowledge was measured using 15 true–false items (e.g. *Only a blood relative is able to be a living kidney donor. A living kidney donor must have his/her own health insurance to cover the costs of surgery.*), yielding a total score ranging from 0 to 15. Patient willingness to discuss LDKT with others was assessed with the following question: *How willing are you to talk to family members and/or friends about donating a kidney to you for transplantation?* (1 = 'not at all' to 7 = 'extremely'). Finally, we measured patients' concerns about LDKT with a 21-item true–false questionnaire (e.g. *I am concerned that the donor would no longer be able to do activities that they enjoy. I am worried that I might do something to 'waste' the kidney that someone donates to me – for example, by not living healthy or not taking my medications.* $\alpha = 0.79$). For all three measures, change scores from baseline to post-clinic education were calculated for all patients and change scores from post-clinic education to post-home visit education were also calculated for patients in the CB+HB group.

Interventions

In the CB alone group, patients (and whoever accompanied them to clinic) had a brief discussion about LDKT with the transplant surgeon and/or nephrologist in the context of a routine clinic visit, received written information about LDKT, and attended a 60-min education session with other transplant patients. This group session was conducted by one of the transplant nurse coordinators and included general information about kidney transplantation, transplant medications, medical management while on the waiting list, insurance and financial issues, post-transplant recovery and LDKT. Written brochures and booklets on living kidney donation were distributed to all in attendance. These included an LDKT pamphlet developed by the transplant program that addressed living donation evaluation processes, risks, and benefits and *The Living Gift: Education about Living Kidney Donation* (Missouri Kidney Program and International Transplant Nursing Society, 2002). These print materials were selected after an exhaustive review of patient education resources and based on the clarity of writing and presentation, brevity, lack of technical jargon, and degree to which the materials addressed the known barriers to living donation and LDKT.

In the CB+HB group, patients received the CB education described above. Prior to leaving clinic that day, patients were asked to generate a preliminary 'guest list' of people to invite to the HB intervention. A home visit was scheduled on a date and time convenient for the patient and the patient was given study pamphlets to distribute to invited guests. The pamphlets described the purpose of this study, the general nature and topics of the HB education, and the scheduled date and time of the home visit. A reminder phone call was made to patients one week in advance of the scheduled visit.

Home visits, which were conducted by one or two trained health educators and usually within six weeks of study enrollment, lasted 60–90 min and were highly interactive. The health educators were selected on the basis of their strong interpersonal and communication skills, and they were not involved in the CB education process. They received 80+ h of

Table 1: Primary content of the HB education session

| |
|---|
| Benefits of transplantation before dialysis (or as soon as possible after dialysis) |
| Relationship between dialysis time and transplant outcomes |
| Average waiting times for transplantation |
| Transplant evaluation process |
| Types of transplant and donors (deceased donor, including standard criteria, expanded criteria, and donation after cardiac death; living donor) |
| Transplant outcomes |
| Current deceased donation rates |
| Differences in donation rates (living and deceased) by race |
| Living donor evaluation process |
| Living donor eligibility criteria |
| Living donor surgery (open, laparoscopic) |
| Typical donor recovery |
| Risks of living donation |
| Benefits of living donation |
| Common donor concerns |
| Common recipient concerns |
| Possible indirect costs |
| Helpful resources for transplant patients |
| Helpful resources for living donors |
| Transplant center contact information |

education and training on kidney disease, dialysis, transplantation and living donation directed by the senior investigators and other members of the transplant service. They were also required to behaviorally rehearse delivering the educational module in a simulated home visit and they conducted at least two home visits with a senior health educator before leading one of their own home visit sessions. Finally, the health educators received training in crisis management and the protection of human research participants. While there was flexibility in how the home visits were conducted (e.g. based on number of participants, nature of questions, etc.), health educators were required to deliver the same content prior to ending the education session (Table 1). In comparison to the CB education, which was done in lecture format and covered topics more generally, the home visits were done in a 'roundtable' discussion format with less formality and more information specific to the patient's unique situation. In addition, a 13-min videotape (A Gift for Life: Living Kidney Donation, Fujisawa Healthcare, Inc.) was played to supplement the discussion. The same written brochures and booklets on living kidney donation that were distributed during the CB education were distributed to all in attendance during the home visit.

Statistical methods

Descriptive statistics were calculated for all continuous (means, standard deviations) and categorical (frequencies, percents) variables. We used *t*-tests and chi-square analyses to examine the differences between the two groups at baseline and between study completers and dropouts. Fisher's exact tests were used to examine between-group differences on the primary outcomes (proportion of patients with donor inquiries, donor evaluations and LDKT). Logistic regression analyses were conducted to delineate those variables that were most predictive of LDKT. *t*-tests were used to examine differences on potential donors educated per patient. Regarding LDKT knowledge, willingness and concern measures, both groups completed assessments at baseline and following the clinic education; however, only CB+HB patients completed the measures a third time. For those patients assigned to CB alone, we carried forward their post-clinic education scores on these measures and then conducted repeated measures analysis of variance, with one between subjects factor (group: CB alone,

CB+HB) and one within subjects factor (time). This allowed us to examine whether the CB+HB education yielded any significant incremental benefit beyond the CB education alone. Post hoc tests were conducted to examine group by time interaction effects. All data were entered and analyzed using the Statistical Package for the Social Sciences database (SPSS, Version 14, Chicago IL).

Results

Participants

Two hundred thirty-seven patients who met initial screening criteria were informed about the study between October 2002 and February 2006. Twenty-one patients were subsequently excluded from recruitment because they lived too far from the transplant center, their transplant listing status was not active, or there were apparent language barriers. Two hundred and sixteen patients were formally invited to participate in this study and 169 consented to do so. Of the 169 patients randomized, 39 dropped out of this study either by withdrawing consent or by not completing the randomized intervention (Figure 1). Dropout rates varied significantly by group (10% for CB patients vs. 31% for HB patients). Study completers and dropouts did not differ significantly on sociodemographic characteristics or baseline measures, except that African Americans were more likely to drop out compared to White patients ($p = 0.03$). The final response rate was 89.6% for the CB group and 68.5% for the CB+HB group. All statistical analyses are based on the 132 patients who completed this study. Baseline sociodemographic and medical characteristics of the two groups and total sample are summarized in Table 2.

Primary outcomes

Overall, 96 patients (72.7%) had one or more living donor inquiries, 62 (47.0%) had one or more possible living donors evaluated, and 54 (40.9%) had undergone LDKT. The 40.9% LDKT rate observed in this study is higher than the LDKT rate at this same transplant center in the three years preceding study implementation (30.1%) and comparable to the national LDKT rate during the study time period (41.5%) (8). During the course of this study, nine patients (6.8%; 5 CB, 4 CB+HB) received a deceased donor kidney transplant and 3 patients (2.3%; 2 CB, 1 CB+HB) died while awaiting transplantation.

Group comparisons on the primary outcome measures are illustrated in Figure 2. Relative to patients in the CB alone group, the CB+HB group had a significantly higher percentage of patients with living donor inquiries (63.8% vs. 82.5%, $p = 0.019$), living donor evaluations (34.8% vs. 60.3%, $p = 0.005$) and LDKTs (30.4% vs. 52.4%, $p = 0.013$). The 30.4% LDKT rate in the CB alone group does not differ significantly from the LDKT rate at this transplant center during the three years prior to study initiation (30.1%, $p > 0.05$).

Home-Based Educational Intervention to Increase LDKT

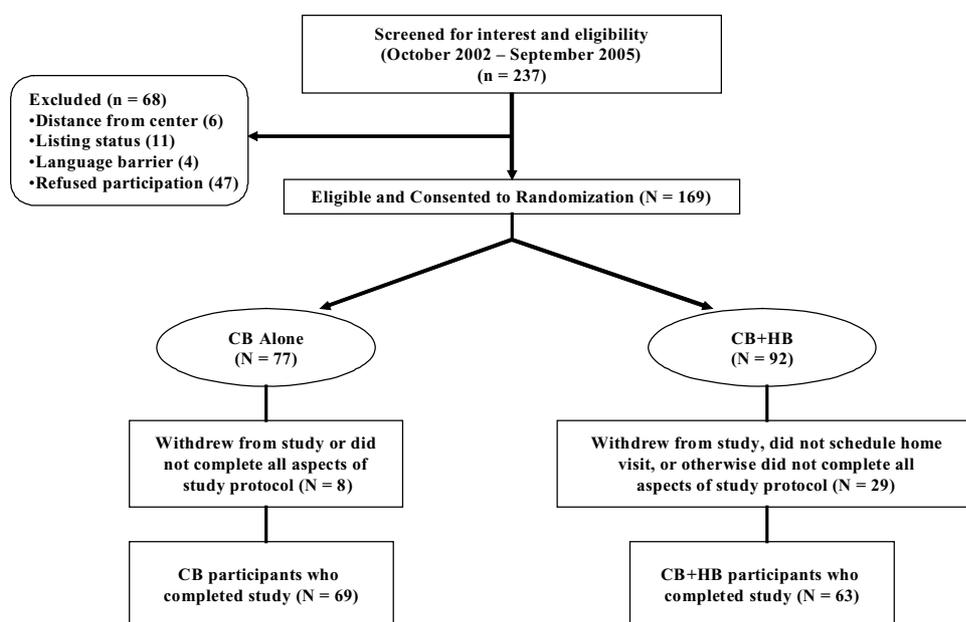


Figure 1: Summary of recruitment and participation rates.

Logistic regression analysis was used to examine the relative contribution of assigned group, sociodemographic/medical characteristics (gender, age, ethnicity, education, marital status, dialysis status, prior transplant status) and modifiable variables (i.e. knowledge, willingness to talk to others, concerns) in predicting LDKT. Group assignment was entered first and sociodemographic/medical characteristics were entered second, followed by those variables that lend themselves to some modification. The final score on the measures of knowledge, willingness and concerns was used in the analysis. The total model was statistically significant ($p = 0.004$) and predicted LDKT in 83.1% of the cases. Assignment to the CB+HB group (OR = 2.97, CI = 1.4, 6.3), white race (OR = 2.36, CI = 1.3, 4.4), higher LDKT knowledge (OR = 1.38, CI = 1.1, 1.7), more willingness to discuss LDKT with others (OR = 1.42, CI = 1.1, 1.9), and fewer LDKT concerns (OR = 0.42,

CI = 0.21, 0.86) were all significant predictors of LDKT ($p < 0.05$).

Secondary outcomes

There were no group differences in the mean number of adults (i.e. potential donors) who accompanied patients during the CB education session (CB = 1.0 ± 0.66 vs. CB+HB = 0.97 ± 0.74 , $t = 0.26$, $p = 0.80$). However, significantly more adults participated in the HB education, per patient (5.43 ± 3.52 , range = 1 to 23, $p < 0.0001$) compared to the CB education.

Patients' scores on measures of LDKT knowledge, willingness to discuss LDKT with others, and LDKT concerns are presented in Table 3. There was a significant group by time interaction in LDKT knowledge ($F_{2,260} = 45.67$, $p < 0.0001$). Post hoc interaction contrasts showed that

Table 2: Sample characteristics for total sample and by group

| | Total sample (n = 132) | Group | | Test statistic |
|-----------------------------------|------------------------|-------------------|----------------|---|
| | | CB alone (n = 69) | CB+HB (n = 63) | |
| Age, years | 52.1 ± 12.1 | 53.4 ± 11.8 | 50.7 ± 12.4 | $t(130) = 1.28$, $p = 0.20$ |
| Gender, female | 64 (48.5) | 35 (50.7) | 29 (46.0) | Fisher's exact test ¹ , $p = 0.61$ |
| Race, white | 72 (54.5) | 40 (42.0) | 32 (49.2) | Fisher's exact test ¹ , $p = 0.49$ |
| Marital status, married | 76 (57.6) | 42 (60.9) | 34 (54.0) | $\chi^2(4) = 1.91$, $p = 0.75$ |
| Education, ≥ 12 years | 93 (70.5) | 53 (76.8) | 40 (63.5) | $\chi^2(4) = 3.05$, $p = 0.55$ |
| Employed, yes | 36 (27.3) | 20 (29.0) | 16 (25.4) | Fisher's exact test ¹ , $p = 0.70$ |
| Dialysis, yes | 95 (72.0) | 48 (69.6) | 47 (74.6) | Fisher's exact test ¹ , $p = 0.57$ |
| Dialysis time, months | 22.5 ± 18.3 | 20.5 ± 18.2 | 24.5 ± 18.3 | $t(130) = 1.08$, $p = 0.29$ |
| Prior kidney transplantation, yes | 17 (12.9) | 7 (10.1) | 10 (15.9) | Fisher's exact test ¹ , $p = 0.44$ |

Values are M ± SD or No. (%).

¹Only p-value is reported because Fisher's exact test does not yield formal test statistic or critical value.

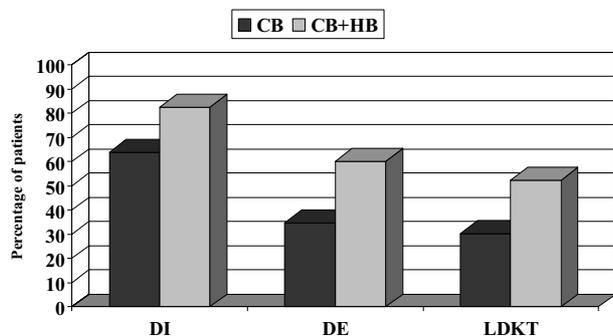


Figure 2: Percentage of patients with living donor inquiries (DI), living donor evaluations (DE) and live donor kidney transplant (LDKT).

knowledge scores improved significantly from the baseline to the post-clinic education assessment for all patients ($p < 0.001$), and that additional knowledge gains were achieved for patients receiving the HB education ($p < 0.0001$). Overall improvement from baseline to post-clinic education averaged 17.0% for all patients and there was an additional 26.9% improvement in knowledge scores after the HB education. Similar group by time interactions were also observed in both willingness to talk to others about LDKT ($F_{2,260} = 60.12, p < 0.0001$) and LDKT concerns ($F_{2,260} = 26.67, p < 0.0001$). The CB education did not yield any significant change in willingness to talk to others or in LDKT concerns for either group of patients ($p > 0.05$). However, patients reported a significant increase in willingness to talk to others about LDKT and a 27.8% decrease in the number of LDKT concerns after the HB education.

Discussion

This is the first prospective randomized clinical trial to examine the effects of an HB educational program on increasing rates of LDKT. Primary analyses demonstrated that supplementing CB education with an intensive HB educational module focused on living kidney donation was effective at increasing living donor inquiries, evaluations and transplants, compared to CB education alone. We also demon-

strated that more potential living donors can be reached and educated about LDKT in an HB outreach program. Also, while CB education effectively increased patients' knowledge about LDKT, an HB program that focused specifically on living donation issues further enhanced patients' knowledge, increased their willingness to talk to others about LDKT, and reduced their LDKT concerns and fears. This is essential since our multivariate analyses demonstrated that these modifiable factors are highly predictive of subsequent LDKT.

There are many possible reasons why the HB intervention was so effective. By delivering an educational program in the home, we were able to more effectively reach African American patients and family members and friends who could not attend clinic appointments with the patient, to clarify misinformation and fears more effectively in an informal setting, to circumvent the issue of asking donors that often makes patients so uncomfortable by having potential donors present during the educational session, and providing an opportunity for potential donors to tell patients directly about their willingness to be living donors. How much each of these factors contributed to higher LDKT rates is unknown and warrants careful study.

Of particular importance was the effectiveness of our HB education at reaching African American patients and their extended support system. In the three years prior to study initiation, only 12.8% of African Americans at the study site received LDKT, which is consistent with the 13.8% rate we observed in the CB group. In contrast, 45.2% of African American patients in the CB+HB group underwent LDKT, which represents a nearly four-fold increase from the three years prior to study implementation. Others have similarly shown that living donation education programs can effectively increase LDKT rates for African Americans. For instance, LDKT rates at the University of Maryland increased from 9% to 17% following the implementation of a focused living donor education program with a strong community outreach component (15–17). Recent findings indicate that African American patients may be less willing to pursue LDKT because of lower knowledge about the potential benefits of LDKT, more concerns about harming potential donors, and fears of losing the transplanted

Table 3: LDKT knowledge, willingness to discuss LDKT with others and LDKT concerns: Group comparisons

| Measure | Group | Baseline (T ₁) | Post-clinic (T ₂) | + / - | Post-home (T ₃) | + / - |
|----------------------------------|-------|----------------------------|-------------------------------|-------|-----------------------------|-------|
| LDKT knowledge ¹ | CB | 8.8 ± 2.1 | 10.3 ± 2.4 | +1.5 | | |
| | CB+HB | 8.8 ± 1.7 | 10.4 ± 2.3 | +1.6 | 13.2 ± 1.4 | +2.8 |
| Willingness to talk ² | CB | 4.0 ± 1.9 | 4.1 ± 1.7 | +0.1 | | |
| | CB+HB | 3.8 ± 1.8 | 3.7 ± 1.5 | -0.1 | 6.1 ± 0.9 | +2.4 |
| LDKT concerns ³ | CB | 9.9 ± 3.7 | 9.9 ± 3.6 | 0.0 | | |
| | CB+HB | 9.3 ± 3.8 | 9.0 ± 3.6 | -0.3 | 6.5 ± 3.0 | -2.5 |

¹Possible scores range from 0 to 15, with higher scores indicating more knowledge.

²Possible scores range from 1 to 7, with higher scores indicating more willingness to talk to others about LDKT.

³Possible scores range from 0 to 21, with higher scores indicating more concerns about pursuing LDKT.

kidney (18,19). An LDKT educational program that is culturally sensitive, includes patients and their extended support system, is community-based and informal, and allows ample time for questions and answers may help to increase donation knowledge, reduce fears and concerns about living donation, and increase willingness to pursue LDKT.

Many individuals who attended the HB education session expressed a strong interest or desire to donate a kidney to the patient. However, consistent with recent research (20), the patients themselves often refused to allow potential donors to be evaluated, largely because of their fears and concerns, which may not have been attenuated by the CB education. The most common patient concerns reported in our study were feeling inadequately informed about the donation evaluation and selection process, feeling guilty if a family member or friend was determined to be an ABO match, too many out-of-pocket expenses for the donor, wasting the donated kidney because of lifestyle factors, the amount of pain the donor would experience, how the donor's work responsibilities would be covered, how long it would take for the donor to resume normal activities, and whether the donor would experience problems in obtaining health or life insurance later in life. Waterman et al. (9,11) has similarly found that such fears and concerns are sometimes in sharp contrast to the generally high willingness of family members and friends to improve the health and well-being of their loved ones via living donation (10,21,22). Similarly, many who attended the HB education, while generally very favorable toward living donation, expressed a great deal of misunderstanding about living donor eligibility criteria, evaluation processes, surgery and recovery, and recipient outcomes. By conducting educational sessions in the patient's natural environment, we were able to directly address the concerns of *both* patients and potential living donors in an interactive way that could not be done during a routine transplant clinic visit. Despite lacking some basic knowledge about living donation, family members and friends often articulated for the patient the many positive benefits they would derive from living donation, which have been substantiated empirically to some degree (10,23–28), including satisfaction in being able to help a loved one, personal growth and enhanced quality of life secondary to reduced patient caregiving activities, among others. Even those who were otherwise unable to be living donors expressed interest in increasing their own awareness of LDKT so that they could effectively help the patient identify and talk to other potential living donors. These individuals have the potential to play an important ambassador role on behalf of patients once they acquire more knowledge about living donation and LDKT.

In light of patients' low baseline knowledge of living donation, it is not surprising that they had numerous concerns and heightened apprehension about pursuing LDKT. Many patients do not know how to ask family members and friends to consider donation (9). Over a third of patients

(38.6%) in our study expressed the concern that nobody would agree to be a living donor if they asked family members and friends to consider it. However, one-third of these patients subsequently went on to receive LDKT. Acquiring a clear understanding and realistic appraisal of the risks and benefits for both the patient and donor may facilitate the request process for patients. It is noteworthy that we spend considerable time and resources on training organ procurement professionals to make a sensitive and effective request of family members to donate a loved one's organs at the time of death (29–31). Why would we not have an equally intensive approach in educating, training and assisting patients to make a similar request for organ donation, albeit from a living donor?

Findings from this study should be evaluated within the context of several important methodological limitations. First, there are inherent self-selection biases in a study of this type. It is possible that those patients who chose to participate in this study were already thinking about LDKT, had more favorable attitudes toward LDKT, were more likely to participate in research, and/or were more emotionally prepared to involve others in LDKT discussions. Indeed, the 64% of CB patients who had living donor inquiries is considerably higher than the proportion of wait-listed patients (approximately 50%) who generally have living donor inquiries at the study site and at other centers (32). It is unknown whether the HB education would have any effect on LDKT rates for those patients who are not yet contemplating LDKT. Second, the dropout rate was significantly higher for patients randomized to receive home visits. While there were no differences between study completers and dropouts on measures of LDKT knowledge, willingness and concerns, the higher dropout rate in this group may reflect greater patient ambivalence about discussing these issues openly with family members and friends. Third, since the secondary outcomes for CB patients were not reassessed a third time (i.e. to correspond with the post-HB assessment), it is possible that the passage of time (4 weeks, on average) was responsible, in part, for the favorable knowledge, willingness and concern changes observed in the CB+HB group. Finally, this was a single-center study conducted in a predominantly rural region of the South, which limits the generalizability of the findings. Moreover, the higher rate of LDKT in the CB+HB group could be explained partly by a CB educational program that is not well designed to address LDKT issues. It is possible that transplant programs with already high LDKT rates may not achieve much additional boost in living donations with an HB educational program.

Notwithstanding these relative limitations, we believe that patients should be encouraged to pursue LDKT because it yields superior outcomes to deceased donor transplantation, avoiding or reducing dialysis for most patients is associated with better graft survival after transplantation, it has been shown to be safe for donors, and the risk of death while awaiting deceased donor transplantation is too

high in light of the severe organ shortage. In addition to ongoing discussions with patients about LDKT, kidney transplant programs should strive to develop and implement a formal LDKT educational program that is culturally sensitive and that involves as many individuals as possible from the patient's support system. The HB educational intervention described herein is one example of an effective community outreach program that incorporates the patient's primary support system in the LDKT educational process.

Finally, future research should evaluate the medical cost-offsets associated with an HB intervention. As implemented in this study, delivering an educational program in the patient's home cost approximately \$365 per patient, which includes health educator training, salaries, travel costs and educational materials. Transplant programs must also bear the cost of more donor inquiries and evaluations, if they do not lead to actual LDKT for the patient. These expenditures, however, are likely offset by the cost savings associated with dialysis avoidance, less transplant waiting time, and better outcomes that are associated with LDKT.

Acknowledgments

We thank the following individuals for their assistance in the preparation and/or conduct of this study: Glenn Ashkanazi, Daniel Baughn, Jason Burns, Sandra Demasters-Reynolds, Steven Durham, Shawna Ehlers, Gary Gefken, Kathleen Giery, Robert Guenther, Joni Lloyd-Turner, Kathleen MacNaughton, Shelly Morgan, Jeanne Renderer, Jeff Stoll, Stephanie Toy, Jennifer Watson and Michelle Widows. We also thank the entire transplant center staff for assistance in recruiting participants and tracking primary outcomes.

This research was supported by a grant from the U.S. Department of Health and Human Services, Health Resources and Services Administration (Division of Transplantation, 5H390T00115).

There are no conflicts of interest to report.

References

1. Sheehy E, Conrad SL, Brigham LE et al. Estimating the number of potential organ donors in the United States. *N Engl J Med* 2003; 349: 667–674.
2. Hariharan S, Johnson C, Bresnahan B, Taranto S, McIntosh M, Stablein D. Improved graft survival after renal transplantation in the United States, 1988 to 1996. *N Engl J Med* 2000; 342: 605–612.
3. U.S. Scientific Registry for Transplant Recipients and the Organ Procurement and Transplantation Network. Website (www.ustransplant.org) accessed August 15, 2006.
4. Mange KC, Joffe MM, Feldman HI. Effect of the use or nonuse of long-term dialysis on the subsequent survival of renal transplants from living donors. *N Engl J Med* 2001; 344: 726–731.
5. Tarantino A. Why should we implement living donation in renal transplantation? *Clin Nephrol* 2000; 53: 55–63.
6. Meier-Kriesche HU, Kaplan B. Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: a paired donor kidney analysis. *Transplantation* 2002; 74: 1377–1381.

7. Smith CR, Woodward RS, Cohen DS et al. Cadaveric versus living donor kidney transplantation: A Medicare payment analysis. *Transplantation* 2000; 69: 311–314.
8. United Network for Organ Sharing. 2004 annual report of the U.S. Scientific Registry for Transplant Recipients and the Organ Procurement and Transplantation Network. UNOS, Richmond, VA, and the Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, U.S. Department of Health and Human Services, Rockville, MD, 2005.
9. Waterman AD, Stanley SL, Covelli T et al. Living donation decision making: recipients' concerns and educational needs. *Prog Transplant* 2006;16:17–23.
10. Burroughs TE, Waterman AD, Hong BA. One organ donation, three perspectives: experiences of donors, recipients, and third parties with living kidney donation. *Prog Transplant* 2003;13:142–150.
11. Waterman AD, Stanley SL, Barrett AC, Waterman BM, Shenoy S, Brennan DC. Refusing living donors? Renal patient predictors of not having living donors evaluated. Paper presented at the World Transplant Congress, Boston, MA, July, 2006.
12. Waterman AD, Barrett AC, Stanley SL et al. Psychosocial and knowledge barriers preventing renal patients from pursuing living and deceased donor transplantation. Poster presented at the World Transplant Congress, Boston, MA, July, 2006.
13. Lunsford SL, Simpson KS, Chavin KD et al. Racial differences in coping with the need for kidney transplantation and willingness to ask for live organ donation. *Am J Kidney Dis* 2006; 47: 324–331.
14. Bronfenbrenner U. The ecology of human development. Cambridge, MA: Harvard University Press, 1979.
15. Foster CE, Philopophe B, Schweitzer EJ et al. A decade of experience with renal transplantation in African-Americans. *Ann Surg* 2002; 236: 794–804.
16. Bartlett ST, Farney AC, Jarrell BE et al. Kidney transplantation at the University of Maryland. *Clin Transpl* 1998; 12: 177–185.
17. Schweitzer EJ, Yoon S, Hart J et al. Increased living donor volunteer rates with a formal recipient family education program. *Am J Kidney Dis* 1997; 29: 739–745.
18. Waterman AD, Barrett AC, Stanley SL et al. Why African Americans are not pursuing living kidney donation. Paper presented at the World Transplant Congress, Boston, MA, July, 2006.
19. Lunsford SL, Simpson KS, Chavin KD et al. Racial differences in coping with the need for kidney transplantation and willingness to ask for live organ donation. *Am J Kidney Dis* 2006; 47: 324–331.
20. Martinez-Alarcon L, Rios A, Conesa C et al. Attitude toward living related donation of patients on the waiting list for a deceased donor solid organ transplant. *Transplant Proc* 2005; 37: 3614–3617.
21. Pradel FG, Mullins CD, Bartlett ST. Exploring donors' and recipients' attitudes about living donor kidney transplantation. *Prog Transplant* 2003; 13: 203–210.
22. Lennerling A, Forsberg A, Meyer K, Nyberg G. Motives for becoming a living kidney donor. *Nephrol Dial Transplant* 2004; 19: 1600–1605.
23. Johnson EM, Anderson JK, Jacobs C et al. Long-term follow-up of living kidney donors: Quality of life after donation. *Transplantation* 1999; 67: 717–721.
24. Switzer GE, Dew MA, Twillman RK. Psychosocial issues in living organ donation. In Trzepacz P, DiMartini A, eds. The transplant patient: Biological, psychiatric and ethical issues in organ transplantation. Cambridge: Cambridge University Press, 2000. pp. 42–66.
25. Rodrigue JR, Cross NJ, Newman RC et al. Patient-reported outcomes for open versus laparoscopic live donor nephrectomy. *Prog Transplant* 2006; 16: 162–169.

26. Fehrman-Ekholm I, Brink B, Ericsson C et al. Kidney donors don't regret. *Transplantation* 2000; 69: 2067–2071.
27. Ku JH. Health-related quality of life of living kidney donors: review of the short form 36-health questionnaire survey. *Transpl Int* 2005; 18: 1309–1317.
28. Schover LR, Stroom SB, Boparai N, Duriak K, Novick AC. The psychosocial impact of donating a kidney: Long-term followup from a urology based center. *J Urol* 1997; 157: 1596–1601.
29. Marks WH, Wagner D, Pearson TC et al. Organ donation and utilization, 1995-2004: entering the collaborative era. *Am J Transplant* 2006; 6: 1101–1110.
30. Zink S, Wertlieb S. A study of the presumptive approach to consent for organ donation: a new solution to an old problem. *Crit Care Nurse* 2006; 26: 129–136.
31. Shafer TJ, Ehrle RN, Davis KD et al. Increasing organ recovery from level I trauma centers: the in-house coordinator intervention. *Prog Transplant* 2004; 14: 250–263.
32. Stothers L, Gourlay WA, Liu L. Attitudes and predictive factors for live kidney donation: A comparison of live kidney donors versus nondonors. *Kidney Int* 2005; 67: 1105–1111.