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Long-term Financial, Psychosocial, and Overall Health-Related Quality of Life After Living Liver Donation.

Muhammad H. Raza¹, Michelle H. Kim^{1,2}, Li Ding³, Tse-Ling Fong^{1,4}, Christian Romero⁵, Yuri Genyk^{1,2}, Linda Sher^{1,2}, Juliet Emamaullee^{1,2}

¹Keck School of Medicine, University of Southern California, Los Angeles, CA USA

²Division of Hepatobiliary and Abdominal Transplant Surgery, Department of Surgery, University of Southern California, Los Angeles, CA USA

³Department of Preventive Medicine, University of Southern California, Los Angeles, CA USA

⁴Department of Gastrointestinal and Liver Diseases, University of Southern California, Los Angeles, CA USA

⁵Department of Surgery, University of Southern California, Los Angeles, CA USA

Abstract

Objective: To assess the impact of living liver donation (LD) in a diverse and aging population up to 20 years post-donation, particularly with regards to medical, financial, psychosocial and overall health-related quality of life (HRQOL).

Methods: Patients undergoing LD between 1999 and 2009 were recruited to respond to the Short-Form 36 (SF-36) and a novel Donor Quality of Life Survey (USC DQLS) at two time points (2010, 2018).

Results: Sixty-eight living liver donors (LLDs) completed validated surveys, with a mean follow-up of 11.5±5.1 years. Per USC DQLS data, physical activity or strength was not impacted by LD in most patients. All respondents returned to school or employment, and 82.4% reported that LD had no impact on school or work performance. LD did not impact health insurability in 95.6% of donors and only one patient experienced difficulty obtaining life insurance. Overall, 97.1% of respondents did not regret LD. SF-36 measured outcomes were similar between LLDs and the general U.S. population. LLDs who responded in both 2010 and 2018 were followed for an overall average of 15.4±2.4 years and HRQOL outcomes in these donors also remained statistically equivalent to U.S. population norms.

Conclusions: This study represents the longest post-donation follow-up and offers unique insight related to HRQOL in a highly diverse patient population. Although LLDs continue to maintain excellent HRQOL outcomes up to 20 years post-donation, continued lifetime follow-up is required to accurately provide young, healthy potential donors with an accurate description of the risks that they may incur upon aging.

Precis:

Corresponding Author: Juliet Emamaullee MD PhD FRCSC, 1510 San Pablo Street, Suite 412, Los Angeles, CA 90033, Tel: 323.442.5908, Fax: 323.442.6887, Juliet.emamaullee@med.usc.edu.

Living liver donors maintain excellent health-related quality of life outcomes even up to 20 years post-donation. However, surgery-related complications may present themselves many years post-donation. Continued lifetime follow-up is required to accurately provide future donors with an accurate description of the risks that they may incur as they age.

Keywords

living liver donation; living donor liver transplantation; quality of life

Introduction

While liver transplantation (LT) is the accepted treatment for patients with end-stage liver disease and liver failure (1), there is a disparity between the number of available deceased donors and the growing number of patients registered on the transplant waiting list (2). Many programs have established living donor liver transplantation (LDLT) programs in light of this critical organ shortage, with more than 4,500 LDLT procedures performed across the U.S. since 1998 (3,4). Although most of the early technical challenges of LDLT have been overcome with experience, LDLT has plateaued at approximately 4% of all liver transplants performed in the U.S. since the early 2000's, likely related to a combination of factors including MELD-based allocation and concerns related to donor morbidity and mortality (3,5–9). Centers must weigh donor safety concerns, psychologic morbidity, and overall complications (8–15) against the benefits of decreased waiting time and waitlist mortality along with equivalent or even superior graft and patient survival when compared to DDLT (16–19).

Living liver donor (LLD) short and long-term outcomes, health-related quality of life (HRQOL), and psychosocial consequences post LDLT continue to be examined (15,20–25). While there are several studies reporting on short- and medium-term outcomes, the lifetime impact of a major liver resection in a healthy individual with no medical indication is less known. As a discipline that has evolved into its current state over the past 30 years (3), data regarding long-term outcomes in LLDs specifically related to medical, physical, financial, and psychosocial outcomes is limited by total experience and the fact that most donors are relatively young (1). While 30 years of data is helpful, there remains a paucity of research utilizing both validated HRQOL assessments and comprehensive transplant-specific survey tools to investigate outcomes in LLDs more than a decade after initial surgery. Further, most U.S. studies assessing HRQOL impacts of LD using standardized survey tools report outcomes for study populations of majority non-Hispanic white LLDs (20,25–29). Thus, many questions regarding the lifetime impact of LD in ethnically diverse donor populations remain unanswered.

The objective of this study was to extend knowledge of the long-term impact of LD beyond previously reported timelines. This was guided by a holistic examination of HRQOL impacts and medical, physical, emotional, employment, and insurability outcomes up to 20 years post-donation in an ethnically diverse population of LLDs from a high-volume LDLT center. Using a novel transplant-specific survey tool called the Donor Quality of Life Survey (USC

DQLS) and a standardized Short-Form 36 Health Survey (SF-36), HRQOL in LLDs followed over a mean duration of 11.5 ± 5.1 years was characterized. These data represent the longest average follow-up reported to date of a diverse but aging LD population and are important for 1) continuously improving upon the donor consent process 2) managing donor expectations and 3) addressing challenges confronting donors well beyond the years of clinical follow-up.

Methods

Study Design

This study was approved by the Institutional Review Board at the University of Southern California (USC). Partial liver donors for all LDs performed at USC between 1999 and 2009 with a minimum of one-year or more post-donation follow-up were approached as potential survey respondents ($n=117$; summarized in Figure 1). Donors were surveyed through two time periods, 2010 (T1) by mail and 2018 (T2) by phone. In these two time periods, donors were asked to complete the SF-36 and USC DQLS. At T2, contact attempts were only made with donors who responded at T1 ($n=68$). An aggregate survey analysis of 68 LLDs was conducted using only the latest validated survey set if responses were obtained by LLDs at both time points ($n=30$). An additional analysis of change in SF-36 outcomes over time was conducted for the 30 LLDs who successfully responded at both time points. Demographic data and post-operative complications (Clavien-Dindo classification) occurring within two years post-donation were retrospectively reviewed (30). Recipient outcomes are reported based on recipient status when donors completed their latest validated survey.

QOL Assessments

The USC DQLS, specifically designed in 2004 as a unique LLD-specific assessment tool by the transplant team, consists of 44 questions assessing donor-reported outcomes across five categories: medical condition, physical activity, employment, insurance, and emotional status (Supplemental Figure 1). For each of the 20 possible open-ended question stems, verbatim narrative responses were recorded. These qualitative data were subjected to content analysis to detect similarities and differences in responses and thematically coded by two members of the research team in accordance with established techniques (31).

The SF-36 is a standardized tool designed to assess generic health outcomes which can be compared to broad population datasets using well-established techniques (32–34). Country-specific weights can be assigned to each of the eight categories to generate standardized and correlated physical (PCS_c) and mental (MCS_c) component summary scores for individual respondents (35). In this study, mean scores in each of the eight categories, along with orthogonal PCS_c and MCS_c , were compared to the latest available U.S. population norm from 1998 (32).

Statistics

For patient demographics and the USC DQLS, mean and standard deviation are reported for continuous variables, and frequencies and percentages are reported for categorical variables. For the SF-36, mean standard normal scores are reported for the eight individual scales. A

two-sided one sample t-test for equivalence was used for comparison of standardized Z-scores with a population mean of 50, using one standard deviation from the norm to set equivalence margins of 40 and 60. Means are reported with 90% confidence interval (CI). A paired t-test was used for standardized Z scores comparison between T1 and T2 time points. The Wilcoxon rank-sum test was used for Z scores comparison of donor outcomes by recipient status. All analysis was performed using SAS v9.4, and figures were generated using Excel v16.30.

Results

Sixty-eight unique LLDs completed surveys between 1.4 to 19.5 years post-donation, with an overall response rate of 58.1% (68/117). Of the 68 study participants, 30 (44.1%) responded to the SF-36 and USC DQLS in both 2010 and 2018. Overall mean follow-up time was 11.5±5.1 years for the aggregate survey analysis of 68 LLDs and 15.4±2.4 years for the longitudinal analysis of 30 LLDs using SF-36 data from two time points.

Demographics

Patient characteristics of LLDs are included in Table 1. The majority of LLDs underwent right lobe hepatectomy (n=66, 97.1%). The average length of hospital stay was 7.3±4.3 days, with a majority of LLDs discharged on post-operative day six (n=21, 30.9%) or seven (26.5%). While 48.5% of the respondents were non-Hispanic white (n=33), our donor population was highly diverse with 44.1% Hispanic, 5.9% Asian, and 1.5% Black LLDs. Adult children (n=25, 36.8%) and siblings (26.5%) of the LDLT recipients represented the most common relationship between the LLD and intended recipient. Recipients labeled 'blood relatives' include individuals who were second degree or higher relatives, such as niece/nephew, aunt/uncle, or cousin (n=8, 11.8%). A total of 45 (66.2%) LDLT recipients were alive at the latest time point of donor follow-up, with 25 (36.8%) free of recurrent liver disease, 20 (29.4%) alive with recurrent liver disease, and 23 (33.8%) deceased.

Intra- and Early Post-operative Complications

In this study of 68 LLDs, no donors experienced intra-operative complications. However, two LLDs underwent a preemptive hepaticojejunostomy patch of the right hepatic duct orifice to prevent future stricture. Review of medical records revealed that a total of 18 early post-operative complications (occurring within two years post-donation) of Clavien-Dindo Grade I or higher were experienced by 14 donors (20.6%), with n=5 Clavien-Dindo Grade I, n=6 Grade II, n=1 Grade IIIa, and n=6 Grade IIIb requiring re-operation (Table 2). Of these, a single donor experienced both a Grade I and IIIb complication while two LLDs experienced two Grade IIIb complications that were treated concurrently. The most common early post-operative complications were bile leak (n=3), infection (n=3), incisional hernia (n=2), and urinary tract infection (n=2). During the study period, the overall complication rate for all LLDs at USC up to two years post-donation was 17.5%, which was no different from the subgroup who participated in this study.

USC DQLS

Medical Issues—Table 3 demonstrates the responses regarding follow-up medical care and conditions. Sixty donors (88.2%) reported seeing a physician other than their surgeons since donation, including 29 (42.6%) who reported receiving a new medical diagnosis which may be relevant to LDLT (Supplemental Table 1). Interestingly, one LLD was diagnosed with primary biliary cholangitis (PBC) 37 months post-donation, which has since been managed with ursodiol therapy. The same donor underwent a hepaticojejunostomy drainage of a dilated orphan duct and incisional hernia repair 23 months post-donation. Twenty-six donors (38.2%) reported undergoing surgery since donation (Supplemental Table 1). Six donors reported undergoing surgery for conditions which may relate to their history significant for LD and include the above mentioned bile duct reconstruction (n=1), uncomplicated appendectomy (n=1), umbilical hernia repair (n=1), incisional hernia repair (n=3), and laparoscopic lysis of adhesions for small bowel obstruction (n=3). Of the LLDs undergoing these specified surgeries, one LLD underwent surgery for both small bowel obstruction and incisional hernia repair on separate occasions. The LLD undergoing surgery for uncomplicated appendectomy reported doing so nine months after donation, presumably at an outside facility, while also undergoing laparoscopic surgery for small bowel obstruction at a later unspecified date. This appendectomy was not noted as a possible early post-donation complication as it could not be verified by our center's electronic medical records.

Physical Activity—Sixty-nine percent of donors (n=47) reported resuming the same level of physical activity post-donation (Table 3), and a further 8.8% (n=6) reported performing more. However, nearly half (n=33, 48.5%) reported restricting the type of physical activity that they performed. Forty donors (58.8%) indicated that they exercise regularly post-donation and 26 went further to list the following as their activities of choice: walking (57.7%), running (19.2%), weight training (15.4%), riding bike (15.4%), hiking (11.5%), yoga (7.7%), aerobics (7.7%), elliptical/treadmill (7.7%), and swimming (3.8%).

Emotional Impact—An overwhelming majority of donors felt positive about their surgery (n=59, 86.8%), positive or neutral about their surgical scar (n=58, 85.3%), and did not regret their decision to donate a portion of their liver (n=68, 97.1%) (Table 3). Of the two individuals reporting to regret their decision, both had donated to friends with whom they no longer shared a positive relationship. A sizeable proportion of responding LLDs (n=22, 32.8%) reported feeling negative or conflicted about the surgery's emotional effects. However, the majority of donors who felt negative or conflicted about the emotional impact of surgery had donated to recipients who were either diagnosed with recurrent liver disease or had died by the time of follow-up (n=16, 72.7%). Approximately half (n=37, 54.4%) of LLDs indicated that the discomfort associated with their surgery was more than initially expected, reflected in their suggestions for future donor education and psychosocial support (Table 4). When asked about their decision to donate, a majority of respondents (n=58, 85.3%) reported their motivation to stem from a desire to save their loved one's life. Five donors reported donating on moral grounds. Four donors chose to donate due to a lack of faith in the healthcare system to match their loved one with a cadaveric organ. One LLD

explicitly cited our center's experience and track record for excellent outcomes as a motivation to move forward with donation.

Employment and Insurance—Prior to donation, all but three donors were either students or employed (n=65, 95.6%) (Table 5). One donor reported not returning to their place of employment post-donation. However, upon further review of the patient's records, this individual had initially returned to work post-donation and subsequently stopped working following breast cancer treatment several years after. Of the 16.2% of donors reporting that surgery affected their job or school performance (n=11), taking more time off from work or school than expected in addition to loss of focus and fatigue upon initial return to employment were the primary reasons. Although 85.3% of donors did not encounter any difficulties at school or work due to donation (n=58), the remaining 13.2% (n=9) reported difficulties due to weightlifting restrictions, fatigue, lack of energy, incisional pain, or an increased urge to visit the restroom. In all, 98.5% of LLDs reported that live donation did not affect their ability to find employment. One LLD reported that surgery affected their job performance and that liver donation impacted their ability to find employment even though they were retired prior to surgery. They noted that although they were not employed before surgery, the effects of the surgery were such that their job performance and ability to find employment would have been hypothetically impacted.

The vast majority of LLDs (n=65, 95.6%) reported that live donation did not impact their health insurance status. Three individuals reported difficulty in obtaining a health insurance policy and that surgery had an adverse impact on their health insurance status, citing a rise in premiums (n=1), an increase in out-of-pocket expenditures due to surgery-related complications (n=1), and no further explanation (n=1). These donors were surveyed 5.6, 10.1, and 15.6 years after donation, respectively. Of note, two out of three of these donors' latest validated USC DQLS was completed in 2010, prior to enactment of The Patient Protection and Affordable Care Act (36). Among 19 donors who attempted to obtain life insurance coverage after surgery, one donor reported that a prior history significant for LD adversely impacted their ability to obtain coverage without providing further explanation.

SF-36—Sixty-eight donors completed the SF-36 at T1 while a total of 30 donors completed the survey at both T1 and T2. Figure 2 depicts mean standard normal SF-36 scale scores and 90% CIs for LLDs across eight measured categories as compared to the general U.S. population norm. PCS_c and MCS_c for LLDs were statistically similar to the U.S. population average. Mean MCS_c and PCS_c scores for non-Hispanic white LLDs (n=33) compared to the remainder of the study population were similar.

There were no differences in SF-36 measured HRQOL outcomes between LLDs experiencing early postoperative complications compared to LLDs who did not experience such complications in the first two years since donation (Table 6, **Part A**). Neither PCS_c ($P=0.64$) nor MCS_c ($P=0.98$) were different between LLDs donating to recipients who were alive compared to deceased at the time of follow-up (Table 6, **Part B**).

Mean PCS_c and MCS_c scores for LLDs as a function of time since donation are depicted in Figure 3, Panel A revealing that even beyond 15 years post-donation, population adjusted

PCS_c and MCS_c remain equivalent between LLDs and the general U.S. population. A serial comparison of SF-36 measured HRQOL outcomes for 30 LLDs surveyed at T1 and T2, representing a mean follow-up of 15.4±2.4 years since donation, is depicted in Figure 3, Panel B. The average age of these LLDs at T1 was 42.0±9.7 years and 50.7±9.7 years at T2 (n=30). Although PCS_c did not change over time ($P=.08$), MCS_c scores did reveal a modest decline ($P=.004$). Nonetheless, these measures remained statistically equivalent to the general U.S. population at both time points.

Discussion

LDLT has an approximately 30-year history, making it newer by contrast to other surgical procedures. Further, due to the fact that donors are generally younger and healthier individuals, long-term outcomes, including the lifetime risk of having had a previous liver resection, must be carefully considered. This information is of paramount importance for properly consenting potential partial liver donors and for the procedure's programmatic expansion. Our findings indicate that LLDs donating between 1999 and 2009 remain largely satisfied with their decision to donate even more than a decade after undergoing surgery, consistent with the experience of the A2ALL Consortium and the Toronto program (5,22).

Early Postoperative Complications

There is a considerable literature outlining potential LLD-experienced complications in the early postoperative period, and complications experienced by our patient population were not unique (5,9,37–40). An early study from the A2ALL cohort consisting of 393 LLDs reported the most common early postoperative complications to be infection (12.5%), biliary leak beyond postoperative day 7 (9.2%), and incisional hernia (5.6%), consistent with the findings of our study (9). The A2ALL Study Group later published another comprehensive report of complications in 740 partial liver donors over a 12-year period from nine centers (5). In this study, 40% of donors developed complications, mostly Clavien-Dindo Grades I and II (89.9%), five Grade III complications, and three Grade IV complications leading to donor death. The authors proposed 40% to be a fairly definitive assessment of the risk of complications in the first year for right-lobe LLDs. However, only 18.2% of right-lobe LLDs (n=12) in our cohort experienced a Clavien-Dindo Grade I or higher complication within the first year of donation, while all were alive at the time of follow-up (no Grade IV complications). This discrepancy may in part be explained by the fact that our analysis of early-postoperative complications relied on center-specific medical records and did not capture possible complications for which treatment by LLDs was either not sought or was received at outside facilities. Another explanation may be include the fact that single-center reports of early-complication rates in LLDs can vary tremendously, with a recent systematic review documenting variability in early-postoperative morbidity rates ranging between 10% and 78.3% (6).

USC DQLS

Medical Condition—Documenting rates of new medical condition diagnoses along with the quantity and underlying reason for post-donation surgeries in LLDs may offer useful insight into the lifetime health-related impact of LD. Humphreville et al., reporting new

medical conditions diagnosed in LLDs with the next longest average follow-up of 7.7 years, do so for a cohort with only 30% of LLDs more than ten years out since surgery. In our study, 54% of all participating LLDs were more than ten years out from LD (n=37), and a further 37% (n=25) underwent LD more than 15 years prior. Still, 42.6% of LLDs in our study reported the diagnosis of a new medical condition or illness since surgery, largely consistent with the previously reported rate of 35% by Humphreville et al. (26). Although continued study of new medical diagnoses in an aging LLD population is merited, these data are reassuring in that rates of new medical diagnoses in the LLD population do not seem to be increasing with time since donation. On the other hand, the most significant surgical complication noted in our study revolved around elevated liver chemistries in one LLD 23 months post-donation, initially thought to indicate bile duct obstruction requiring reconstruction but ultimately diagnosed as PBC at 37 months post-donation. While the later diagnosis of PBC was made in this donor, this was previously unsuspected. Although her liver volume recovered, it is unclear how her liver disease will progress and how a prior liver resection will impact future medical treatment. Thus, it is important that potential LLDs be aware that certain problems may persist following the initial recovery period and be appraised of the potential lifetime health impacts of donation with regards to unexpected future illness. Additionally, the longer follow-up of our study disclosed nine abdominal surgeries in six LLDs potentially related to their history significant for LD. These findings are inconsistent with a recent study of 220 LLDs by Rudow et al. which found no complications (infection, obstruction, stomach muscle pain, hernia, bile leak, or other) present at six years after donation, noting these findings to be a reassuring sign for potential donors (29). We believe continued lifetime follow-up of the LLD population is required to provide young, healthy potential donors with an accurate description of the risks that they may incur as they develop medical issues in the future which inevitably accompany an aging population.

Emotional Status and Physical Activity—Investigating physical and emotional outcomes along with satisfaction with the donation process using quality of life (QOL)-specific tools allows future LLDs to provide informed consent consistent with a robust understanding of potential implications. Our findings are largely in line with those of prior studies looking into these factors (26,27,29,38). In a QOL assessment of 51 LLDs followed for an average of 6.6 years post-donation, Azoulay et al. reported 22% of LLDs restricting their level of vigorous physical activity after donation, lower than the 48.5% of LLDs reporting similar restrictions in our analysis. With regard to emotional outcomes, 86.8% of LLDs in our study reported feeling positive about their surgery, in line with the 90% feeling positive about donation in a study of 517 LLDs from the A2ALL cohort with mean follow-up of 5.8 years (27). Further, 88% of LLDs in our study reported feeling neutral or positive about their personal health more than a decade since surgery, similar to the previously reported 94% (38). We identified that several respondents continue to have physical and digestive symptoms even late after the procedure, consistent with previous findings, most likely due to cholecystectomy (26,29). Of note, a large number of respondents reported feeling inadequately informed on the long-term digestion-related consequences of cholecystectomy which highlights areas where transplant teams can do more to better set donor expectations. On the other hand, it is difficult to replicate some prior reports which

found that 0% of LLDs either regret their decision to donate or would not donate again, given the unique balancing act they must perform by weighing the immensely positive impact of their selfless gift for their recipients and the potential of personally experiencing undue morbidity (26,38). Nonetheless, only 2.9% of LLDs in our analysis reported regretting their decision to donate a portion of their liver, and that too as a consequence of a breakdown in interpersonal relationships with their biologically unrelated recipients. Taken together, this alone should be an encouraging sign for potential donors seeking to donate to an individual in need.

Employment and Insurance—One reason cited to explain an observed decline in rates of LDLT in the U.S. has been a lack of adequate financial coverage for LLDs, highlighting the need to study the financial impact these patients experience as a result of living donation. Of note, when compared to previously published studies, ours represents a remarkably ethnically diverse LLD population reported to date, many of whom come from the surrounding economically challenged areas of Southern California. In our study, more than 95% of LLDs returned to their place of employment after surgery, consistent with previous findings (26,29). Although prior studies have looked at differences in employment status prior to and after donation, a unique finding of our study is that surgery does not affect job or school performance in the vast majority of patients in the long-term. It should be reassuring to potential LLDs that most difficulties encountered at school or the workplace by our patient population stemmed from the short-term post-surgical symptoms, such as fatigue and loss of focus, which almost always resolve. Another unique finding of our study was related to insurance status outcomes. Remarkably, nearly 95% of LLDs who attempted to purchase a life insurance policy reported that LD did not impact their ability to do so. Overall, although most LLDs did not report financial or insurance hardships, there were still patients for whom this was a problem in the long-term. Financial considerations may cause the donor group to self-select to people with the means and ability to move forward with donation. Likewise, since most LLDs tend to be young and healthy individuals with many potential years of productivity ahead of them, costs related to medical diagnoses years after initial surgery possibly related to the donation have the potential to pose significant hardship and deter future donors from volunteering a portion of their liver. To increase the number of potential donors volunteering to come forward in the future, these financial issues must continue to be addressed.

SF-36 Outcomes—There are several studies utilizing the SF-36 to study “long-term” HRQOL along with financial, psychosocial, and emotional risks of partial liver donation, reporting data extending to a mean follow-up of 7.7 years (24–26,28,41). Most studies have concluded that LLDs report similar, if not better, physical and mental outcomes compared to the general population. Although these findings are consistent with our results in that PCS_c and MCS_c remain statistically similar to the general population even 15 years after donation, our patient population reveals statistically significant decline in MCS_c over time (Figure 3, Panel B). It is unknown how many LLDs had predisposing mental health conditions prior to donation. Although it is plausible that these findings are an artifact of natural aging, our findings are consistent with the A2ALL experience and may not be inconsequential (28).

Overall, these data indicate the need to adequately screen donors most at risk prior to donation and provide adequate long-term follow-up care to minimize psychiatric morbidity.

While prior reports have commented on the impact of race or ethnicity on HRQOL as measured by the SF-36, to our knowledge, this is the first report to assess such outcomes in a majority non-white LLD population. Prior A2ALL studies suggest conflicting findings; some report Hispanic ethnicity to be a predictor of poor PCS_c in LLDs (25) while others report no relation between race/ethnicity and SF-36 outcomes (27). We did not observe differences in SF-36 scores for Hispanic donors when compared to non-Hispanic white counterparts. A small sample size also limits our ability to draw definitive conclusions in this regard. To deliver optimal care, assessment of long-term HRQOL outcomes in racially heterogeneous LLD populations remains an important area for continued investigation.

The longer follow-up of our study provides insight into early post-operative complications experienced by LLDs or adverse outcomes experienced by their recipients, ultimately impacting long-term HRQOL. Takada et al. reported better HRQOL scores in LLDs compared to Japanese norms across all time periods for 578 donors with a mean follow-up of 6.8 years post-donation (24). However, they found that if donors were distressed by problems associated with complications for a prolonged period of time, their HRQOL as measured by MCS_c was poorer. Yet, in our analysis, having complications in and of itself did not impact long-term physical or mental status outcomes (Table 6, **Part A**), in line with findings from the A2ALL cohort (25) and those of Humphreville et al. (26). Further, lower SF-36 measured HRQOL outcomes have been reported for LLDs donating to recipients who died post-transplant (25,42). While some have shown no correlation at all (20,24), others have demonstrated that poorer LLD HRQOL is temporally related only in the short-term to recipient outcomes (43). In our patient population, neither PCS_c nor MCS_c were statistically different between LLDs whose recipients were alive compared to deceased at the time of donor follow-up (Table 6, **Part B**). These findings lend credence to the idea that time since donation may play a role in alleviating emotional distress in LLDs stemming from catastrophic outcomes experienced by their recipients.

Limitations—Not unique to QOL studies, there are many challenges to following study participants multiple years after donation. Donors enrolled in 2010 received surveys by mail, and a significant number of potential study participants donated before mobile phones became the norm. Existing contact information in donor databases may have been both inaccurate and insufficient, thereby limiting sample size, particularly with regard to the paired comparison of donor HRQOL outcomes at two time points. Ultimately, this may have led us to underreport on long-term metrics used to assess the lifetime impact of LD. Furthermore, although the USC DQLS was developed under the guidance of experienced transplant professionals, it lacks both the statistical and time-tested validation of standardized HRQOL assessment tools such as the SF-36. Yet, with a large number of open-ended questions, it leaves great flexibility for donors to express any and all concerns related specifically to the liver donation process, thereby allowing for the analysis of a comprehensive donor self-assessment with room for provision of unanticipated responses.

Conclusion—In summary, this study covers an LLD population followed for the longest reported median time of 11.5 years (n=68; mean, 11.5±5.1 years; range, 1.4–19.5 years), offering compelling insight into the potential lifetime impacts of LD in a highly diverse patient population. LLDs continue to maintain excellent HRQOL outcomes up to 20 years post-donation and do not report any lasting physical or psychosocial concerns. Yet, long-term follow-up reveals that surgery-related complications may present themselves many years post-donation, including small bowel obstruction and incisional hernia. Continued lifetime follow-up of the LLD population is required to more accurately provide young, healthy potential donors with an accurate description of the risks that they may incur after donation as they age. This will ensure that potential LLDs are well equipped to provide informed consent with a robust and comprehensive understanding of the long-term implications of their decision to give the ultimate gift of life.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

LD	Living liver donation
LLD	Living liver donor
HRQOL	Health-related quality of life
SF-36	Short-Form 36 Survey
USC DQLS	Donor Quality of Life Survey
LT	Liver transplantation
LDLT	Living donor liver transplantation
LT	Liver transplantation
MELD	Model for end-stage liver disease
USC	University of Southern California
T1	Time-point 1, 2010
T2	Time-point 2, 2018

PCS_c	Correlated physical component summary score
MCS_c	Correlated mental component summary score
CI	Confidence interval
PBC	Primary biliary cholangitis
QOL	Quality of life

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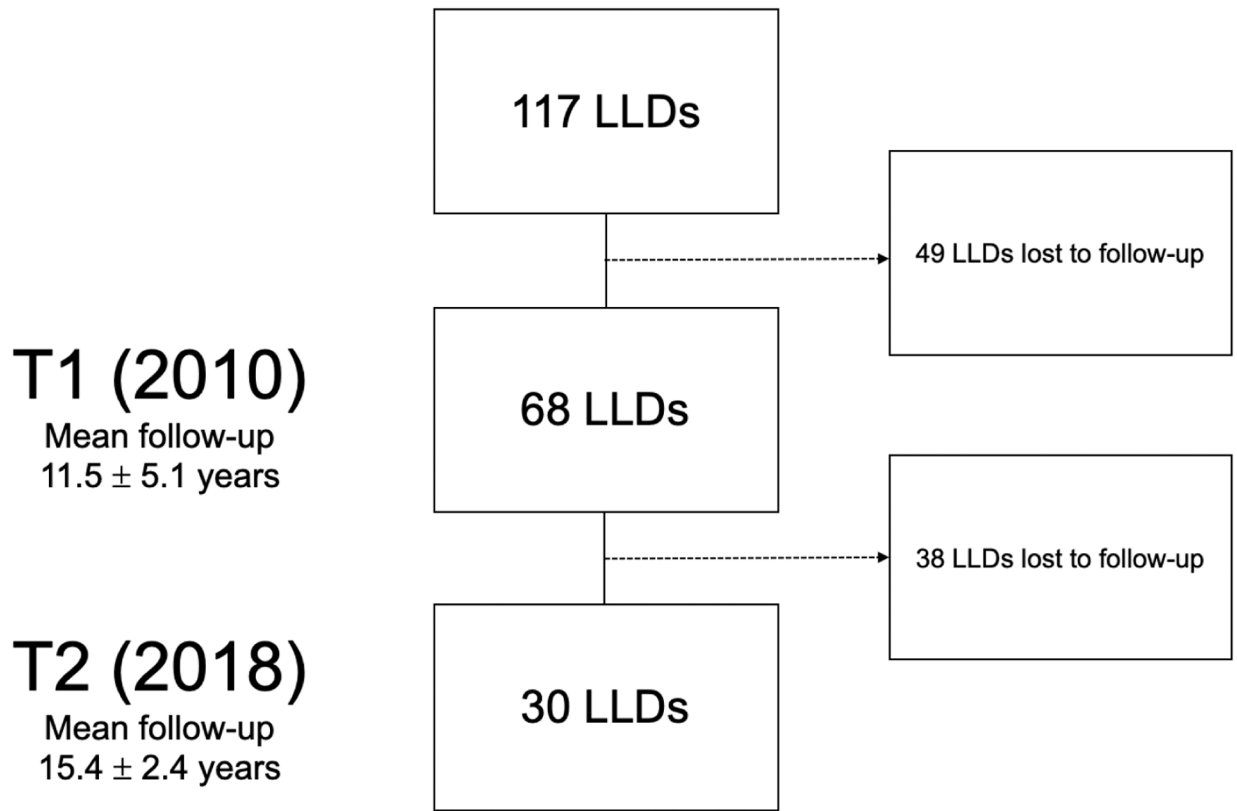
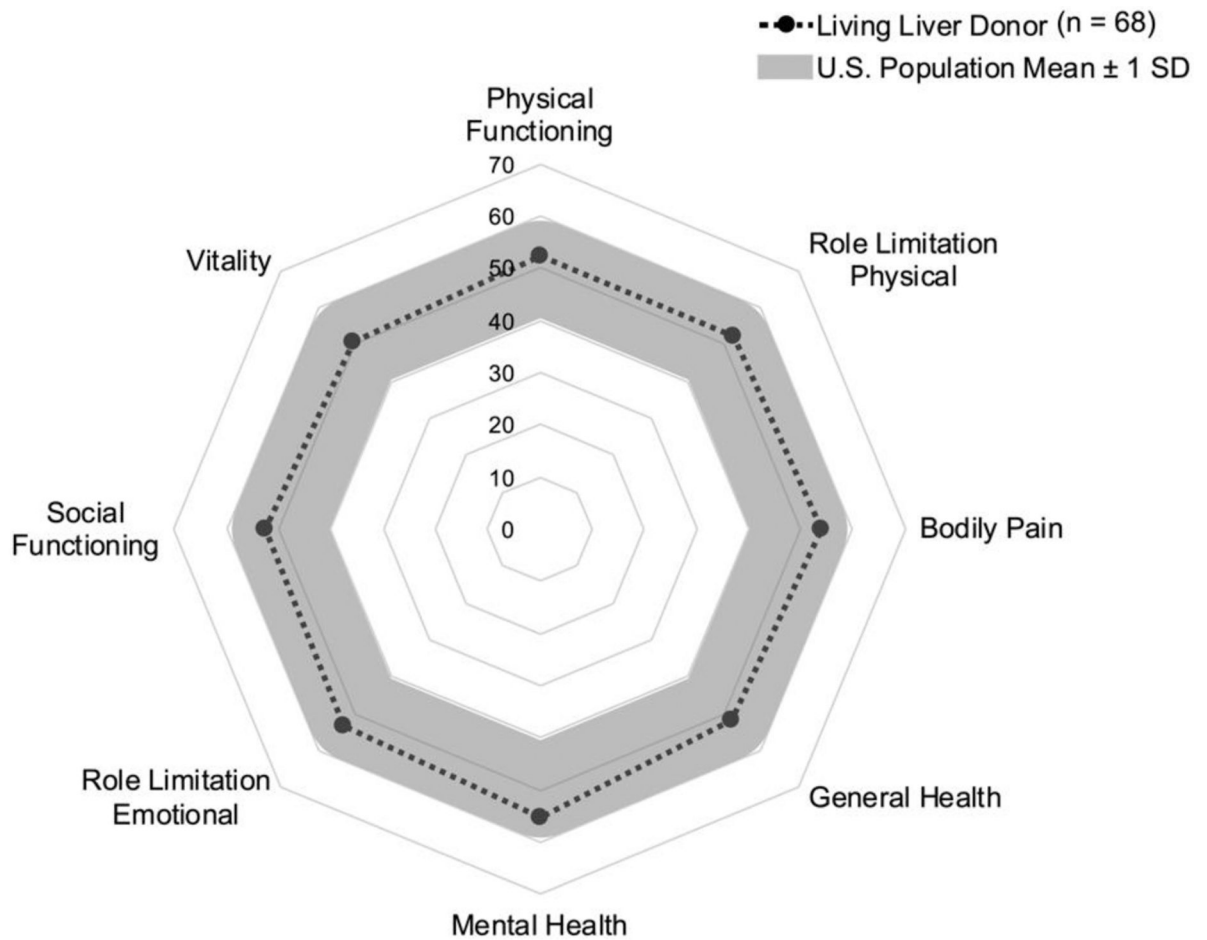


Figure 1:
Flow of study participants.



	Mean Score	90% CI	P Value	
			Lower	Upper
Physical Component Summary (PCS_c)	52.8	[51.1, 54.6]	<.001	<.001
Mental Component Summary (MCS_c)	53.4	[51.5, 55.4]	<.001	<.001

Figure 2: HRQOL estimated by mean standard normal SF-36 scale scores in LLDs.
P values for two-sided one-sample t test.

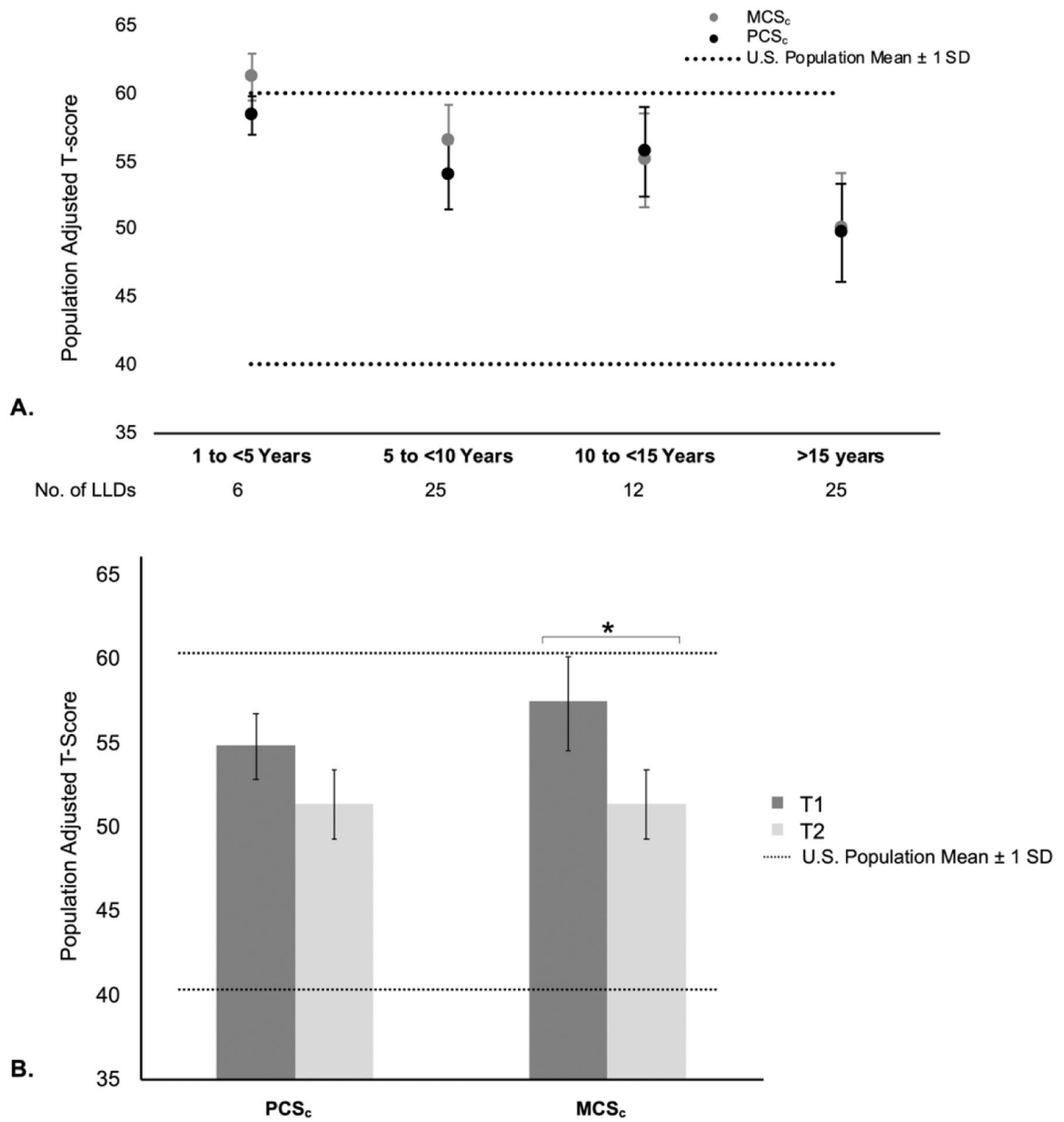


Figure 3: SF-36 outcomes in LLDs over time and 90% CIs.

Panel A depicts trends in mean PCS_c and MCS_c as a function of time since donation. Panel B depicts PCS_c and MCS_c in LLDs surveyed in 2010 (T1) and 2018 (T2) (n = 30). *Paired t-test, $P < .05$

Table 1:

Characteristics of LLDs responding to the SF-36 and USC DQLS.

Total respondents	68 (58.1)
Type of donation	
Right lobe	66 (97.1)
Left lobe	2 (2.9)
Age at Donation (Years), Mean \pm SD	36.8 \pm 9.8
18 to <35 years	34 (50.0)
35 to <45 years	21 (30.9)
45 to <55 years	10 (14.7)
55 years or older	3 (4.4)
Age at Survey (Years), Mean \pm SD	48.2 \pm 10.8
18 to <35 years	6 (8.8)
35 to <45 years	23 (33.8)
45 to <55 years	18 (26.5)
55 years or older	21 (30.8)
Follow-up (Years), Mean \pm SD	11.5 \pm 5.1
Length of hospital stay (Days), Mean \pm SD	7.3 \pm 4.3
Sex, N (% male)	35 (51.5)
Race/Ethnicity	
Non-Hispanic white	33 (48.5)
Hispanic	30 (44.1)
Asian	4 (5.9)
Black	1 (1.5)
Relationship to recipient, N (% of total donors)	
Parent	5 (7.4)
Child	25 (36.8)
Spouse	2 (2.9)
Sibling	18 (26.5)
Relative	
Blood related	8 (11.8)
Non-blood related	1 (1.5)
Friend	8 (11.8)
Anonymous	1 (1.5)
Recipient status, N (% of total donors)	
Alive, no recurrent liver disease	25 (36.8)
Alive, recurrent liver disease	20 (29.4)
Alive, relisted for transplant	0 (0)
Alive, re-transplanted	0 (0)
Deceased	23 (33.8)

Note: Recipient status reported at time of latest LLD completed survey. All data are given as n (%) unless otherwise indicated.

Table 2:

Early post-operative complications experienced by LLDs.

Part A: Within 30 days					
Patient	Type of Donation	LOS (days)	Complication	Clavien Score	Treatment
1	RTH	4	Uncomplicated urinary tract infection POD 7	II	IV hydration and Levofloxacin 500mg IV QD, discharged POD 8 on Levofloxacin 500mg PO QD for 5 days
2	RTH	6	Wound infection POD 6	I	Local wound care
3	RTH	6	Febrile POD 9	I	Self-resolving
4	RTH	6	Nausea and vomiting secondary to ileus POD 2	I	Self-resolving
5	RTH	6	Fever of 101.0 secondary to atelectasis POD 1	I	Self-resolving
6	RTH	8	Right brachial plexus palsy with loss of sensation in arm and elbow POD 1	I	Corticosteroids and Gabapentin
7	RTH	39	Bile leak POD 10	IIIb	Exploratory laparotomy and drainage
8	RTH	8	Fever of 103.1 secondary to coagulase negative oxacillin sensitive Staph phlebitis POD 2 Intra-abdominal bleeding POD 1	II IIIb	IV antibiotics, discharged on Clindamycin 450mg PO QID Exploratory laparotomy for blood clot evacuation and ligation of small arterial bleed
9	RTH	14	Bile leak POD 1	IIIb	Bile leak from hilar plate controlled with single stitch
10	RTH	10	Gram negative bacteremia (<i>E. coli</i>) POD 9	II	Vancomycin 750mg IV Q8h POD 9, discharged POD 10 on Levofloxacin 500 mg PO QD for 10 days
11	LL	6	Acute exacerbation of gout POD 1 Urosepsis (<i>E. coli</i>) POD 27	II II	Indomethacin 500mg PO BID and colchicine 0.6mg PO BID PRN; Levofloxacin 500 mg PO QD for 10 days
Part B: Between 1–24 months					
Patient	Type of Donation	LOS (days)	Complication	Clavien Score	Treatment
2	RTH	5	Incisional hernia POM 7	IIIb	Incisional hernia repair
12	RTH	5	Biliary stricture POM 23 Incisional hernia POM 23	IIIb IIIb	Biliary tree reconstruction; Incisional hernia repair
13	RTH	8	Non-bleeding duodenal ulcer POM 3	IIIa	Upper intestinal tract endoscopy with biopsy
14	RTH	5	Biloma POD 48	II	Fluid leak too small for acute intervention, discharged POD 50 on Levofloxacin 500 mg PO QD for 10 days

LOS = length of initial hospital stay; RTH = right hepatectomy; LL = left lobectomy; POD = post-operative day; POM = post-operative month; PO = oral; QD = once daily; BID = twice daily; PRN = as needed

Table 3:

Medical, physical, and emotional status USC DQLS results.

Medical Condition	Total Respondents (n = 68)
1. Have you seen a physician other than your surgeons since surgery?	Yes: 60 (88.2) No: 8 (11.8)
2. Have you been diagnosed with any medical conditions or illnesses since your surgery?	Yes: 29 (42.6) No: 34 (50) No answer: 5 (7.4)
3. Have you had any surgery since your partial liver donation?	Yes: 26 (38.2) No: 42 (61.8)
4. Do you take any new medications since your surgery?	Yes: 24 (35.3) No: 44 (64.7)
5. Have you required hospitalization since your surgery?	Yes: 19 (27.9) No: 48 (70.6) No Response: 1 (1.5)
Physical Activity Status	
1. Have you resumed the same level of physical activity as prior to surgery?	Yes: 47 (69.1) No: 21 (30.9)
2. Do you restrict your physical activity because of your surgery?	Yes: 33 (48.5) No: 35 (51.5)
3. Do you exercise?	Yes: 40 (58.8) No: 28 (41.2)
4. Compared to before your surgery, do you feel that your strength is less, equal to, or greater now?	Less: 21 (30.8) Equal: 39 (57.4) Greater: 6 (8.8) No Response: 2 (2.9)
Emotional Status	
1. How do you feel about your surgery?	Positive: 59 (86.8) Neutral: 2 (2.9) Conflicted: 4 (5.9) Negative: 2 (2.9) No Response: 1 (1.5)
2. How do you feel about your surgical scar?	Positive: 21 (30.9) Neutral: 37 (54.4) Conflicted: 1 (1.5) Negative: 9 (13.2)
3. Do you regret your decision to donate a portion of your liver?	Yes: 2 (2.9) No: 66 (97.1)
4. How do you feel about your overall health since the surgery?	Positive: 40 (58.8) Neutral: 20 (29.4) Conflicted: 2 (2.9) Negative: 6 (8.8)
5. How do you feel the surgery affected you?	Positive: 21 (30.9) Neutral: 24 (35.3) Conflicted: 9 (13.2) Negative: 13 (19.1) No Response: 1 (1.5)
6. Was the discomfort associated with the surgery more, the same, or less than what you expected?	More: 37 (54.4) Same: 16 (23.5) Less: 13 (19.1) No Response: 2 (2.9)
7. Is there anything the doctors could have told you that would have better prepared you for your surgery?	Yes: 28 (41.2) No: 40 (58.8)
8. Why did you decide to donate a portion of your liver?	Friend: 6 (8.8) Blood Relative: 49 (72.1) Non-blood Relative: 2 (2.9) Spouse: 1 (1.5)

Moral: 5 (7.4)
Other: 5 (7.4)

Note: All data are given as n (%).

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Table 4:

LLD open-ended comments and suggestions for improvement in the donation process at USC.

No suggestions for improvement (n = 40)
Suggestions for improvement (n = 28)
Education
Setting more realistic expectations of postoperative pain
Gallbladder removal and subsequent consequences
Extensive recovery time
Preoperative diet
Postoperative nausea
Postoperative muscle weakness and fatigue
Degree of liver regeneration
Long-term effects of abdominal swelling
Evaluation
Greater notice before scheduling of surgery
Less work-up to reduce evaluation time
More follow-up after donation
Psychosocial
Connecting new donors with existing donors prior to surgery to help set expectations
Connecting with post-donation support groups
Financial
Counseling on building savings in anticipation of short-term disability

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Table 5:

Employment and insurance status USC DQLS results.

Employment Status	Total Respondents (n = 68)
1–2. Were you in school or employed prior to your surgery?	School: 2 (3.0) Employed: 58 (85.3) School and Employed: 5 (7.4) Neither School nor Employed: 3 (4.4)
3. Have you returned to your school or work since your surgery?	Yes: 65 (95.6) No: 1 (1.5) Retired: 2 (2.9)
4. Did your surgery affect your job or school performance?	Yes: 11 (16.2) No: 56 (82.4) Not Applicable: 1 (1.5)
5. Did you encounter any difficulties at school or work due to your surgery?	Yes: 9 (13.2) No: 58 (85.3) Not Applicable: 1 (1.5)
6. Has your surgery affected your ability to find employment?	Yes: 1 (1.5) No: 67 (98.5)
Insurance Status	
1. Has your health insurance been affected by your surgery?	Yes: 3 (4.4) No: 65 (95.6)
2. Have you encountered any difficulty obtaining an insurance policy since your surgery?	Yes: 3 (4.4) No: 65 (95.6)
3. Since your liver surgery, have you applied for a life insurance policy?	Yes: 19 (27.9) No: 47 (69.1) No Response: 2 (2.9)
a. If yes, did the surgery affect your ability to purchase this policy?	Yes: 1 (5.3) No: 18 (94.7) (among 19 who applied)

Note: All data are given as n (%).

Table 6:
HRQOL outcomes in LLDs as estimated by population adjusted SF-36 measures.

Part A compares HRQOL outcomes in LLDs with early post-operative complications to the general U.S. population with *P* values for two-sided one-sample t test. Part B reports HRQOL outcomes in LLDs based on recipient status with *P* values for Wilcoxon rank sum test.

A. LLDs experiencing complications (n = 14)	Mean Score	90% CI	P Value	
			Lower	Upper
Physical Component Summary (PCSc)	52.8	[48.3, 57.3]	.007	<.001
Mental Component Summary (MCSc)	51.7	[45.9, 57.4]	.01	.002

B. LLDs by recipient status (n = 68)	Alive (n = 45)		Deceased (n = 23)		P Value
	Median Score	IQR	Median Score	IQR	
Physical Component Summary (PCSc)	56.8	[50.4 – 58.8]	54.3	[47.2 – 59.1]	.64
Mental Component Summary (MCSc)	56.5	[52.0 – 59.0]	57.7	[45.2 – 60.3]	.98

Note: IQR = interquartile range

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