Research Article

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Informed consent for live liver donors: A qualitative, prospective study

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Transplantation

Background & Aims: Adult-to-adult live donor liver transplantation (LDLT) poses serious health risks and no direct health benefits to donors. Ensuring live donors' autonomy through informed consent is critical. We assessed live liver donors' (LD) comprehension, information needs, risk perceptions, and demographics.
Methods: Semi-structured interviews were prospectively conducted with LDs after completing donor evaluation and informed consent at our transplant center. Likert scales measured informed consent domains. Open-ended responses underwent thematic analysis.
Results: Thirty LDs participated (100% participation rate). Although 90% of LDs reported being *informed* about donation 'a great deal', only 66% reported *understanding* information about donation 'a great deal.' Many (40%) reported difficulty understanding medical terminology. Information LDs most desired to feel comfortable with their decision included: incidence and type of donor complications (67%), description of donation procedure (57%), and the process of donor preparation (43%). Most (83%) LDs rated risks to themselves as 'not at all' to 'somewhat' risky, and minimized these risks.
Conclusions: Although LDs perceived that they were adequately informed, their actual comprehension about donation was inadequate. Findings suggest the value of informed consent for preparation for the procedure and potential periprocedural risks rather than for decision-making. More comprehensible information disclosure may optimize informed consent.

Keywords: Bioethics; Liver transplantation; Information needs; Informed consent; Education; Qualitative research; Risk communication.
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Abbreviations: A2ALL, Adult-to-Adult Living Donor Liver Transplantation Cohort Study; CMS, Centers for Medicare and Medicaid Services; HIT, Health Information Technology; LD, Live Liver donor; LDLT, Adult-to-adult live donor liver transplantation; NMH, Northwestern Memorial Hospital; OPTN/UNOS, Organ Procurement and Transplant Network/United Network for Organ Sharing; SRTR, Scientific Registry of Transplant Recipients; US, United States.

Introduction

The organ shortage poses a major challenge facing transplant patients and clinicians. Although more than 15,600 patients are currently waiting for a liver transplant in the US, only about 6300 receive a liver transplant each year [1], resulting in over 1400 deaths from end-stage liver disease in 2013 [1]. Adult-to-adult living donor liver transplantation (LDLT) has been utilized in the US since 1998 as an attractive option to address the organ shortage [2]. However, the number of LDLTs performed has plateaued, only 4% of all liver transplants in the US are adult-to-adult LDLT [1]. Amongst the reasons for this trend are ethical and logistical concerns.

LDLT is an optimal treatment alternative for liver patients as it confers comparable surgical outcomes compared to deceased donor liver transplants, although LDLT is associated with more donor surgical complications [3]. However, LDLT has received little support from Health Resources Services Administration (HRSA) and Centers for Medicare and Medicaid Services (CMS) compared to alternative treatment options. For example, HRSA and CMS mandate increases to donation after cardiac death (DCD) donors even though DCD donors generally have poorer outcomes compared to donation following brain death [4].

Transplant clinicians, ethicists, and policy-makers remain concerned about the ethical soundness of subjecting live liver donors (LD), who are otherwise healthy, to serious health risks because they experience no direct medical benefits and little was known before 2012 about long-term donor outcomes [2]. Furthermore, a defined, consistent complication rate of ~40% is associated with donation [5]. The practice of LDLT underscores the ethical need to ensure donor autonomy through informed consent [6,7]. In order for surgeons to ethically proceed with transplant surgery, there must be evidence that LDs understand the information about the LDLT process and have made an autonomous decision to undergo the procedure with its associated risks [8,9].

Questions have been raised as to whether the current informed consent process adequately informs LDs about the risks of LDLT. Inherent to the doctrine of informed consent is that the donor expresses their autonomy and assures that their consent is given voluntarily [10,11]. Despite CMS requirements [12], and Organ Procurement and Transplantation Network (OPTN) guidelines [13] for informed consent of living donors, studies report

inconsistencies and problems with the informed consent process. The NIH-sponsored Adult-to-Adult Living Donor Liver Transplantation Cohort Study (A2ALL) documented LDs' competency to donate [14,15]. However, a systematic review of decision making and informed consent of LDs found that they have unmet information needs [16,17] and have limited knowledge about the risks associated with the procedure [16,18]. Furthermore, many LDs perceive unrealistically low risks [18,19], have difficulty appreciating risks [20], and experience greater morbidity than expected (29%) [16,21–23]. While quantitative studies have documented the presence or absence of information needs, few studies have described the specific types of information that LDs have needed but actually lacked in order to provide informed consent [24,25].

To address these gaps, we employed a prospective, mixed-methods research approach to assess LDs' comprehension, information needs, perceptions of risks of donation, and perceptions of the adequacy of informed consent. We do not report LDs' decision-making, which has been described extensively elsewhere [26]. Combining qualitative with quantitative data is essential when describing a phenomenon that has undergone relatively little prior examination [27]. Additionally, qualitative research is valuable for revealing unforeseen topics from the individual's point of view, gaining insight into patients' attitudes and beliefs, describing phenomena in-depth, examining the meaning that individuals ascribe to experiences, situating respondents' experiences within broader social, cultural, and historical contexts, and for generating, rather than testing, hypotheses [27].

Materials and methods

Living donor informed consent and evaluation process

Potential LDs at Northwestern Memorial Hospital (NMH) undergo a comprehensive four-phase process of evaluation: Phase I entails group education about living donation and blood tests for ABO compatibility testing. Approximately a week later, phase II/phase III (same day) involve psychosocial assessment by the social worker and donor advocate, as well as history and physical assessment by an impartial physician. Additional tests (e.g., blood, special protocol MRI) are also performed to determine suitability for donation. Importantly, the visit with the independent living donor advocate includes disclosure about key elements of informed consent. A multidisciplinary team reviews all pertinent information about the LD, including the anatomic complexities of the MRI, scan and render a determination as to whether the donor will be cleared for donation. After the donor is informed of this decision, a "cooling off" period generally ensues for ~ten days, during which time the LD can contemplate whether they wish to proceed with donation. The final part of the process, phase IV, is then scheduled several days before the living donor procedure. This entails discussion between the potential donor and transplant nurse to review preoperative instructions, donation risks and specific details of the recipient surgery. If potential LDs wish to proceed, their right lobe hepatectomy is typically performed two days later. Disclosure of the risks, benefits, procedures, and alternatives of donation occurs throughout this process.

Throughout the evaluation process, the living donor surgeon meets with the LD a total of three times. The living donor surgeon meets with all potential living donors initially by phone, when LDs call the donor hotline for their initial encounter, then again in person, during the donor medical/surgical evaluation (phase II/III), and lastly in person two days prior to the scheduled surgery to review surgical risks (phase IV).

Study population and data collection

All consecutive LDs ($\geqslant$18 years) were invited to participate in this qualitative study after they completed the final phase of evaluation and informed consent for donation on Mondays, according to standardized institutional and A2ALL protocols, two days before the donor operation, between January 2009 and February 2011 at NMH. This group represented 98% of all phase IV LDs. We limited our study to adult-to-adult liver donors, to maintain a more homogeneous population in terms of their operative risks [28] and motivation for donation [29]. Recruitment was conducted in person in the transplant clinic by a social scientist (EJG) or trained qualitative researcher (JR), both uninvolved in the clinical evaluation process.

Participation involved one voluntary, face-to-face, semi-structured interview two days before the scheduled donation. Semi-structured interviews include some pre-set topics but allow for flexibility in the flow of conversation through the use of probes to ask spontaneous follow-up questions to seek greater depth from respondents' comments [30]. Semi-structured interviews commonly include open- and closed-ended questions; while the former generate rich in-depth qualitative data, the latter enable statistical comparison of quantitative data across the sample [30]. Open-ended questions provide respondents with the freedom to respond to questions in-depth, and in a way meaningful to them.

The interview guide was developed by consulting the liver donation literature [31] and liver transplant clinicians. Topics covered in the interview included open- and closed-ended questions about: a) the decision-making process, b) information needs about donation, c) comprehension about the donation process, d) sources of information about LDLT, e) perceptions of the informed consent process, f) perceptions of undue pressure, and g) demographics (age, gender, race/ethnicity, marital status, years of education, employment status, and total household income). (The interview guide is available from the authors upon request). Donors' perceptions of informed consent for LDLT were quantitatively assessed using five-point Likert scales anchored by (1) "not at all," and (5) "a great deal" with higher scores reflecting perceptions of greater information disclosure, comprehension, and overall consent process. Interviews lasted approximately 25 minutes, and were audio-recorded. No financial compensation was provided to participants. Institutional Review Board approval was obtained from Northwestern University and verbal informed consent was obtained.

Qualitative analysis

All recordings were transcribed verbatim. An ethnographic methodological approach guided the analysis wherein the objectives were to understand donors' experiences from their point of view and reveal tacit assumptions shared amongst donors [32]. Open-ended responses were analyzed by thematic analysis, a systematic search for themes, patterns, and repetitions emergent from the data, assisted by a qualitative data analysis software program, The Ethnograph version 6 (Qualis Research, Colorado Springs, CO) [33]. As open-ended interview questions do not have pre-set response options, the responses reflect comments by those who volunteered. In other words, participants' responses do not reflect binary categories of thought, but rather, the themes that emerged from participants. We inductively generated codes by using the constant comparative method to compare and differentiate text segments into categories [34,35]. Codes were applied to a new group of patient responses, and the coding scheme was revised to adjust for new responses, and modified codes were applied to the previous set of responses. This process was repeated until reaching saturation, the point at which no new themes emerged from the data [33]. Two authors (EJG and JR) independently coded 33% of all interview transcripts, then compared codes and resolved discrepancies in codes to reach consensus in the use and definition of codes to establish the code book [36–38]. After the code book was finalized, and new transcripts were independently coded, inter-rater reliability (Kappa >0.90) was established using methods advocated by Kuraski [39]. Thereafter, all transcripts were coded by JR. In qualitative research, validity or "credibility" [40] is attained, not through a generalizable sample as with quantitative research, but by employing multiple methods, theoretical approaches, and research investigators with diverse areas of expertise [38,41]. Such triangulation is necessary to obtain different perspectives to enhance the coherence and soundness of the interpretations.

Statistical analysis

Descriptive statistics were used to summarize the data using univariate and graphical methods. Race/ethnicity was dichotomized (white versus non-white) due to limited variation in the sample. Simple analyses of demographic predictors of DRS were based on the comparison of means for categorical predictors. Two-sample t tests were computed for dichotomous predictors and one-way analysis of variance was used for predictors with three categories. Respondents who did not answer a question were excluded from analysis of that item. All tests were two-tailed and p <0.05 was considered statistically significant. All statistical analyses were performed using SPSS 19.0 (Chicago, IL).