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Original research

Towards a standardized informed consent procedure for live donor nephrectomy: What do surgeons tell their donors?

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HIGHLIGHTS

- Surgeons vary in the information they provide to living kidney donors.
- Important complications are not always disclosed.
- Risk of mortality is not disclosed in 13% of preoperative surgical consults.
- Donors should be optimally informed and prepared for donor nephrectomy.
- A standardized format informed consent procedure may help to achieve this goal.

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ABSTRACT

Introduction: Living kidney donors comprise a unique group of "patients", undergoing an operation for the benefit of others. The informed consent process is therefore valued differently. Although this is a team effort, the surgeon is responsible for performing the donor nephrectomy, and often the one held accountable, should adverse events occur. Although there is some consensus on how the informed consent procedure should be arranged, practices vary. The aim of this study was to evaluate the surgical informed consent procedure for live donor nephrectomy, with special regards to disclosure of complications.

Methods: A web-based survey was sent to all kidney transplant surgeons (n = 50) in eight transplant centers with questions regarding the local procedure and disclosure of specific details.

Results: Response rate was 98% (n = 49), of which 32 (65%) were involved in living donor education; overall, transplant- (50%), vascular- (31%), and abdominal surgeons (13%), and urologists (6%) performed donor nephrectomies in the eight centers. Informed consent procedures varied, ranging from assumed to signed consent. Bleeding was the only complication every surgeon mentioned. Risk of death was always mentioned by 16 surgeons (50%), sometimes by 13 (41%), three surgeons (9%) never disclosed this disastrous complication. Reported mortality rates ranged from 0.003% to 0.1%. Mentioning frequencies for all other complications varied.

Conclusion: Important complications are not always disclosed during the surgical informed consent process for live donor nephrectomy. Informed consent procedures vary. To optimally prepare living kidney donors for the procedure, a standardized informed consent procedure for live donor nephrectomy is highly recommended.

1. Introduction

Living kidney donors comprise a unique group of "patients", undergoing an operation for the benefit of others. Even though the surgical technique for the live donor nephrectomy is fully implemented, and associated with low complication rates, the burden of responsibility may feel different to surgeons operating on living donors instead of actual patients [1]. Every patient needs to be fully informed about the details and risks of a procedure, but because

List of abbreviations: HAL, hand assisted laparoscopic; HARP, hand assisted retroperitoneoscopic; NSAID, non-steroidal anti-inflammatory drugs; NTS, nederlandse transplantatie stichting (Dutch Transplant Foundation); PKE, paired kidney exchange; SPSS, statistical package for the social sciences.

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surgeons may have an increased fear of inflicting unnecessary injury and expectation of perfection with living donors [1], the informed consent procedure is valued differently. To enable donors to make a fully informed decision, it is the transplant team's responsibility to provide them with all the necessary information. This is a joint effort of the whole transplant team, but the surgeon is the one responsible for the donor nephrectomy, and is often the last in the chain of information providers. In addition, should adverse event occur, the surgeon is often the one held responsible. He should therefore ensure that the donor has been informed about all essential details and risks either by providing these himself or confirming that the rest of the team has done so. There should be no doubt about the donor's consent, and the transplant team should confirm the voluntary and informed nature hereof [2].

There are many uncertainties when it comes to information provision and informed consent, in patients in general, let alone living kidney donors. What information do they need, which details are vital in their educational process? And at what stage during this educational process should the actual informed consent be obtained? In addition, the manner in which informed consent should be documented is a much-debated subject. In the Netherlands, the law on organ donation stems from May 1996. Consent has to be obtained in writing, signed and dated. But the contents of information provision are not stated in any legal document, although some specifications can be found in the EU Directive, requiring Member States to adhere to minimum standards in live organ donation [3]. In the United States, a more detailed guideline is available [4], but compliance with this guideline varies.

A recent systematic review demonstrated that there is no consensus on how the informed consent procedure in live donor nephrectomy should be arranged [5]. There are many discrepancies in the procedure itself, provided information and the manner in which consent is obtained between different countries, transplant centers and even transplant professionals within one center. Previous surveys have demonstrated that transplant professionals vary in information and details they provide to potential donors [6,7]. It has been suggested that donors as well as transplant professionals would greatly benefit from a standardized informed consent procedure [5,8], and many agree that there is a need for a standardized informed consent procedure.

The Netherlands have a leading role when it comes to live kidney donation with more than half of all kidney transplants involving a living donor. In 2014, 534 live donor nephrectomies were performed out of a total of 1004 kidney transplantations (53.2%) [9]. Not every center employs the same surgical technique, which makes completely uniform information provision virtually impossible. Still, uniformity should be pursued, especially seen in light of the successful paired kidney exchange program (PKE) in the Netherlands (3.5% of all live donor nephrectomies are within the PKE program) [10]. In contrast to some other countries, where the kidney is transported from the donor's center to the recipient's center, standard national policy in the Netherlands involves donors traveling to the recipient's center for surgery, but receiving education in their own center. Most donors visit the outpatient clinic of the second center prior to surgery, and are seen by the local surgeon on the day of admission for donor nephrectomy. If information received in "their own" center differs greatly from information received in the "new" center this could be quite troubling for the donor.

Hospital logistics and local practice are bound to vary. But standardization of the contents of the informed consent procedure should be possible, and is expected to further improve this process for potential living kidney donors. The first step to create this standardized format is to assess the current situation. How is the informed consent procedure arranged in the eight Dutch kidney transplant centers? And which specific details are discussed with potential donors?

The aim of this study was to provide an overview of the current situation in the Netherlands with regard to the surgical part of the informed consent procedure. Special interest is addressed to the disclosure of different complications by transplant surgeons to potential donors.

2. Materials and methods

To gain better insight in the information disclosed by kidney transplant surgeons, a web-based survey (supporting document I - appendix I) was created (SurveyMonkey, Palo Alto, CA, USA) and sent to all surgeons in the Netherlands who were, or had been in the past, involved in kidney transplantation, identified from prior surveys, registration details and by contacting the surgical kidney transplant program director in each center. Specialists included transplant, abdominal and vascular surgeons and urologists, both consultant surgeons and surgical fellows. Because the questionnaire was distributed to colleagues and included only questions regarding their own practice habits, no approval from the local ethics committee was obtained.

Questions were divided into four subgroups: personal experience, hospital logistics, contents of informed consent and the actual informed consent procedure. A list of (medical) items was created based on currently available literature [5], combined with our own experience, that could be provided to potential donors during the informed consent procedure. These items included details regarding surgical technique (n = 6, *e.g.* laparoscopy, hand-assistance, conversion), short- and long-term complications (n = 22, *e.g.* bleeding, wound infection, mortality, incisional hernia, kidney failure), duration of admission and convalescence. For each possible complication, the respondents were given three options: "I always mention this complication to potential donors", "I sometimes mention this complication to potential donors", or "I never mention this complication to potential donors". Results were compared between center, type of surgeon, and personal experience.

Statistical analysis was performed using SPSS version 21. For continuous variables the student-t test or one-way Anova was used. For nominal variables the Chi-square test was used, or the Fisher's Exact test for small samples. A p-value of <0.05 was considered statistically significant.

3. Results

A total of 50 surgeons were invited to complete the survey and a response rate of 98% was reached (n = 49). Of these respondents, 17 indicated they were not involved in the preoperative care for living kidney donors, 32 individual responses remained for analysis; 28 consultants and four surgical fellows. Sixteen respondents were transplant-, ten were vascular-, four abdominal surgeons, and two were urologists. Five different techniques for live donor nephrectomy are employed in the Netherlands: pure laparoscopic, hand-assisted laparoscopic (HAL), hand-assisted retroperitoneoscopic (HARP), robot assisted and mini-open. Not every center offers every technique. Two centers use only one technique, whereas the other six choose from two or more techniques. Only one center offers robotic assisted donor nephrectomy, the other techniques are available in at least two centers.

3.1. Hospital logistics & informed consent

Informed consent procedures vary among centers, but even surgeons from the same center report different practices. All but