Differences Between Centers in Psychosocial Evaluations for Living Kidney Donors Do Not Influence Outcome: Results From an Observational Multicenter Study

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INTRODUCTION
Organ shortage has led to an increase of kidney transplantations from living donors during the past decades.

Background. Rather little is known about how psychosocial evaluations for living kidney donation (LKD) are performed. We aimed to explore whether Swiss transplant centers (STCs) vary regarding the rate of living kidney donors refused for psychosocial reasons, the psychosocial evaluation process, and the characteristics of the donors. Methods. We investigated 310 consecutive candidates for LKD in 4 of 6 existing STC during mandatory psychosocial evaluations. We registered (i) sociodemographic data, (ii) the type of the decision-making process regarding LKD (ie, snap decision, postponed, deliberate, other), (iii) the evaluator’s perception of the donor’s emotional bonding and his/her conflicts with the recipient, (iv) the donor’s prognosis from a psychosocial perspective, (v) time taken for the psychosocial evaluation, and (vi) its result (eligible, eligible with additional requirements, not eligible). Results. Centers had comparable proportions of noneligible donors (2.9%–6.0%) but differed significantly in the percentage of donors accepted with additional requirements (3.4%–66%, \(P < 0.001\)). Significant differences emerged between centers regarding the time needed for evaluation (75–160 min [interquartile range (IQR) 75–180 min] per single exploration, \(P < 0.001\)), the perception of the donor’s emotional bonding (visual analogue scale [VAS] 9–9 [IQR 6–10], \(P < 0.001\)), his/her conflicts with the recipient (VAS 1.5–2 [IQR 0–3], \(P = 0.006\)), the donor’s psychosocial prognosis (VAS 8–9 [IQR 7–10], \(P < 0.001\)), and the type of decision concerning LKD (59%–82% with snap decision “yes,” \(P = 0.008\)). However, despite differences in the psychosocial evaluation process, the rates of patients accepted for transplantation (eligible and eligible with additional requirements versus noneligible) were comparable across STC (\(P = 0.72\)). Conclusions. Our results emphasize that it is more important to establish clear guidelines to identify potential psychosocial risks than to stringently standardize the procedure for psychosocial evaluation of living kidney donors.

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In Switzerland, LKD has been performed since the beginning of kidney transplantation in 1970s. Nowadays, kidney transplantations with a kidney from a living donor are

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performed in 1 of 3 of all kidney transplantations (Swiss transplant cohort annual report; https://www.swisstransplant.org). There exist several advantages of LKD for the kidney recipient like pre-emptive transplantation, shorter time on dialysis as well as shorter cold ischemia time and therefore improved allograft and patient long-term survival.1,3 Even though LKD has several advantages, careful exploration of potential living kidney donors including evaluation of the medical condition and psychosocial situation is crucial to justify this procedure.4,6

Despite the existence of several reports on the psychosocial evaluation process of living kidney donor candidates,7,9 so far only a few studies were performed and published.10,11 In 2007, under the auspices of the United Network for Organ Sharing, experts of the American Society of Transplant Surgeons and the American Society of Transplantation for the first time published their guidelines for the psychosocial evaluation of living unrelated kidney donors in the United States.7 Besides specification of risk factors of unrelated donors for poor donor psychosocial outcomes as well as potential protective factors against it, they summarized the process and content of the psychosocial evaluation in LKD.7 Further, an earlier review on 34 identified publications worldwide, including 7 guidelines, 6 consensus statements, and 21 papers describing living donor evaluation protocols or programs, respectively, highlighted that the evaluation procedures were very heterogeneous and more conditioned by opinions and individual center experiences rather than based on empirical evidence.10 Authors expressed their concerns that psychosocial donor evaluations would either ignore relevant psychosocial aspects or put too many efforts in measuring psychosocial factors that might be irrelevant. They clearly favored the development of uniform and standardized evaluation criteria and measures to meet the needs of this evolving clinical domain and permit comparisons between transplant centers.10 They claimed that the scientific basis of predonation psychosocial evaluation needs to be strengthened.10 De Zwaan et al described how psychosocial evaluations for living kidney donors are conducted in Germany,11 and detected a wide variety in structure and content of the psychosocial evaluations. They also argued for a standardization of the psychosocial evaluation process, to enable comparisons between centers but also to achieve equal opportunities for living kidney donors and their recipients. In addition, 2 psychosocial assessment tools (ie, the LDAT in the United States and the EPAT in Europe) have been developed with the aim to uniform the screening process across institutions and to predict psychosocial outcomes after donation.8,9

Based on the applicable Swiss Federal Transplantation Act (https://www.fedlex.admin.ch) organs may only be removed from a living person if an independent professional experienced in such investigations has ascertained that the donation is voluntary and unpaid. In 2008, the Swiss Academy of Medical Sciences (SAMW) published medical-ethical guidelines on living donation. These guidelines also specify how this legally required psychosocial evaluation of potential living organ donors is carried out in detail. Since then, these guidelines have been serving as a framework for the psychosocial evaluation in Switzerland (https://www.samw.ch). The guidelines present that the psychosocial evaluation must be conducted by a psychologist or psychiatrist, who is independent from the transplantation team. The same clinician can perform the psychosocial evaluation of both, the potential donor as well as the transplant recipient. Furthermore, 6 conditions are depicted as challenging and potentially high risk from a psychosocial perspective concerning LKD: donors with a psychiatric disorder, donors with a partner who refuses donation, donors with a differing cultural background, donors who refuse blood transfusion, donors who do not wish to donate but are unable to admit it, and donors whose potential organ recipient shows adherence problems. However, there is no clear evidence, if the presence of 1 of the 6 mentioned risk factors should be necessarily considered as a contraindication or if the explorer should rather focus on the identification of needs and the providing of potential interventions to minimize these risk factors and to enable the organ donation. Furthermore, little is known on how psychosocial evaluations are performed in practice and whether existing guidelines are followed in real life. Therefore, the aim of the study was to determine whether transplant centers in Switzerland vary regarding the rates of donors considered as unsuitable for psychosocial reasons, the practical handling of psychosocial evaluations, and the characteristics of the donors. For that reason, we performed a prospective multicenter study of consecutive potential candidates for LKD. We chose a naturalistic study design, being interested in how psychosocial evaluations actually are performed in STCs.

MATERIALS AND METHODS

Patient Population
All 6 STCs evaluating potential living kidney donors were requested to participate in the study. Four of 6 centers agreed to participate (ie, the University Hospitals of Zurich [ZU], Basel [BS], Lausanne [LS], and the Cantonal Hospital of St. Gallen [STG]) and 2 declined. All consecutive candidates for living kidney donation in the 4 participating centers between 2010 and 2012 were included. The local ethics committees of all 4 participating centers approved the study and all potential donors gave written informed consent.

Psychosocial Evaluation Process
The mandatory psychosocial evaluations were conducted according to the local practice of each center; no additional testing was included. In general, a psychosocial evaluation consists of a semistructured face-to-face interview performed by an accredited explorer (ie, a psychologist or psychiatrist). It always includes a psychosocial anamnesis. Furthermore, the donor’s motivation, his/her comprehension of the risks of donation, and their relationship to the recipient are assessed. Psychosocial risk factors as mentioned before are ruled out. Each explorer writes a detailed report in which he describes the results of the evaluation: (i) is the donor eligible? (ii) is the donor eligible with additional requirements? (eg, further psychological counseling) or (iii) is the donor not eligible? There does not exist any further consensus on how the exploration is performed. Although in 3 of 4 participating STCs (BS, LS, and ZU), clinical psychologists performed the evaluation, in 1 center (STG), the evaluation was conducted by a psychiatrist. In 3 centers (BS, LS, STG), the same clinician evaluated the donor and the recipient, and in 1 center (ZU) there was a separate clinician for the psychosocial evaluation of the recipient and of the donor, respectively.
Database
After each psychosocial evaluation, the local explorer entered the data of the evaluation according to predefined data fields in a coded database. The database was restricted to data collected during the psychosocial evaluation process and had been adapted for feasibility and content during a pilot phase before the start of the study. It included self-reported sociodemographic status, working and living conditions, relationship between the donor and the recipient, the existence of a past and present psychiatric diagnosis, use of psychotropic drugs, the type of the decision-making process to donate an organ (ie, snap decision, postponed, deliberate, or other) as noticed by the explorer, the number of other potential donors, time for the psychosocial evaluation in minutes, and the result of the psychosocial evaluation process (ie, eligible, eligible with additional requirements, noneligible).

Eligibility to Donate
Eligibility to donate from a psychosocial perspective was given when donors were accepted without hesitation. Eligibility to donate with additional requirements was given when the psychosocial situation of the donor allowed to donate but further clarification or adaptions were considered as necessary by the explorer to ensure a safe donation procedure (eg, neuropsychological testing, further psychological counseling to accompany the donation process, appointment with a social worker).

Scoring of Donor Characteristics
Investigators scored their perceptions of the donor’s emotional relationship with the recipient, potential conflicts with the recipient and his or her prognosis for the potential donor from a psychosocial perspective on visual analogue scales (VASs) (from 0 to 10). Cases, for which the investigators hesitated in their ratings, were discussed during biannual meetings with representatives of the participating centers. Additional data were collected on the usefulness of the current SAMW guidelines for psychosocial evaluation of living kidney donors in Switzerland (https://www.samw.ch), which will be reported elsewhere and will be used for further revision of the guidelines.

Outcomes
The primary outcome was to determine whether the STCs varied regarding the rates of donors considered as unsuitable for LKD. Secondary outcomes were the characterization of the donors and analysis of the practical handling of the psychosocial evaluations.

Statistical Analyses
Outcomes and donor characteristics were summarized using counts and proportions if they were categorical and median and interquartile range (IQR) if they were continuous if not stated otherwise. Proportions in different subgroups were compared using Freeman-Halton test, an extension of Fisher’s exact test to general RxC tables. Differences in continuous characteristics between subgroups were tested using the Kruskal-Wallis Test. All comparisons were performed using 2-tailed tests and a P value <0.05 was considered statistically significant. The statistical analyses were carried out using SAS release 9.4 (SAS Institute Inc., 2002–2012, Cary, NC, United States).

RESULTS
Characteristics of the Potential Living Kidney Donors
Data were collected from 2010 to 2012. Out of initially 311 consecutive donors, 1 person had to be excluded due to the fact, that the planned evaluation never took place because the corresponding recipient refused a donation from this person and the evaluation was canceled.

Donor characteristics of the entire potential living kidney donor population (n = 310) and stratified by the STCs are summarized in Table 1. There were no significant sociodemographic differences across sites related to age, gender, nationality as well as marital status (Table 1). However, translators were deployed more often for the psychosocial interview in ZU compared with other centers (P = 0.043). Further, significantly more employees in higher professional positions were among potential donors in Lausanne, and more nonworking spouses and students were among potential donors in STG, respectively (P < 0.001). In addition, the time spent for the psychosocial evaluation, which included the interview as well as the writing of a report differed substantially between the STCs (ranging from 75 min [STG, BS] to 160 min [ZU], respectively [P < 0.001, Table 1]). Next, we evaluated the frequencies of a psychiatric history of each individual potential living kidney donor and compared it among the different STCs. The percentage of subjects with past and present mental disorders in potential donors was comparable among all centers as well as the use of psychotropic drugs (P = 0.913, P = 0.987, and P = 0.452 respectively, Table 1).

Eligibility of Potential Donors for LKD
Concerning the main outcome, we grouped the potential donors stratified by the decision of the psychosocial evaluation process into 3 groups (eligible for donation, eligible with additional requirements, not eligible for donation). Concerning all STC, 209 of 310 potential donors were accepted without additional requirements (67.4%), n = 88 (28.4%) were eligible with requirements and n = 13 (4.2%) were not suitable for donation due to psychosocial reasons (Table 1). Among these 13 potential donors, 6 corresponding recipients had another potential donor. Overall, the frequency of potential living kidney donors estimated as not eligible for LKD was small among the STC and ranged between 2.9% and 6.0% of all potential donors (Table 1). Furthermore, there was no indication for differences across the STCs in the proportion of potential donors who were rejected for donation for psychosocial reasons (P = 0.799). However, there were significant differences regarding eligibility and eligibility with psychosocial requirements, with LS having the highest frequency of patients eligible with requirements (66%) and STG having the smallest (3.4%), respectively (Table 1).

Are There Differences Between Eligible Living Kidney Donors, Donors With Additional Requirements, and Noneligible Donors?
We further investigated the characteristics of the potential living kidney donors within the 3 stratified groups (eligible for donation, eligible with additional requirements, not eligible) as shown in Table 2. Noneligible donors compared with the other 2 groups were younger and more often lived alone (P = 0.017 and P = 0.005, respectively, Table 2). In comparison to eligible donors and donors with additional requirements,
there were more nondirected donors and donors of weak emotional relationship with the recipient (eg, acquaintances, colleagues) among noneligible donors ($P<0.001$, Table 2). However, there were no indications for differences between the 3 groups with respect to gender, nationality, education, and profession ($P\geq0.321$, Table 2).

**Psychosocial Evaluation**

The total time for the psychosocial evaluation, including the recording and data entry of the psychiatric history, donor’s relationship with the recipient, the conflicts with the recipient, the psychosocial prognosis, and the specific type of decision-making are further summarized within Table 3. Potential living kidney donors who were judged as not eligible for LKD had significantly more often a psychiatric history (eg, past and present) and used more often psychotropic drugs (all $P$ values <0.001, Table 3). Further, their decision-making was significantly different from the 2 other groups: only 4 of them (30.8%) made a snap decision, whereas $n=58$ (65.9%) of the donors with additional requirements and $n=158$ (76%) of the eligible donors decided spontaneously to give 1 of their kidneys ($P<0.001$, Table 3). In general, the evaluators rated the emotional relationship of noneligible donors with the recipient as significantly weaker and considered their psychosocial prognosis worse as compared with eligible donors and donors with additional requirements (both $P$ values <0.001, Table 3).

In addition, noneligible donors had more conflicts with their potential recipients compared with eligible donors and donors with additional requirements, respectively ($P=0.001$, Table 3). Finally, psychosocial evaluations for donors with requirements took more time than for the 2 other groups ($P<0.001$, Table 3).

**How Many Transplantations Were Performed?**

Nine months after the psychosocial evaluation, 184 of 310 potential living kidney donors had effectuated their donation, as shown in Table 3. In detail, 70% of the eligible donors ($n=136$) had donated, as well as 56% of the donors eligible with additional requirements, respectively ($n=58$). No LKD was performed of any noneligible donor from a psychosocial point-of-view (Table 3). There were no indications for differences between the centers regarding the frequency of effectuated transplantations ($P=0.529$). Despite differences in the psychosocial evaluation process and other important factors, the rates of patients accepted for transplantation (eligible and eligible with additional requirements versus not eligible) were comparable across centers ($P=0.72$) (data not shown).

**TABLE 1.**

Characteristics of the potential kidney donors: overall ($n=310$) and stratified by the specific Swiss transplant centers

| Characteristics               | All ($n=310$) | BS ($n=100$) | LS ($n=74$) | STG ($n=29$) | ZU ($n=107$) | $P^a$  |
|-------------------------------|--------------|-------------|-------------|--------------|-------------|--------|
| **Age**                       | Median (IQR), y | 53.2 (45.4–60.8) | 54.8 (47.7–63.3) | 51.7 (41.5–58.7) | 53.9 (47.3–60.6) | 54.5 (45.3–61.2) | 0.162 |
| **Sex**                       | Female, n (%) | 200 (64.7) | 56 (56.6) | 50 (67.6) | 20 (69.0) | 74 (69.2) | 0.245 |
| **Nationality**               | Non-Swiss, n (%) | 103 (33.3) | 25 (25.3) | 30 (40.9) | 9 (31.0) | 39 (36.5) | 0.148 |
| **Transmitter**               | Yes, n (%) | 51 (16.5) | 17 (17.0) | 7 (9.5) | 2 (6.9) | 25 (23.4) | 0.043 |
| **Education**                 | None, n (%) | 13 (4.2) | 4 (4.0) | 2 (2.7) | 0 (0.0) | 7 (6.5) | 0.123 |
| **Profession**                | Independent/business, n (%) | 67 (21.5) | 22 (22.0) | 16 (21.6) | 6 (20.7) | 23 (21.5) | <0.001 |
| **Employee high/middle**      | n (%) | 52 (16.8) | 13 (13.0) | 23 (31.0) | 4 (13.8) | 12 (11.2) |
| **Employee low**              | n (%) | 142 (45.8) | 43 (43.0) | 24 (32.4) | 11 (37.9) | 64 (58.9) |
| **NW spouse/student**         | n (%) | 35 (11.3) | 14 (14.0) | 9 (12.2) | 5 (17.4) | 7 (6.5) |
| **Other/no answer**           | n (%) | 14 (4.5) | 8 (8.0) | 2 (2.7) | 3 (10.3) | 1 (0.9) |
| **Living alone**              | Yes, n (%) | 69 (22.3) | 23 (23.0) | 15 (20.3) | 8 (27.6) | 23 (21.5) | 0.854 |
| **Relationship to the recipient** |  | 67 (21.7) | 27 (27.3) | 8 (10.8) | 9 (31.0) | 23 (21.5) | 0.066 |
| **Child to parent**           | n (%) | 1 (0.3) | 1 (1.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| **Partner**                   | n (%) | 113 (36.6) | 36 (36.4) | 27 (36.5) | 6 (20.7) | 44 (41.1) |
| **Sibling**                   | n (%) | 69 (22.3) | 23 (23.0) | 15 (20.3) | 8 (27.6) | 23 (21.5) | 0.854 |
| **Friend/relative**           | n (%) | 45 (14.5) | 8 (8.1) | 14 (18.9) | 5 (17.2) | 18 (16.8) |
| **Far acquaintance**          | n (%) | 15 (4.9) | 5 (5.0) | 3 (4.1) | 1 (3.5) | 6 (5.6) |

| Time per evaluation          | Median (IQR), min (n = 305) | 90.0 (75.0–170.0) | 75.0 (75.0–90.0) | 145.0 (90.0–180.0) | 75.0 (70.0–75.0) | 160.0 (130.0–180.0) | <0.001 |
| **Psychiatric history**      | Past mental disorder, n (%) | 62 (20.0) | 22 (22.0) | 13 (17.6) | 6 (20.7) | 21 (19.6) | 0.913 |
|                              | Current mental disorder, n (%) | 37 (12.0) | 11 (11.1) | 9 (12.2) | 3 (10.3) | 14 (13.1) | 0.987 |
|                              | Psychotropic drugs, n (%) | 28 (9.1) | 7 (7.1) | 10 (13.5) | 3 (10.3) | 8 (7.5) | 0.452 |
| **Eligibility**              | Eligible, n (%) | 209 (67.4) | 78 (78.0) | 23 (31.1) | 27 (93.1) | 81 (75.7) | <0.001b |
|                              | Eligible with requirements, n (%) | 88 (28.4) | 16 (16.0) | 49 (66.0) | 1 (3.4) | 22 (20.7) |
|                              | Noneligible, n (%) | 13 (4.2) | 6 (6.0) | 2 (2.9) | 1 (3.4) | 4 (3.6) |

$^a$Freeman-Halton test for proportions and Kruskal-Wallis for comparison of subgroups.

$^b$P=0.709 for the comparison of eligible vs not eligible.

BS, Basel; IQR, interquartile range; LS, Lausanne; NW, nonworking; STG, St. Gallen; ZU, Zurich.
DISCUSSION

The key observation of this study was that the percentage of potential donors not suitable for donation due to psychosocial reasons was relatively low (overall 4.2%) and largely comparable across all 4 participating transplant centers in Switzerland. It is important to note that the refusal rate was virtually equal to the 4% of contraindications due to psychosocial reasons within German transplant centers, as reported by De Zwaan et al.11 Further, in an earlier single-center study on living donor evaluation, Lapasia et al showed that the exclusion rate of potential living kidney donors for psychosocial reasons was 4.5%.12 In other studies, the rates of potential living kidney donors who were judged as not eligible for donation for nonmedical reasons were higher (between
ultimately, the potential living kidney donors of the 4 transplant centers shared similar sociodemographic (eg, age, gender, education, living situation, nationality) and psychosocial characteristics (present and past psychiatric history, use of psychotropic drugs) but differed in type of profession and the need for a translator for the evaluation, which is probably due to socioeconomic and regional differences within the country. According to our results, it does not seem necessary to follow exactly the same psychosocial evaluation procedures across transplant centers to achieve a comparable outcome of the evaluation. Transplant centers though should respect clear guidelines on psychosocial risks for LKD as described for instance in the EPAT red flag checklist and in the 9 domains of the LDAT. However, a structured psychosocial assessment that goes beyond the use of these guidelines or checklists and specifies how exactly the psychosocial assessment should be performed does not seem to be necessary in clinical practice. In our view, it is more useful for the training of new evaluators, for research purposes, and for quality control.

Concerning the situation in Switzerland, we would welcome a more specific description of psychosocial risk factors in the SAMW guidelines. Therefore, future studies should focus on psychosocial risk factors of LKD. Furthermore, our findings indicate that there is no clear need for a separate psychosocial evaluator for the donor and the recipient. In this study, having the same or a different clinician for the psychosocial evaluation of the living donor and the recipient, did not play a decisive role regarding the acceptance or refusal rates of potential donors for psychosocial reasons.

The study has some limitations. First, we included all consecutive candidates for living kidney donation in the 4 participating centers between 2010 and 2012, which is a while ago. However, the procedure of the psychosocial evaluation process is still the same (ie, performance of a semistructured face-to-face interview by an accredited psychologist or psychiatrist, including a psychosocial anamnesis; further, exploring the donor’s motivation, his/her comprehension of the risks of donation, and their relationship to the recipient as well as whether there exist psychosocial risk factors) and we could expect comparable results today. These statements are based on the fact, that nearly all authors of this study, have long-term experience, not only in performing research projects, but more importantly they have been actively involved within the psychosocial and medical evaluation process of living kidney donors and recipients for many years. Furthermore, to the best of our knowledge, this is the first study that questioned whether the way the psychosocial evaluation is practiced has an influence on the outcome of the evaluation or not. This is indeed a hot topic in connection with the nowadays much-discussed guidelines. Thus, the results of this study are up to date and the conclusion that can be drawn from the results provides a good baseline for a future validation study, which can be an important contribution when reviewing current medical-ethical guidelines like for example the SAMW guidelines. In addition, a validation study may substantiate the hypothesis that even if potential changes over time occur, this would hardly
have any influence on the core outcome of the psychosocial evaluation. To summarize and taking these arguments into account, we believe that the data are of clinical value and a promising starting point on which to build future studies on the psychosocial evaluation of potential donors. Therefore, we argue that the results are still valid and important to discuss, irrespective of whether the study was performed a while ago.

Second, another limitation is the fact that only 4 of 6 STCs participated in the research project. We cannot exclude that center characteristics and therefore refusal rates for psychosocial reasons would have been different in the missing transplant centers. Third, evaluators of the 4 centers had a different professional background (eg, 3 psychologists, 1 psychiatrist), different levels of experience in the domain of exploring potential living kidney donors, and followed different psychosocial evaluation procedures (eg, some centers employing separate clinicians for the psychosocial evaluation of the recipient and the donor). These issues might have influenced the evaluation procedure itself, but most importantly they did not have an influence on the results. Finally, we did not assess specific psychiatric disorders with structured or standardized clinical interviews. However, the recording of a psychiatric diagnosis could have helped to understand better the psychiatric problems, especially of noneligible donors and eligible donors with additional requirements.

In conclusion, this study focused on comparing psychosocial evaluation practices in 4 of 6 transplant centers in Switzerland and delineated the differences within the procedural and center-specific characteristics. Overall, the study highlighted that although differences in the psychosocial evaluation process exist in real-life, the eligibility rates for potential living kidney donors were comparable across centers.

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