Risk of subsequent health disorders among living kidney donors

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Abstract

Few studies have investigated the risk of physiological sequelae in living kidney donors (KD). We conducted a population-based cohort study using the National Health Insurance Research Database of Taiwan, which covers more than 99% of citizens.

We comprehensively investigated the risk of medical disorders after kidney donation in living KDs using a maximum follow-up of 13 years. From January 1997 to December 2010, 1081 living KDs and 1082 age- and sex-matched non-KDs were eligible. Primary outcomes comprised end-stage renal disease, chronic kidney disease, stroke, cancer, acute myocardial infarction, acute renal failure (ARF), and diabetes.

The adjusted hazard ratios (HRs) for developing ARF, diabetes, hyperlipidemia, hypertension, cancer, end-stage renal disease, acute myocardial infarction, and stroke were similar between the KD and non-KD cohorts ($P > .05$). Although differences in the adjusted HRs of ARF were nonsignificant, the cumulative incidence rate of ARF 13 years after donation was 7.48 per 1000 person-years in the KD cohort compared with 3.46 in the matched non-KD cohort. The incidence rate ratio for ARF between donors and nondonors significantly increased to 2.16 (95% confidence interval, 1.61–2.71).

Living KDs experienced no significant health disorders following kidney donation but should be alert to the higher incidence rate of ARF.

Abbreviations: AMI = acute myocardial infarction, ARF = acute renal failure, CI = confidence interval, CKD = chronic kidney disease, ESRD = end-stage renal disease, HR = hazard ratio, ICD-9-CM = International Classification of Diseases, Ninth Revision, Clinical Modification, KD = kidney donor, KT = kidney transplantation.

Keywords: acute renal failure, end-stage renal disease, kidney transplantation, living kidney donor, retrospective cohort study

1. Introduction

Since the first operation in 1954, kidney transplantation (KT) has achieved more favorable outcomes for patients with end-stage renal disease (ESRD) than maintenance dialysis.\textsuperscript{1,2} Despite the advantages of KT, the increasing prevalence of ESRD has drastically increased the demand for KT; thus, the extreme shortage of available cadaveric organs is exacerbated.\textsuperscript{3} Research has noted that half of older candidates for KT could not endure a long waiting period for an available cadaveric renal allograft.\textsuperscript{41} Therefore, KT using living donors has inevitably become a global trend to benefit both the recipient and graft kidney.\textsuperscript{5}

Studies have shown that living kidney donations are generally accepted, with minimal risk of complications noted during nephrectomy or in long-term follow-up periods.\textsuperscript{6,7} However,
other studies have reported living kidney donors (KDs) who developed ESRD and found themselves on the waiting list for KT.[7,8] Thus, the effect of reduced renal mass remains a concern for donors. Taiwan has considerably higher incidence and prevalence rates of chronic kidney disease (CKD) and ESRD than any other country.[9] Because patients with ESRD generally receive kidneys from living donors, a pilot study in an area with high ESRD prevalence to assess the long-term effects of kidney donation on living KDs would be both compelling and beneficial. Therefore, we conducted a nationwide retrospective cohort study using a 13-year well-organized tracking database to evaluate the long-term outcomes of living donors to provide more comprehensive risk evaluation for hypertension, diabetes, hyperlipidemia, acute renal failure (ARF), renal diseases, ESRD, stroke, acute myocardial infarction (AMI), and cancer.

2. Methods

2.1. Study setting

The National Health Insurance (NHI) program of Taiwan is a single-payer social insurance program that was established in 1995 through the consolidation of 13 insurance programs into one national system. By the end of 1999, more than 99% of the 23.7 million citizens of Taiwan were enrolled in the program.[10] The National Health Research Institutes (NHRI) has been in charge of maintaining and updating the National Health Insurance Research Database (NHIRD). This study obtained inpatient claims data of the insured population from the NHIRD for the period of 1996 to 2010. For data analysis, we retrieved inpatient claims data of the insured population from the NHIRD encrypts patient personal information to protect privacy and provides researchers with anonymous identification numbers associated with relevant claims information, including sex, date of birth, medical services received, and prescriptions. Therefore, patient consent is not required to access the NHIRD. This study was approved by the Institutional Review Board (IRB) of China Medical University and fulfilled the conditions for exemption (CMUH104-REC2-115-CR3). The IRB also specifically waived the consent requirement.

2.2. Ethics statement

The NHIRD encrypts patient personal information to protect privacy and provides researchers with anonymous identification numbers associated with relevant claims information, including sex, date of birth, medical services received, and prescriptions. Therefore, patient consent is not required to access the NHIRD. This study was approved by the Institutional Review Board (IRB) of China Medical University and fulfilled the conditions for exemption (CMUH104-REC2-115-CR3). The IRB also specifically waived the consent requirement.

2.6. Statistical analysis

Data analysis entailed comparing baseline distributions of sex, age, income (New Taiwan dollars), urbanization level, and comorbidities between the KD and non-KD cohorts. We examined categorical variables using a chi-squared test or Fisher’s exact test and continuous variables using a t test. The follow-up time in person-years was estimated for each participant. We measured incident density rates of ESRD and other disorders for each cohort and the incidence rate ratio (IRR) between the cohorts as well as the corresponding 95% confidence interval (CI) for each event. Poisson regression was used to estimate the IRR of the KD cohort to the non-KD cohort with a 95% CI. Factors significant in the single-variable Cox model were included in the multivariable model. We estimated the hazard
Table 1
Demographic and comorbidity comparison of kidney donors and nondonors at baseline.

| Kidney donors               | No (N=1081) | Yes (N=1082) | P-value |
|-----------------------------|-------------|--------------|---------|
| Age (years)                 | n           | %            | n       | %            | 0.99   |
| <35                         | 392         | 36.3         | 392     | 36.2         |        |
| 35–55                       | 546         | 50.5         | 547     | 50.6         | 0.64   |
| 55+                         | 143         | 13.2         | 143     | 13.2         |        |
| Mean (SD)*                  | 39.8        | 13.6         | 40.1    | 13.3         |        |
| Sex                         |             |              |         |              | 0.98   |
| Female                      | 552         | 51.1         | 552     | 51.0         |        |
| Male                        | 529         | 48.9         | 530     | 49.0         |        |
| Income (NTD)                |             |              |         |              | 0.99   |
| <15,000                     | 375         | 34.7         | 375     | 34.7         |        |
| 15,000–22,799               | 465         | 43.0         | 466     | 43.1         |        |
| ≥22,800                     | 241         | 22.3         | 241     | 22.3         |        |
| Urbanization level†         |             |              |         |              | 0.99   |
| 1 (highest)                 | 327         | 30.3         | 327     | 30.2         |        |
| 2                           | 338         | 31.3         | 338     | 31.2         |        |
| 3                           | 196         | 18.1         | 196     | 18.1         |        |
| 4 (lowest)                 | 220         | 20.4         | 221     | 20.4         |        |
| Comorbidity                 |             |              |         |              | 0.99   |
| Hypertension                | 40          | 3.70         | 40      | 3.70         |        |
| Hyperlipidemia              | 7           | 0.65         | 8       | 0.74         | 0.72   |
| Obesity§                    | 0           | 0.00         | 1       | 0.09         | 0.09   |
| Chronic obstructive pulmonary disease† | 3     | 0.28         | 3       | 0.28         |        |

CV-squared test. NTD = New Taiwan dollar. SD = standard deviation.
† The urbanization level was categorized into four levels by population density of the residential area, with level 1 being the most urbanized and level 4 being the least urbanized.
‡ Fisher’s exact test.

ratio (HR) of medical disorders and the corresponding 95% CI using multivariable Cox proportional hazards regression with adjustment for hypertension. We further evaluated whether the risk changed over time for disorders with higher incidence by stratifying the follow-up period into two segments (<3 and >3 years), with both the IRR and HR measured for the KD and non-KD cohorts. Statistical analyses were performed using the SAS statistical package (version 9.2 for Windows; SAS Institute, Inc., Cary, NC, USA). Results with statistical significance (P < .05) were accepted.

3. Results

3.1. Demographic characteristics of KD and comparison cohorts

This study identified 1082 patients in the KD cohort and selected 1081 frequency-matched individuals for the non-KD cohort. Table 1 shows that the cohorts were similar in terms of mean age (approximately 40 years) and sex distribution (49% men). Both cohorts had a low income (34.7%), and most individuals lived in urbanized areas (Table 1).

3.2. Incidence of ESRD, CKD, other renal diseases, stroke, cancer, AMI, ARF, and diabetes

Table 2 presents the incidence rates and adjusted relative risk of ESRD, CKD, other renal diseases, stroke, cancer, AMI, ARF, and diabetes. During the follow-up period, the incidence of ESRD, CKD, other renal diseases, and ARF was higher in the KD and non-KD cohorts. The IRRs of ESRD, CKD, other renal diseases, and ARF of the KD and non-KD cohorts were significantly different in the follow-up period, at 1.50 (95% CI, 1.06–1.95), 2.53 (95% CI, 1.88–3.41), 1.44 (95% CI, 1.03–2.03), and 2.16 (95% CI, 1.61–2.91), respectively. After adjustment for hypertension, the risks of ESRD, CKD, other renal diseases, stroke, cancer, AMI, ARF, and diabetes in the KD cohort were not significantly higher than those in the non-KD cohort (Table 2).

Table 3 presents the IRR of donors to nondonors for CKD, which increased from 2.05 within the first 3 years to 2.05 in the later follow-up period. The IRR of cancers decreased from 1.37 within the first 3 years to 0.57 in the later follow-up period. After adjustment for hypertension, the risk of ESRD, CKD, other renal diseases, stroke, cancer, AMI, ARF, and diabetes by follow-up years (<3 years or >3 years) in the KD cohort was not statistically significantly higher than in the non-KD cohort.

Figure 1A–H demonstrate that the KD cohort did not exhibit a significantly higher cumulative proportion of ESRD (P = .75,
Fig. 1A), CKD ($P = .06$, Fig. 1B), other renal diseases ($P = .76$, Fig. 1C), stroke ($P = .33$, Fig. 1D), cancer ($P = .74$, Fig. 1E), AMI ($P = .94$, Fig. 1F), ARF ($P = .31$, Fig. 1G), or diabetes ($P = .99$, Fig. 1H) than the non-KD cohort.

4. Discussion

The general health status of living KDs was not inferior to that of the matched comparison non-KD cohort. The results regarding the risk of metabolic syndrome, ESRD, stroke, AMI, and cancers were similar for the KD and non-KD cohorts during the follow-up period. However, KDs were tended to have a higher incidence rate of ARF than non-KDs.

Our data suggest the favorability of living kidney donation, similar to previous studies. Our data suggest the favorability of living kidney donation, similar to previous studies.[14,15] Notably, living KDs did not have a significantly higher risk of metabolic syndrome or diabetes. Other studies have focused on the mortality and renal function reserves of living KDs. Researchers have found that renal insufficiency is associated with hyperuricemia and metabolic syndrome.[16,17] Mildly elevated uric acid levels, blood
pressure, and insulin resistance can cause endothelial cell
dysfunction and glomerular sclerosis.[18–20] Moreover, mildly
reduced renal reserve can reduce the excretion of uric acid,
leading to vicious cycles of renal function decline, hypertension,
endothelial cell dysfunction, and hyperuricemia.[21] In our study,
the risks of metabolic syndrome, ESRD, stroke, and AMI were
similar for the KD and non-KD cohorts. Our data might
complement previous findings that living kidney donation is not
related to major health disorders.[14,22–23] However, two KD
studies have demonstrated that the risk of developing diabetes
after kidney donation varies among ethnic groups.[26,27]

Canadian aboriginal and US African American populations
are both disadvantaged with respect to health care compared
with their countries’ respective general populations and thus are
at a higher risk of diabetes following kidney donation.[26–28] Our
data suggest the benefit of kidney donation for Asian populations
or for medicare beneficiaries in well-covered countries such as
Taiwan.

Although the difference in the risk of ARF was nonsignificant
between the KD cohort and non-KD cohorts, the higher incidence
rate of ARF in the KD cohort warrants special attention. Kidokoro
et al described the clinical course of ARF leading to CKD or
ESRD in several living KDs.[29] Reduced renal mass might remain
a concern for renal reserve capacity in living KDs. Remaining
kidney capacity after kidney donation might be insufficient for
some KDs when facing illness or stress. Our further analysis
revealed that no ARF cases in the KD or non-KD cohorts required
temporary dialysis (data not shown). Our result was consistent
with that of Lam et al[30] who used acute dialysis as a primary
outcome and found no statistically significant difference in the
risk of receiving acute dialysis between KDs and nondonors.[30]
Interestingly, most ARF events occurred after the first 3 years
following kidney donation (too few events to compare); events
were not concentrated immediately after kidney donation. Thus,
a single contributing cause such as perioperative morbidity or
renal aging might not completely account for this finding. We
propose that events or stresses may cause ARF in the first 3 years
after kidney donation in KDs with insufficient renal reserves for
coping with potential prerenal, renal, or postrenal insults.

Our KD cohort exhibited lower incidence rates of all types of
cancer than the non-KD cohort. This finding is consistent with that
of Lenten et al, who reported that the rate of total nonskin cancers
was significantly lower among donors than among controls.[28]
One possible reason for this finding is that a malignancy exclusion
protocol was used to select living donor candidates; therefore, the
risk of cancer for KT donors was reduced.[31]

Our study has several strengths. First, the study applied a
longitudinal design that was based on the NHIRD that covers
more than 99% of Taiwan’s citizens and contains comprehensive
medical claims data.[10] Therefore, the results are reliable and
representative. Second, the selection criteria for the comparison
cohort were strict. Because living KDs receive careful physical
and psychological evaluations before donation, they are believed
to be healthier than the general population.[32] We cautiously
selected a comparison cohort through not only age and sex
matching but also the exclusion of all comorbidities to achieve
an ideal comparison between cohorts. To our knowledge, only Segev
et al made such an effort to select appropriately matched
cohorts.[33] Third, the follow-up period was relatively long and
accompanied by the nationwide and comprehensive longitudinal
medical claims of each individual in the cohorts. Because KDs are
believed to be healthier than the general population, the long-
term medical consequences of KT would not appear until after a

long period. Other studies with long follow-up periods of living
KD donors have been conducted at single academic centers; thus, they
lacked generalizability and involved a limited number of patients
who completed the follow-up study or employed nationwide data
but inappropriately selected comparison cohorts, possibly
resulting in statistical artifacts.[24] Our study also has several
limitations. First, we did not have the actual blood pressure,
glucose level, or glomerular filtration rate data of the study
participants, as one previous study did.[33] However, to
determine the diagnosis of these disorders correctly, we utilized
the ICD-9-CM codes of HTN, diabetes, and renal diseases based on
the NHIRD, which is strictly evaluated under the supervision of
the NHRI. Moreover, the NHIRD lacks information about
smoking, body mass index (BMI), and family history, which
might affect the development of conditions including stroke,
AMI, and ESRD. Research has suggested creating suitable
comparison cohorts for KDs.[32] We adopted a similar study
design and used proxies such as obesity for BMI, COPD, and
smoking habits. Thus, the comparison controls in this study were
not only age and sex matched but also matched in terms of
primary cardiovascular risk factors. The possible bias of some
unavailable information might have been minimized in this study.
Because of the limitations of ICD-9-CM codes, data regarding
classification (prerenal, intrinsic, postrenal) of ARF in donors and
nondonors were unavailable in this study. Thus, we could not
analyze the causes of ARF.

Long-term outcomes, including metabolic risk factors, AMI,
ESRD, cancer, and stroke, of living donors were similar to those of
the general population in this 13-year follow-up study. Our
results bolster the evidence that kidney donation might have
nonsignificant physiological or medical sequelae. We recommend
carefully informing living donors about the risk of ARF and
associated sequelae before donation; educating them to avoid
nephrotoxins and regularly following them are necessary for the
prevention, early identification, and modification of sequelae
associated with ARF.

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