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Emerging Long-Term Risks of Living Kidney Donation and Its Implications for Living Donor Work up in Nigeria

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Abstract: Kidney transplantation remains the best renal replacement option and living kidney donation is increasingly being performed. However, there are emerging data suggesting that there are risks associated with kidney donation. There is need to reappraise existing donor work up guidelines to align with present realities. Most centres in developing countries like Nigeria rely on protocols from transplant centres in developed countries. There is need to suggest a draft protocol for living donor work up for Nigerians in line with the realities of our environment.

Introduction

Living donor kidney transplantation (LDKT) is increasingly being performed in many centres as it provides better clinical outcomes than deceased donor kidney transplantation (DDKT) [1, 2]. It also provides timely access to kidneys and invariably reduces complications arising from time spent on the waiting list [3]. The first living kidney donor recorded in the literature was a 23year old twin who donated a kidney to his identical twin brother in 1954 [4]. He lived with a solitary kidney for another 56years and died at the age of 79 years [4]. There have since been reassuring data about the safety of living kidney donation (LKD). However, two papers published in 2014 from America and Norway raised concerns about emerging risks of LKD [5, 6].

Interestingly, there are guidelines designed to ensure fairness as well as protect the interest of donors. Kidney disease improving global outcome (KDIGO) summarized these guidelines and the third edition of joint British Transplant Society/Renal Association guidelines for LKD was published in May 2011 [7]. They are collective expert opinions which have no force of the law. For this reason, the strength of the evidence and recommendations are graded. The quality of evidence is graded as one of A, B, C and D which represent high, moderate, low and very low respectively. Also, the weight of recommendation is 1, 2 and 3, which represent 'we recommend', 'we suggest' and 'not strong enough to be graded' respectively. Despite all these activities about LDKT, little or nothing is known about the protocol being used in emerging transplant centres for donor work up. Also, there is the paucity of reports about donor long-term outcomes from emerging transplant communities like Nigeria. There is a heavy reliance on data and protocol from transplant centres in developed countries. This is not best practice when one considers the fact that there are significant disparities in geographical, socio-economic and age-related factors even within these countries [2]. There is need to identify and document long-term complications in emerging kidney transplant communities. Also, there is a need for a donor work up protocol that will take into consideration the peculiarities of Nigerians. Bamgboye in 2009 identified and reported factors that serve as barriers and the peculiarities of kidney transplantation in Nigeria. These include a low level of education, poverty, the absence of functional dialysis and transplant units, lack of appropriate health policies as well as inadequate and poorly motivated caregivers [8]. Similarly, Arogundade in 2011 described kidney transplant outcomes in Nigeria between 2000 and 2010. One- year graft and patient survival was 83.2% and 90.2% respectively while the 5-year graft and patient survival was 58.7% and 73.4% respectively [9]. Also, Adekoya and colleagues in 2012 reported that Nigerians were willing to donate a kidney [10]. However, there is no report on donor outcome in Nigeria.

This review is aimed at critically appraising relevant literature and producing a draft protocol for donor work up that will take into consideration the peculiarities of the transplant environment in Nigeria.

Discussion

Living kidney donation has recently been reported to be associated with increased long-

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term risk of end-stage renal disease [5, 6, 11], cardiovascular disease [12] as well as all-cause mortality. Similarly, donors have been reported to have increased risk of gestational hypertension [13] and pre-eclampsia in pregnancy [13]. All these support the need for a local protocol for donor work up.

British Transplant Society (BTS) guidelines (2011) on pre-donation glomerular filtration rate (GFR) for living kidney donors

The recommendation is that pre-donation GFR should be measured using a reference procedure e.g. 51cr EDTA. A prospective donor whose corrected GFR is predicted to fall below a satisfactory level of kidney function within his or her lifespan should not be considered for donation. The acceptable minimum standard is a predicted GFR of 37.5ml/min/1.73m2 by 80years of age (grade B1). There is, however, no evidence that serves as a guide for an acceptable level of kidney function after 60 years of age.

The guidelines also recommend that estimated glomerular filtration rate (eGFR) should not be used to predict the risk of ESRD in a living donor (grade B1). Also, BTS guideline considers a LKD with normal pre-donation GFR not to be at greater risk of ESRD than individuals in the general population. This section of the guideline needs to be interpreted with caution as some emerging data published after its release in May 2011 are suggesting otherwise. Prospective donors in Nigeria presently have pre-donation kidney function assessed using creatinine clearance and eGFR.

Long term risk of end stage renal disease following Kidney donation

Previous reports of estimated kidney function following kidney donation suggested that donors had lower or no difference in long-term risk of end-stage renal disease when compared with individuals who were otherwise well enough to donate a kidney [14]. However, this has been attributed to the fact that donors were thoroughly screened and would invariably be healthier than matched healthy non-donors [14-16]. Conversely, there are recent studies where issues relating to matching in control recruitments were addressed and these studies reported a significant increased long-term risk of ESRD in LKD when compared with healthy controls [5, 6].

MjØen et al in 2013 reported 1901 LKD from a single centre between 1963-2007. They excluded 41 donors with eGFR less than 70ml/min/1.73m2 and 89 older donors (age > 70 years). They also excluded those with hypertension or on antihypertensive medication (n=106) as well as those with body mass index (BMI) > 30kg/m2 (n=125). The mean eGFR before donation was 105ml/min/1.73m2. The control group comprised 32621 healthy individuals selected from a population-based survey [Health study of Nord-TrØndelag (HUNT)]. LKD were followed up for a median duration of 15.1 years (1.5-43.9) years. They reported that 9 (0.47%) LKD developed ESRD 18.7 (10.3-24.3) years after donating a kidney. This was significantly higher than 22 (0.07%) healthy controls that progressed to ESRD [5]. In addition, they reported that all 9 LKD who later had ESRD were biologically related to the recipients and that immunological renal disease was the primary cause of ESRD in these LKD. This suggests the possibility of a hereditary factor in ESRD in LKD following transplantation [17]. Although, there was no report on the cause of ESRD in the LKD from this Norwegian study.

Similarly, Muzaale et al in 2014 related their experience from a study conducted in the United State of America (USA). They reported on 96217 LKD who had donor nephrectomy between 1994 and 2011. The median follow up period in that study was 7.6years. The maximum follow up period was 15years and the mean eGFR at donation was 101ml/min/1.73m2. They selected controls from the third National Health and Nutrition Examination Survey (NHANES III) that were enrolled between 1988 and 1994. They excluded 10660 individuals remaining 9364 healthy controls, 36 (0.04%) developed ESRD. This was significantly less than the 99 (0.10%) of LKD who developed ESRD over the follow up period. ESRD occurred at about 8.6± 3.2 years (mean ± SD). The absolute increase in the estimated 15 years' incidence of ESRD attributable to live kidney donation was significantly higher in African-American than Caucasians (50.8 per 10,000 vs 22.7 per 10,000) respectively [6]. One third of LKD in that study were related to the recipient and 84% of reported ESRD in LKD were from those who were biologically related to the recipient. This seems to agree with the hereditary factors discussed earlier. However, 15 years' cumulative incidence of ESRD was not significantly different between biologically related and unrelated donors. This increased incidence of ESRD in African-American could have a genetic basis as a variant in the gene for Apolipoprotein L1 (APOL1) has been described in blacks. This suggests that blacks should be screened for APOL1 risk alleles [18]. Also, racial difference in medical outcomes has been reported in LKD [19, 20]. In Nigeria, there is need to screen LKD for APOL1 risk alleles. This is because reports from the Human Genomic Diversity Project and the International HapMap project shows that Yoruba ethnic group of Nigeria clearly harbour the APLO1 alleles in the region of chromosome 22 [21, 22]. Similarly, Ulasi et al in 2015 reported that APOL1 risk variant was common among Igbos which is another Nigerian ethnic group [23]. They reported a strong association between APOL1 risks variants and development of non-diabetic chronic kidney disease (CKD). Tayo and colleagues in 2013 in a case-control study examined the frequency of APOL1 variants among native Africans and their association with non-diabetic forms of CKD. They concluded that APOL1 risk variants are associated with non-diabetic forms of CKD among Yoruba ethnic group of Nigerians [24]. However, the issue of cost will surely be a major factor against large-scale screening for this gene now.

Prospective donors in Nigeria whose pre-donation kidney sizes, as evident from renal imaging shows a difference of greater than 2cm should have the kidney function reassessed. Only one centre in Nigeria performs isotope scan to assess kidney function now.

Grams and colleagues [24] developed a tool that can estimate a prospective donor's probable long-term risk of ESRD [25]. This is not without its limitation [26] but can still be used as a guide. Furthermore, the BTS/Renal Association has adopted the use of age-related threshold GFR (Figure 1) and this can be used as a guide to estimate kidney function in prospective donors in Nigeria as part of pre-donation screening [27].

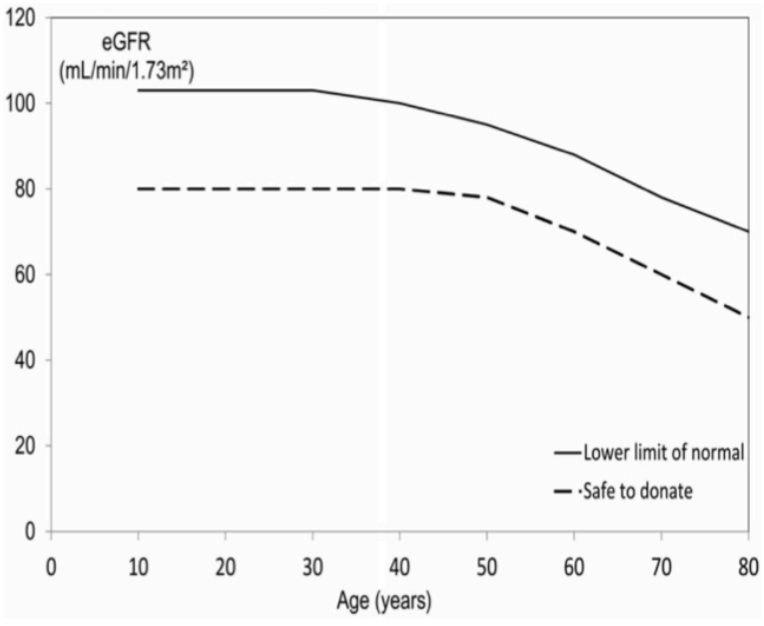

Figure 1: Age-related threshold GFR. The minimum acceptable will be a GFR above 50ml/min/1.73 m2 at the age of 80 years 27].

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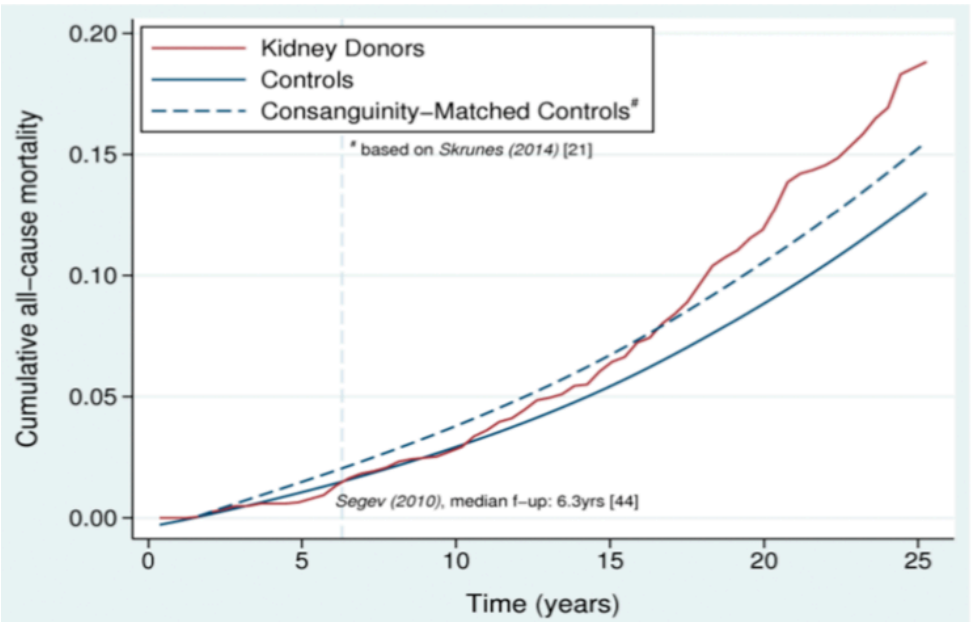

Figure 2: The figure represents the observed mortality in the study by Mjøen et al. in donors (red line) and controls (blue line). Applying a relative risk of 1.10 to 80% of the controls (i.e. the proportional hazard assumption with a first-degree relative with ESRD), under the proportional hazard assumption, the blue line shifts upwards to the dotted blue line, which represents the mortality that would have been observed in the matched controls had the study been adjusted for consanguinity. The distance between the dotted and solid blue line can be regarded as the potential bias in the study, caused by the fact that controls were 'too good' compared with donors because of a less frequent family history of ESRD. The vertical light blue dotted line represents the median follow-up of the study by Segev et al underpinning the fact that the timespan of this study was much shorter than that of the study by Mjøen et al. [26].

Cardiovascular and all-cause mortality

All guidelines consider individual with blood pressure above 140/90 mmHg as being hypertensive. The BTS guideline suggested that hypertensive whose blood pressure is well controlled on 1 or 2 medications should be considered for kidney donation as long as there is no evidence of end organ damage (B1). In Nigeria, prospective donors with blood pressure >140/90mmHg are presently not accepted.

Long term risk of cardiovascular disease and all-cause mortality following live kidney donation

Matas et al in 2017 reviewed the long-term non-ESRD risks associated with kidney donation and concluded that there is serious under-reporting of non-ESRD risks following kidney donation (12). However, three studies in the literature (one from Canada and 2 from the United States of America) compared LKD with healthy non-donors [28-30] and concluded that there is no difference in risks of cardiovascular disease (CVD) as well as all-cause mortality between the two groups. Interestingly, the mean follow- up duration in these three studies was 8yrs. This was rather short when compared with registry study from Norway described above with a follow-up period of 15years [5]. The follow-up duration is quite important as the longer duration study (the Norwegian study) reported increased mortality in LKD compared with healthy non-donors. Other than the duration of follow-up, another major limitation of all these studies is the sharp discrepancies between the LKD and controls. This was addressed in the Norwegian study.

There were reports of racial difference in the cardiovascular disease risk following kidney donation [19, 20, 31]. Lentine et al in 2010 reported a greater risk of hypertension in black as compared to white donors in a retrospective study of registry data [19]. This raises concern about the need for stricter cardiovascular screening for donors in Nigeria and the importance of explaining these potential long-term risk to them. In a recent consensus report [26], Developing Education Science and Care for Renal Transplantation in European State (DESCARTES) board members concluded that the long-term risk of cardiovascular and all-cause mortality risks is not as strong as reported in the Norwegian study (figure 2)

Long term risk of gestational hypertension and preeclampsia following kidney donation

There is an association between chronic kidney disease and increase risk of gestational hypertension (GH), preeclampsia as well as intrauterine growth retardation [32, 33]. Despite these associations, there were previous reports on the pregnancy outcome following LKD showing that there was no increased risk of adverse events like gestational hypertension and preeclampsia [34, 35]. However, neither of these studies compared pre-donation with post-donation pregnancies in the same woman. Conversely, Reisaeter and colleagues (2009) reviewed registry data of kidney donors in Norway between 1967 and 2002 and identified 326 donors with 726 pregnancies (106 after donation). In an adjusted analysis, they observed that preeclampsia was commoner in pregnancies after donation [36]. Interestingly, the authors admitted that their observations should be interpreted with caution as they only identified 6 cases out of 106 post-donation pregnancies (5.7%). Similarly, Ibrahim and colleagues (2009) reviewed the record of 3698 LKD between November 1963 and December 2007 in Minnesota. Two thousand, one hundred and two of these donors were women, 1589 of whom participated in the survey. They observed a significant gestation hypertension and preeclampsia post- donation in the participants and concluded that post-donation pregnancy is associated with increased risk of these adverse outcomes. These outcomes were not different from reported cases in the general population but were observed to be inferior to the pre-donation outcomes [37]. In a Canadian study, Garg and colleagues (2015) reviewed records of 85 women (131 pregnancies) who donated a kidney between 1992 and 2009 in Ontario. Pregnancy outcomes in them were compared with that of 510 healthy non-donors from the general population. They observed that gestational hypertension or preeclampsia was more common in LKD than non-donors who had common baseline health indicators [13].

Reports of pregnancy outcome after kidney donation are lacking in Nigeria. There is a need to inform young women presenting as prospective LKD about the possible long-term risk of adverse pregnancy outcomes. This needs to be supported by evidence-based recommendation. Current European Renal Best Practice Guideline recommend that a woman in her reproductive age who is considered fit for donation should be informed that she is better than an average woman in the general population pre-donation and that donating a kidney will make her be at the same level as those in the general population in terms of risk of gestational hypertension and preeclampsia [38].

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Table 1: Proposed protocaol for living donation work up in Nigeria

A. History (look for/ask about)

1. Family history of kidney disease
2. Hypertension
3. Diabetes
4. Willingness to donate kidney
5. Infections
6. Medications-Non steroidalanti inflammatory drug, vocational drugs, intravenous drug use

B. Physical Examination (look for)

1. Blood pressure
2. Height/weight-Body Mass Index
3. Autoimmunity
4. Cancer
5. Cardiovascular disease
6. Arthrits

C. Laboratory investigations
Urinalysis and urine microscopy
Blood group and genotype
Electrolyte, Liver function test, Lipid profile, fasting blood sugar, Full blood count, 24hour urine protein and creatinine clearance, urine albumin creatinine ratio.
Antiviral screening(HBV,HCV,CMV,HIV,EBV)
Immunological assessments
Tuberculosis screening- Purified protien derivative test
Electrocardiogram, Chest radiograph, echocardiography
Prostate examination for men. PAP smear for women
Where indicated in respect of age/family history: Excercise tolerance test, colonoscopy, mammography, prostate specific antigen.

D. Anotomical examination
Abdominopelvic ultrasound
Computed tomography angiography

Table 2: Proposed contraindications to living kidney donation in Nigeria

Absolute contraindications

1. Uncontrolled hypertension
2. Diabetes mellitus
3. Active malignancy
4. Chronic infection (chronic lung disease)
5. Significant kidney stones (Bilateral/association metabolic abnormalities/history of kidney stones)
6. History of thrombosis or thromboembolism
7. HIV infection
8. Microscopic hematuria
9. Proteinuria (>300mg/24hr)
10. Age less than 18years
11. Evidence of financial inducement

Relative contraindications

1. Obesity (Body mass index greater than 35kg/m^2
2. Psychiatric disorder
3. Drug or alcohol abuse
4. Multicystic kidney disease
5. Small kidneys (bipolar length <9cm suggestive of CKD)

Conclusions.

Live kidney transplantation is increasingly being performed as a renal replacement option. There are reports showing that LKDs have no long-term risks of ESRD, CVD and pregnancy outcomes. However, there are emerging data concluding that reverse is the case. Although the evidence may not be too strong to change the practice of living kidney donation, the onus is on caregivers to outline these risks to intending donors and allow them to make an informed decision. Also, Kidney donors need appropriate work up that is evidence-based and appropriate for the local settings. Hence there is the need for local research that will produce evidence which can then be translated into statements.

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