Comparison of estimated glomerular filtration rate of marginal versus standard renal allograft: A prospective cohort study

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ABSTRACT

Introduction: The end-stage renal disease (ESRD) population is increasing worldwide and organ shortage is an important issue. The disparity between the availability of organs and waitlisted patients for transplants has forced many transplant centers across the world to use marginal kidney donors. We assess and compare postoperative estimated glomerular filtration rate (eGFR) in patients who received a graft from marginal renal donor (MRD) versus those who received a graft from standard renal donor (SRD).

Methods: A total of 214 patients with ESRD underwent open live donor renal allografting from September 2015 to September 2017. Out of 214 donors, 165 (77.1%) were SRD and 49 (22.9%) were MRD. Post-transplant eGFR was calculated at 2 months for donors and at days 1, 3, 5, and 7 and month 1, 3, 6, and 12 for recipients.

Results: There was no statistically significant difference in eGFR of recipients at preoperative and postoperative period between SRD and MRD groups. Although at 12 months of follow–up eGFR was relatively high in SRD group, it did not show any statistically significant difference. The recipient survival rate at 1-year follow-up was 98.2% in SRD and 100% in MRD group.

Conclusions: Renal transplant recipients using MRDs have a comparable glomerular filtration rate to SRDs at the end of 1 year. Short-term outcomes in recipients receiving marginal renal grafts were similar when compared to the allograft from standard donors.

INTRODUCTION

The end-stage renal disease (ESRD) population is increasing worldwide. Renal transplantation improves patient survival and quality of life in ESRD. In India, about 80,000 patients are added annually to the pool of ESRD; however, only 2.4% undergo transplant.[1-3]

The United Network for Organ Sharing (UNOS) renal transplant registry data shows an annual 10% increase in the number of patients on waiting lists for kidney transplantation, whereas the annual increase in the number of renal transplants is only 4%. For cadaveric donor–recipients, the waiting list is of more than 5 years. Approximately 7% of the waiting list candidates die annually. The organ shortage is a preeminent issue in the current era of transplantation. This disparity between availability of organs and waitlisted patients for transplants has forced many transplant centers across the world to accept kidneys from marginal kidney donors if the standard donor kidney is not available.[3,4]

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The terms 'marginal donor' or 'extended criteria donor' means accepting a suboptimal quality renal graft, either from a living or a deceased donor with acceptable medical risks. The absence of uniformity in defining a suboptimal donor deprives us of having uniform recommendations. The clinical characteristics that differentiate "marginal" renal allograft of such donors are derived from (a) the social and medical history of the donor (age, history of hypertension (HTN) or diabetes, and/or malignancy), (b) the mechanism of donor death (brain death vs. cardiac death), (c) the morphology on biopsy (glomerulosclerosis, interstitial nephritis and/or fibrosis), and (d) the functional profile.[3,5-7]

In developing countries like India, where cadaveric donor program is still in its infancy and an acute shortage of standard renal donor (SRD), the use of marginal donors becomes particularly important. Using grafts with marginal criteria expands the donor pool for renal transplantation. The recipient with marginal renal grafts has an advantage of extra survival as compared to waitlisted dialysis patients; however, they have decreased long-term graft function.[8,9] The aim of this study was to assess the outcome of marginal renal graft in renal transplant by comparing post-transplant graft function in recipients with graft from marginal donor and standard donor.

METHODS

This prospective observational study was conducted in a single multidisciplinary hospital and referral center in India from September 2015 to September 2017 (the last patient recruited was admitted in August 2016 and then followed for 12 months).

The primary objective was to assess and compare postoperative graft estimated glomerular filtration rate (eGFR) in recipients who received grafts from marginal renal donors (MRDs) versus grafts from SRDs. Secondary objectives were post-transplant surgical complications graded according to the Clavien–Dindo classification, graft rejection rate, delayed graft function (DGF), and post-nephrectomy donor eGFR.

All patients with ESRD admitted for open live donor renal allografting surgery along with their matched live related donor who underwent donor nephrectomy were included in this study. Marginal donor included donors with one or more of the following basic characteristics: age more than 60 years, split function of graft kidney <40%, HTN controlled on more than single medication, and pre-diabetes mellitus (DM) (hemoglobin A1c – 5.7%–6.4%). All other healthy donors were considered standard donors. Exclusion criteria were donor age more than 70 years, robotic, pediatric, and cadaveric transplant. Informed consent was obtained from all patients. This study was approved by the Hospital's Institutional Ethics Committee (MICR-512/2015).

Donors and recipients were evaluated on an outdoor basis; both underwent full biochemical and radiological investigation including renal angiography and diethylenetriaminepentaacetate (DTPA) scan for donors and color Doppler of iliac vessels for recipients. After full preoperative evaluation and workup, both donors and recipients underwent planned surgery.

All donors underwent transperitoneal laparoscopic donor nephrectomy (LDN) through a four-port approach. Steps of standard LDN were followed. The artery, vein, and ureter were dissected and clipped, and the kidney was delivered through a Pfannenstiel incision. Warm ischemia time (WIT) was noted.

The open recipient procedure was performed using the standard extraperitoneal approach at the right iliac fossa. Graft renal artery was anastomosed end to end to internal iliac artery or if indicated end to side to external iliac artery and the graft renal vein was anastomosed end to side with an external iliac vein. A standard ureterovesical anastomosis (Lich Gregoir) was done. Donors were usually discharged on postoperative day 4. At discharge, donors and recipients were instructed to adhere to a standard institution-designed follow-up protocol. Both donors and recipients were followed up for 1 year. Postoperative eGFR was calculated at 2 months for donors and at days 1, 3, 5, 7, and 1, 3, 6, and 12 months for recipients. Graft eGFR was calculated by using the formula proposed by chronic kidney disease epidemiology collaboration. Recipients were analyzed into two subgroups: recipients with marginal renal graft (MRD group) and recipients with standard renal graft (SRD group).

WIT was defined as the time from clamping of the renal artery until starting allograft perfusion with cold perfusate. Cold ischemia time was defined as starting of allograft perfusion with cold perfusate to restoration of blood supply after vascular anastomosis. Total ischemia time includes both warm and cold ischemia time. Total operative time includes incision time to skin closure time. DGF was defined as the need for hemodialysis on postoperative days 1–7.

Both recipient groups had similar induction and maintenance immunosuppression protocol. Thymoglobulin (1.5 mg/kg body weight on day 0 and day 2) and basiliximab (20 mg on day 0 and day 4) were used for induction depending upon the risk status. Maintenance protocol was as followed: (i) tacrolimus: 8–12 ng/ml for 2 months, 6–8 ng/ml for next 4 months, and then 5 ng/ml as maintenance; (ii) prednisolone: 20 mg at discharge, 10 mg at 1 month, 7.5 mg at 3 months up to 6 months, and then 5 mg as maintenance; and (iii) mycophenolate mofetil: 720 mg twice a day for 6 months and then 360 mg twice a day as maintenance.

We calculated the sample size using the mean eGFR of graft in recipients. Considering the mean recipient graft eGFR 41.6 ± 21.1 in MRD group and 51.7 ± 22.0 in SRD group and under the assumption that unequal groups of MRD and SRD, sample ratio was expected in the ratio of 1:3 for MRD and SRD. The sample size was 173 patients combined for both groups (43 for MRD and 129 SRD) for a desired confidence level of 95% and power of 80%.

Statistical analysis

Statistical analysis was performed using SPSS version 24.0 software (IBM, Bengaluru, Karnataka, India). Continuous data were presented in terms of means and standard deviation. Categorical data were presented as absolute numbers and proportions. Continuous variables were analyzed using the independent Student's *t*-test and categorical variables were analyzed using Chi-square. General linear models were fitted to examine the relation between eGFR at 12 months and the risk factors for recipients. $P < 0.05$ was considered statistically significant.

RESULTS

Out of 254 recipients admitted for renal allografting, data were procured for 214 patients for statistical analysis after excluding 40 patients as per the predefined exclusion criteria. All these factors could independently affect the graft outcome. Patients were divided into two groups based upon criteria for marginal donors. Out of 214 donors, 165 (77.1%) were SRD and 49 (22.9%) were MRD. A total of 16 patients (12 from SRD and 4 from MRD group) were lost to follow-up, so 1-year follow-up data were of 198 patients (153 patients in SRD and 45 patients in MRD group).

Both donor groups had similar demographic profile except mean donor age which was significantly high in MRD group (53.9 ± 8.9 vs. 44.1 ± 10.6 years, $P < 0.001$). The male-to-female ratio of all donors was 49:165. The ratio of left to right-sided donor nephrectomy was 195:19. Both groups did not show any statistically significant difference in the laterality of retrieval. The most common mode of retrieval was laparoscopy used in 213 (99.5%) donors; only one donor electively underwent open donor nephrectomy in view of previous abdominal surgeries.

No difference in intraoperative parameters was noted between the two groups. Mean preoperative serum creatinine level in both groups was similar (0.68 ± 0.2 mg/dl in SRD vs. 0.70 ± 0.2 mg/dl in MRD). On follow-up at 2 months, mean serum creatinine level in MRD group was slightly higher than SRD (0.99 ± 0.2 mg/dl vs. 0.95 ± 0.7 mg/dl, $P = 0.629$). Mean preoperative and postoperative eGFR was significantly low in the MRD group [Table 1].

Out of 49 marginal donors, pre-DM (alone and in combinations) being the most common criteria was seen in 22 (44.89%) donors and HTN not controlled on a single drug was reported in 18 (36.73%) donors. Fifteen (30.61%) donors were more than 60 years. Only one donor had differential graft GFR of <40% in the age group of more than 60 years and 6 (12.2%) donors had multiple marginal criteria.

Out of a total of 214 donors, who were started laparoscopically, only one from the MRD group was converted to an open approach due to intra-abdominal adhesion. Of the 214 patients, 8 (3.7%) donors developed paralytic ileus (4 from each group), atelectasis in 5 (2.3%) donors (3 in SRD and 2 in MRD group), bowel injuries in form of small serosal tear in descending colon in 2 (0.9%) donors (one from each group), and wound infection in one donor from SRD group. Both patients had a small serosal tear of the descending colon, which was repaired laparoscopically.

Both recipients groups had a comparable demographic profile with no statistically significant difference. Out of 214 recipients, 85.99% were male and 14.01% were female. A total of 21 (9.81%) recipients underwent pre-emptive transplants and the rest were on dialysis before transplantation. Intraoperative parameters were comparable in both groups [Table 2].

Postoperative complications developed in 77 patients (56 patients in SRD group and 21 patients in MRD group). Complication rates were similar in both groups (SRD vs. MRD: 33.9% vs. 42.9%, $P = 0.445$). Two recipients (0.9%) (one in each group) underwent re-exploration, both were found to have a perigraft hematoma. According to Clavien–Dindo classification, minor complications (Grade 1 and 2) constitute 98.2% in SRD group and 95.2% in MRD group. Major complications (Grade 3, 4 and 5) constitute 1.8% in SRD and in MRD group [Table 3].

There was no statistically significant difference in eGFR of recipients in postoperative period between SRD and MRD groups. Although at 12 months of follow-up eGFR was relatively high in SRD group, it did not reach statistical significance [Table 4].

Graft biopsy was done in 27 recipients (16.4%) in SRD group and 9 recipients (18.4%) in MRD group ($P = 0.740$). Biopsy findings did not show a statistically significant difference between both groups. In SRD group, acute tubular necrosis (ATN), acute cellular rejection (ACR), and antibody-mediated rejection (AMR) were found in 5.4%, 9.6%, and 1.2% recipients, respectively. Similarly in the MRD group, ATN, ACR, and AMR were found in 6.1%, 10.2%, and 2% of recipients, respectively.

DGF was seen in 2 recipients (1.2%) in SRD group and 2 recipients (4.1%) in MRD group ($P = 0.193$). In MRD group,

Table 1: Demographics and perioperative parameters of donors (*n*=214)

Parameters	SRD (*n*=165)	MRD (*n*=49)	P
Mean age±SD (years)	44.1±10.6	53.9±8.9	<0.001
Male: Female	1:2.7	1:2.7	0.999
Mean BMI±SD (kg/m²)	25.6±4.5	25.6±4.5	0.964
Mean preoperative serum creatinine±SD (mg/dl)	0.68±0.2	0.70±0.2	0.462
Mean preoperative eGFR±SD (ml/min)	125.6±35.07	107.9±26.9	0.001
Side, *n* (%)			
Right (*n*=19)	16 (9.7)	3 (6.1)	0.435
Left (*n*=195)	149 (90.3)	46 (93.9)	0.392
Mode of harvest, *n* (%)			
Laparoscopic (*n*=213)	165 (100)	48 (98)	0.06
Open (*n*=1)	0	1 (2)	-
Mean total operative time±SD (min)	148±22.9	146.10±22.6	0.611
Mean total blood loss±SD (ml)	49±9.4	49.9±14	0.629
Mean serum creatinine±SD at 2 months (mg/dl)	0.95±0.7	0.99±0.2	0.629
Mean postoperative eGFR±SD (ml/min)	98.3±19.1	87.8±18.7	0.001

BMI=Body mass index, SD=Standard deviation, eGFR=Estimated glomerular filtration rate, SRD=Standard renal donor, MRD=Marginal renal donor

Table 2: Demographics and perioperative parameters of recipients (*n*=214)

Parameters	SRD (*n*=165)	MRD (*n*=49)	P
Mean age±SD (years)	40.1±11.3	40.4±13.4	0.889
Male: Female	6.1:1	6:1	0.951
Mean BMI±SD (kg/m²)	22.7±3.7	23.1±4.4	0.575
Preemptive transplants (*n*=21), *n* (%)	14 (8.5)	7 (14.3)	0.205
Mean dialysis vintage±SD (months)	5.7±5.9	4.6±5.1	0.274
Pretransplant mean serum creatinine±SD (mg/dl)	9.5±3.8	9.1±2.9	0.472
Mean number of HLA mismatch in all recipients±SD	30.3±30.3	32.2±25.9	0.685
ABO incompatible, *n* (%)	6 (3.6)	2 (4.08)	0.896
Mean warm ischemia time±SD (min)	3.5±1.0	3.6±1.7	0.334
Mean total ischemia time±SD (min)	56.9±11.9	54.8±11.4	0.261
Mean total operative time±SD (min)	179.3±31.5	181.4±38.5	0.334
Mean blood loss±SD (ml)	121.7±25.8	121±24.0	0.990
Mean hospital stay±SD (days)	7.7±0.7	7.6±1.3	0.157

BMI=Body mass index, SD=Standard deviation, SRD=Standard renal donor, MRD=Marginal renal donor, HLA=Human leukocyte antigen

Table 3: Comparison of complications between the two groups of recipients (according to Clavien–Dindo classification) (*n*=80)

Grade	Complications	SRD (*n*=165), *n* (%)	MRD (*n*=49), *n* (%)	P
I	Paralytic ileus (*n*=12)	9 (5.5)	3 (6.1)	0.246
	Hematoma (*n*=2)	1 (0.6)	1 (2.04)	0.424
	Wound related (*n*=3)	1 (0.6)	2 (4.08)	0.096
	Total complication (*n*=17)	11 (6.7)	6 (12.2)	0.329
II	Blood transfusion (*n*=29)	23 (13.9)	6 (12.2)	0.409
	Bacterial UTI (*n*=20)	15 (9.1)	5 (10.2)	0.854
	Viral infections (*n*=9)	6 (3.6)	3 (6.1)	0.614
	Total complication (*n*=58)	44 (26.7)	14 (28.6)	0.542
IIIA	-	-	-	-
IIIB	Re-exploration (*n*=2)	1 (0.6)	1 (2.04)	0.424
IVA	-	-	-	-
IVB	-	-	-	-
V				

UTI=Urinary tract infection, SRD=Standard renal donor, MRD=Marginal renal donor

one recipient had kidney from hypertensive donor and the other had kidney from 70 years old donor. On the biopsy report, one recipient had ACR and the other had AMR in MRD group. Both the patients had AMR in SRD group.

The recipient survival rate at 1-year follow-up was 98.2% in SRD and 100% in MRD group (*P* = 0.482). Three patients (1.8%) succumb to life in SRD group. Two patients expired due to respiratory infection and one patient had

myocardial infarction. All these three patients had functional graft at the time of death. There was no graft loss in either group.

DISCUSSION

The UNOS renal transplant registry data show a large gap between the number of patients waiting for a transplant and the number receiving a transplant. Pool of kidney donor can

Table 4: Comparison of estimated glomerular filtration rate of recipient between standard renal donor and marginal renal donor group (n=198)

eGFR (ml/min) at mean±SD	SRD (n=153)	MRD (n=45)	P
Preoperative	9.9±3.4	10.2±3.5	0.595
Day 1	31.6±16.1	36.5±25.3	0.106
Day 3	72.7±28.2	77.7±32.3	0.289
Day 5	76.7±27.3	80.7±30.5	0.395
Day 7	79.8±25.8	85.0±29.3	0.235
1 month	75.1±23.3	77.4±24.7	0.555
3 months	70.8±22.6	72.2±22.7	0.715
6 months	69.7±21	71.2±21.3	0.658
12 months	66±19.7	63.1±15.8	0.362

SD=Standard deviation, eGFR=Estimated glomerular filtration rate, SRD=Standard renal donor, MRD=Marginal renal donor

be increased by expanding criteria for the safe selection of a selected group of donors by almost 20%–25%.[1] In most series, when outcomes were compared between marginal and standard renal graft, although there was inferior outcome with marginal renal graft, it had significant survival advantages over waitlisted dialysis patients.[3] The 5-year graft and patient survival rates were 53% and 74% respectively for MRD recipients as compared to 67% (*P* = 0.001) and 80% (*P* = 0.001) for SRD recipients. However, mean life expectancy for MRD recipients was increased for 5 years (range 3–10 years) as compared to waitlisted dialysis patients with no transplant. The cost–benefit ratio analysis also suggests that transplantation with a marginal donor kidney is more cost-effective than dialysis.[9,10]

Various studies have reported the incidence of MRD in the range of 23% to 45%.[10-12] Most common criteria to define MRD were varying in different studies. In our study, pre-DM was the most common criteria (44.89%), followed by HTN not controlled on a single drug (36.73%). In other studies, older age and HTN were the leading criteria.[9,11,13,14]

The outcomes of marginal donor nephrectomy in terms of residual renal function remain a poorly understood phenomenon. Although the proven risk of ESRD in a diabetic subject eliminates them from the armamentarium of renal donor pool, the risk of ESRD in prediabetic individual should be studied further. A patient with hemoglobin A1c level of <6.5% has considered a marginal donor in Japanese guidelines; however, its validity has been not well examined.[11,14]

In our study at 1-year follow–up, all hypertensive donors were able to maintain their blood pressure control on the same drug regimen without changing the dose of drugs and none of normotensive donor developed HTN. Perioperative complications rate was comparable in both donor groups with no statistically significant difference.

Both recipients groups had comparable demographic profile and intraoperative and postoperative recipient parameters

with no statistically significant difference. Complication rate was similar in both groups (SRD vs. MRD: 33.9% vs. 42.95%, *P* = 0.445).

In our study, there was no statistically significant difference in postoperative eGFR till 1 year between the two groups. On postoperative days 1, 3, 5, and 7, eGFR was slightly high in MRD group (on day 7, SRD: 79.8 ± 25.8 vs. 85.0 ± 29.3, *P* = 0.106). At 12 months of follow-up, eGFR was slightly high in SRD group but did not show any statistically significant difference (66 ± 19.7 vs. 63.1 ± 15.8 ml/min, *P* = 0.362). There was no statistically significant difference in eGFR at 1 week in other studies, but it was significantly lower in the marginal group than in the standard group at 1 year after kidney transplantation.[14-16] There was a dramatic improvement of mean eGFR on days 3, 5, and 7 in both groups. This may be due to high-volume solute diuresis in the immediate postoperative period leading to a rapid fall in serum creatinine. In a meta-analysis, recipients of younger kidneys had a statistically higher 1-year GFR than recipients of older kidneys, but the absolute difference was small (3 ml/min, 95% confidence interval 1.1-4.8,).[17] In our study, eGFR at 12 months in the SRD group was 66.0 ± 19.7 ml/min and in MRD with age more than 60 years, it was 60.8 ± 14.8 ml/min (*P* = 0.332).

In our study, eGFR in SRD group recipient was slightly high compared to a recipient using marginal kidney from a donor with HTN not controlled on the single antihypertensive drug at 1-year follow-up (66.0 ± 19.7 vs. 61.4 ± 14.2 ml/min respectively, *P* = 0.352). Ojo *et al.* concluded that because the negative impact of donor HTN and DM on transplant outcome was of moderate degree except when the duration of donor HTN was > 10 years, use of affected donors should not be discouraged.[9]

GFR of single-kidney nondiabetic and single-kidney type 2 DM patients were similar at 6 months (71.7 ± 21.4 ml/min vs. 73.0 ± 21.5 ml/min, respectively).[18] We found no statistically significant difference in eGFR at pre- and postoperative period between pre-DM MRD group and SRD groups. At the end of 1 year, eGFR was similar (66.0 ± 19.7 in SRD vs. 65.0 ± 17.6 in MRD, *P* = 0.822).

Recipients of kidneys from MRD with lower GFR had significantly low GFR as compared to recipients with SRD at 2-year follow-up (53 ± 16 vs. 60 ± 21 ml/min, *P* < 0.01).[19] We observed comparable eGFR between MRD with split function of graft kidney < 40% and SRD during follow-up at 1, 3, 6, and 12 months (62 in MRD vs. 66 ml/min in SRD at 12 months).

Various studies reported more episodes of acute rejection in MRD group without statistically significant difference, the same findings seen in our study.[13,16,19,20] There is contradiction for DGF in different studies. Dahmane *et al.*

found significantly more DGF in MRD group (63% vs. 32%, $P = 0.0001$), but other authors found no difference.[6,16,21] We also did not find any significant difference (1.2% in SRD vs. 4.1% in MRD, $P = 0.193$).

The survival benefits seen in recipients of MRD are inferior compared with those in recipients of SRD but significantly better than in those remaining on hemodialysis. Diabetic donors had lower graft survival, compared with that of controls.[22,23] In the present study, there was no graft loss up to 12 months in both groups with no difference in recipient survival rate (98.2% in SRD and 100% in MRD). Various studies suggested a similar graft survival rate.[6,21] Our study had a better graft survival rate as compared to the literature, it may be due to the short follow-up period of our patients as compared to others.

The limitation of our study was the short-term follow-up (1 year) which precludes more accurate long-term consequences in both donor and recipient. There is a lack of standard criteria to define MRD in literature. We did not perform preimplant graft biopsy for studying the type and extent of structural changes in graft kidney and its consequent effect on the recipient because of complications associated with graft biopsy and the observational nature of this study. However, our findings need to be reconfirmed in further studies with larger sample size, multi-institutional nature, and long-term follow-up for validating outcomes in donor and recipient.

CONCLUSIONS

Renal transplant recipients using MRDs have a comparable glomerular filtration rate to SRDs at the end of 1 year. Short-term outcomes in recipients receiving marginal renal grafts were similar when compared to the allograft from standard donors.

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