A Multicenter Clinical Study of Single-Kidney Transplantation vs En Bloc Transplantation with Kidneys from Deceased Pediatric Donors

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ABSTRACT

Background. There are still disputes regarding the choice of surgical approach to harvest organs from pediatric donors for organ recipients. The primary goal of this multicenter, retrospective analysis was to compare outcomes between single-kidney transplantation (SKT) and en bloc kidney transplantation (EBKT).

Methods. Data from donors and recipients aged 4 to 18 months from 3 transplant centers over 5 year were collected to compare postoperative complications and recoveries of renal function between SKT and EBKT and to determine whether there is a difference in the 1-year patient and kidney survival rate between the 2 groups.

Results. Between the SKT and EBKT groups, the incidence of delayed graft function was significantly higher in the SKT group than in the EBKT group (44.1% vs 17.3%, $P = .03$), and there were no significant differences in other complications (47.0% vs 59.0%, $P = .36$). Moreover, no significant differences were observed for the overall patient survival rate ($P = .08$) or the overall graft survival rate ($P = .71$).

Conclusions. The short-term effects of SKT make it worthy of consideration. For infants aged 4 to 18 months, SKT can provide good results, alleviating the current tense situation in kidney donation.

END-STAGE renal disease is a common outcome of various progressive chronic kidney diseases, and kidney transplantation is a more effective and rational treatment method for patients at this stage compared to dialysis [1]. However, a graft shortage has severely limited kidney transplants. Since 2015, donation after citizen death has been the main source of grafts in China [2], and deceased infants and young children are especially suited as kidney donors due to their relatively simple social relationships. Currently, there are 2 ways to transplant pediatric donor kidneys: single-kidney transplantation (SKT) and en bloc kidney transplantation (EBKT). Researchers are concerned about inadequate "nephron doses" because of the relatively small kidney sizes in infants and young children and secondary high-reperfusion injuries. Some transplant centers use EBKT for kidneys with donors aged 5 years or younger or with a weight of 21 kg or less and have achieved long-term outcomes comparable to those of transplants with more conventional kidney grafts [3]. However, it is obvious that the donor efficiency of EBKT is significantly lower than that of SKT. At present, most reports at home and abroad involve pediatric donor kidneys $\geq$ 3 years old [4–6] and most studies have focused on contrasting standard kidney donations or simply reporting prognoses [7–10]. Fewer studies have involved comparisons of SKT and EBKT. For children younger than 2 years of age, many donor centers are still in the undeveloped

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stage, which also leads to an increase in the rate of renal abandonment in pediatric kidney donation [6]. Therefore, in this study, we, along with 2 other transplantation centers in the country, collected information on the early complications and short-term curative effects of 3 central renal allografts in infants using SKT and EBKT from January 1, 2012 to January 1, 2017 to verify the effectiveness and safety of SKT in infants and young children. This can alleviate difficulties in kidney donation and improve the utilization efficiency, and explore as a new standard for the use of donor kidneys in infants and young children.

MATERIALS AND METHODS

Group Assignments and Inclusion Criteria

This was a retrospective, multicenter control study during which we collected data from kidney transplants with kidneys from infants and young children from 3 transplant centers in China over a 5-year period along with data about the recipients. The kidney grafts were from all-organ harvests and were allocated by the China Organ Transplant Response System. The graft criteria were as follows: (1) donors from 4 to 18 months of age with no major underlying diseases or hereditary diseases; (2) end-stage renal disease recipients who were able to undergo kidney transplantation and who had a preoperative panel reactive antibody (PRA) level $\leq$ 5%; (3) complement dependent cytotoxicity (CDC) negative; and (4) no serious comorbidities unrelated to transplantation. The recipients were assigned to the SKT group or the EBKT group according to the type of kidney transplant. We initially collected data from 101 cases of kidney donation from infants $\leq$ 3 years old and the corresponding data for 149 recipients. According to the operative method, we found that there was a significant statistical difference in the donor age between the 2 groups. This is obviously not in accordance with the principle of a control study. Therefore, we set the donor age range as 4 to 18 months of age. Under this condition, there is no statistical difference in the general conditions of the donors between the 2 groups except for the different forms of surgery. Our research program was reviewed by the Medical Ethics Committee of Zhujiang Hospital, Southern Medical University, with approval number 2017-QGYZK-002.

Kidney Transplantation and Medical Plan

For the SKT group, the preferred transplant site was the right iliac fossa. To connect the vessels, the graft renal vein was connected to the recipient's external iliac vein, and the graft renal artery was connected to the side of the recipient's internal or external iliac artery. The urinary tract was reconstructed via ureter-to-bladder mucosal anastomosis, and a ureteral stent was placed.

For the EBKT group, EBKT with entire kidney block was performed. The distal end of the graft's abdominal aortic artery was connected to the side of the recipient's external iliac artery, and the distal end of the graft's inferior vena cava was connected to the recipient's external iliac vein. The urinary tract was reconstructed in the same manner as in SKT.

All of the patients received antibiotics after surgery to prevent infections. The anti-infective regimen was developed based on the past experiences of each transplant center. Glucocorticoid shock therapy was the first-line treatment for acute rejection. An immunosuppressive regimen was developed according to the standard procedures at each center, which usually included basiliximab or rabbit antihuman thymocyte immunoglobulin. Heparin was given for a short period after surgery.

Indicators and End Points

The data were obtained by reviewing the case data at the time of follow-up examination. Kidney function was evaluated through creatinine and estimated glomerular filtration rate (eGFR, estimated using the Modification of Diet in Renal Disease study equation) findings at postoperative day 7, month 1, month 3, month 6, and year 1. Postoperative complications included delayed graft function (DGF, at least 1 dialysis treatment during postoperative week 1), vascular complications (including graft vascular stenosis, thrombosis, vessel rupture, graft rupture), urinary complications (urinary fistula, urinary obstruction, urinary infection), medical complications (lung infection, liver dysfunction), rejection, and lymph node leakage. Moreover, postoperative 1-year patient and graft survival rates were analyzed. The end of the follow-up period occurred at graft loss or patient death.

Statistical Analysis

SPSS Statistics, version 20 (IBM, Armonk, NY, United States) was used for the statistical analysis of the data. The data were analyzed with a 2-sample t test. Dichotomous variables, such as sex and postoperative complications, were analyzed using the χ^2 test or Fisher exact test, while creatinine and eGFR were analyzed using multivariate analyses of variance. Postoperative 1-year patient and graft survival rates were analyzed using a survival analysis. All of the tests were 2-sided, and $P \leq .05$ was considered statistically significant.

RESULTS

General Information

A total of 57 recipients underwent kidney transplantation with kidneys from 42 infants and young children from 4 to 18 months of age. As of November 1, 2017, the recipients had been followed up with for 1 day to 59 months. A total of 34 recipients and 19 donors were included in the SKT group, the average follow-up period was 18.18 months, and 2 patients were lost to follow-up. The lost to follow-up ratio was 5.6%. The EBKT group included 23 recipients and 23 donors; the average follow-up time was 26.56 months, and 1 patient was lost to follow-up, giving a lost to follow-up ratio of 4.3%. The PRA level was $\leq$ 5% and the CDC was negative in all recipients. Table 1 shows the demographics of the donors and recipients.

Table 1. Donor and Recipient Demographics

Variable	SKT	EBKT	*P* Value
Donor	N = 19	N = 23	
Mean age (mo) ± SD	11.16 ± 3.9	9.32 ± 3.9	.14
Male/female	9/10	14/9	.45
Mean weight (kg) ± SD	9.031 ± 2.8	7.96 ± 1.6	.44
Recipient	N = 34	N = 23	
Mean age (y) ± SD	32.35 ± 11.1	32.26 ± 13.7	.97
Male/female	16/18	14/9	.30
Mean weight (kg) ± SD	49.82 ± 12.9	46.66 ± 11.7	.35
Mean waiting time (mo), ± SD	24.06 ± 21.5	19.27 ± 13.0	.35

Abbreviations: EBKT, en bloc kidney transplantation; SKT, single-kidney transplantation.

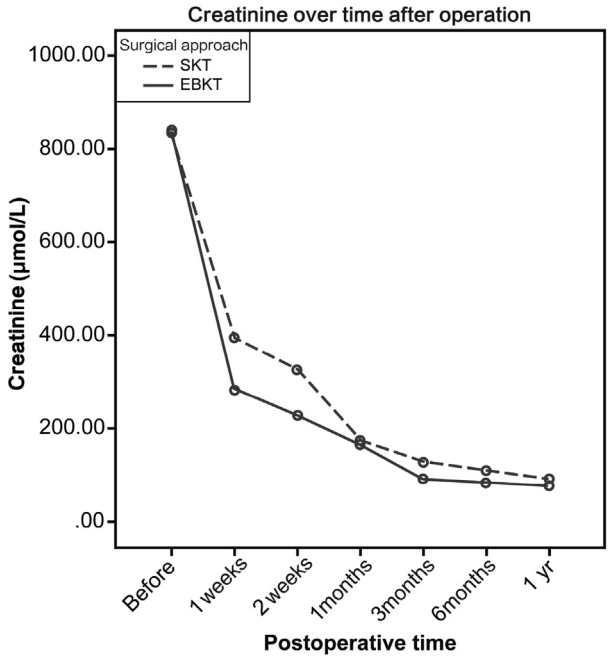

Fig 1. The change of creatinine in two groups with postoperative time.

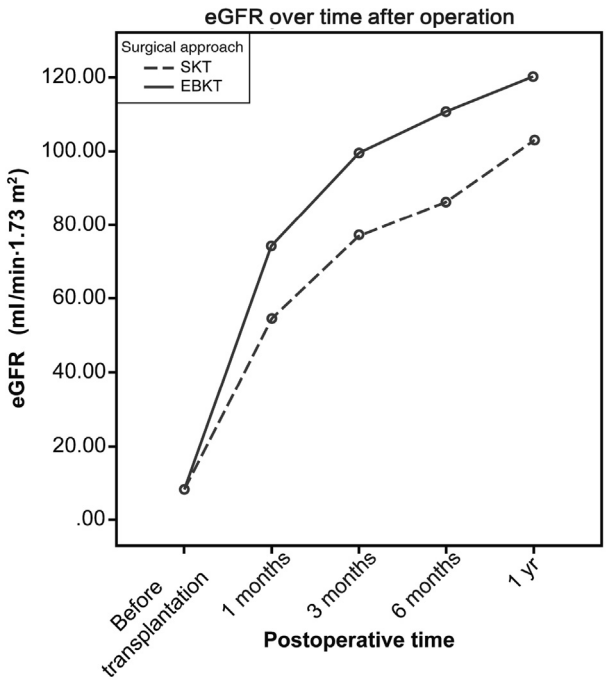

Fig 3. The change of eGFR in two groups with postoperative time.

No significant between-group differences were observed for donor age, sex, or weight. Reports from the transplant centers indicated that the warm ischemia times were approximately 10 to 30 minutes and the cold ischemia times were usually 6 to 10 hours. Moreover, no significant between-group differences were observed for recipient age, weight, sex, or the mean waiting time. The HLA mismatch was 0 to 3 sites according to the standard procedures at each center.

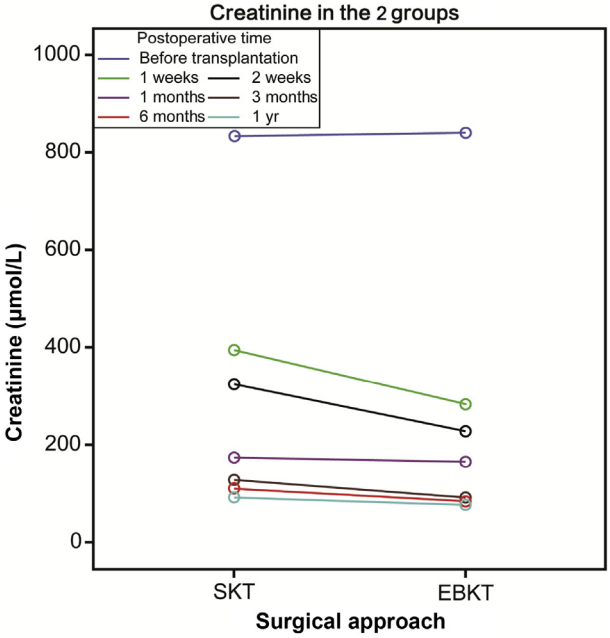

Fig 2. Creatinine at different follow-up times for two surgical approach.

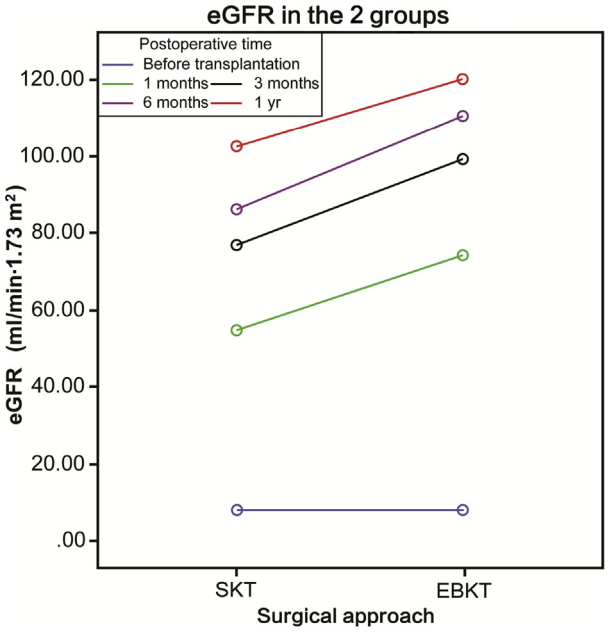

Fig 4. eGFR at different follow-up times for two surgical approach.

Table 2. Comparison of Renal Function Recovery

	Creatinine (umol/l) mean (SD)		eGFR mean (SD)	
	SKT	EBKT	SKT	EBKT
Before	904.6 (250.3)	923.8 (314.4)	6.2 (2.7)	6.2 (1.9)
1 week	460.8 (270.9)	290.7 (245.5)	None	None
2 weeks	414.5 (308.1)	244.1 (262.3)	None	None
1 mo	266.2 (216.1)	181.3 (197.1)	37.5 (23.0)	60.9 (30.7)
3 mo	146.4 (73.4)	96.4 (35.4)	55.9 (27.9)	90.9 (59.1)
6 mo	143.2 (107.8)	111.2 (107.3)	62.6 (34.0)	89.2 (44.6)
1 yr	94.7 (31.9)	77.6 (19.3)	82.9 (37.3)	98.5 (19.6)
Total analysis: Two-way Repeated Measures Anova F,p				
Inter-group analysis	1.41	0.24*	3.55	0.06†
Inter-group analysis: Student's t test t, p				
	SKT VS EBKT		SKT VS EBKT	
Before	−2.42	0.80	−0.89	0.92
1 week	2.31	0.02	None	
2 weeks	2.15	0.03	None	
1 mo	1.44	0.15	−3.11	0.003
3 mo	3.19	0.06	−2.79	0.007
6 mo	1.02	0.31	−2.34	0.02
1 yr	2.03	0.05	−1.55	0.12

Abbreviations: EBKT, En Bloc Transplantation; SKT, Single–Kidney Transplantation.
*The influences on creatinine caused by surgical approach have no statistical different.
†The influences on eGFR caused by surgical approach have no statistical different.

Kidney function was significantly improved after surgery in both groups, as evidenced by a continuous decline in creatinine and a continuous increase in the eGFR. Creatinine was significantly lower in the EBKT group than in the SKT group at postoperative month 1, but the difference disappeared from month 1 to year 1. Moreover, the eGFR rose much faster in the EBKT group than in the SKT group after surgery, but the difference disappeared by 1 year after surgery. Figures 1 and 2 show creatinine over time in the 2 groups, and Figs 3 and 4 show the eGFR over time in the 2 groups. The numeric data for creatinine and the eGFR are summarized in Table 2.

Table 3 shows postoperative complications and postoperative 1-year patient and graft survival rates. In both groups, the most common medical complication was pneumonia, while the most common surgical complications were vascular complications and urinary tract complications. The incidence of complications had no significant between-group differences. The incidence of DGF was higher in the SKT group than in the EBKT group, and the difference

Table 3. Comparison of Complications

	SKT (34)	EBKT (23)	*P* (value)
Complication n (%)	16 (47.0)	13 (59.0)	0.36
Vascular n (%)	5 (14.7)	2 (8.6)	0.31
Anastomotic rupture	0	0	
Thrombus	3	2	
Stenosis	1	0	
Renal rupture	1	0	
Urinary tract n (%)	5 (14.7)	3 (13.0)	0.59
Obstruction	1	0	
Urine leak	3	3	
Urinary infection	1	0	
Pneumonia n (%)	5 (14.7)	8 (34.7)	0.07
Other n (%)	1 (2.9%)	0 (0)	0.59
Acute Rejection	1	0	
Lymphocele	0	0	
DGF n (%)	15 (44. 1)	4 (17.3)	0.03
Patient/ renal survival after 1 yr			
Patient survival n (%)	32 (94.1)	22 (95.6)	0.65
Renal survival n (%)	27 (79.4)	19 (82.6)	0.52

Abbreviations: DGF, Delayed Graft Function; EBKT, En Bloc Transplantation; SKT, Single–Kidney Transplantation.

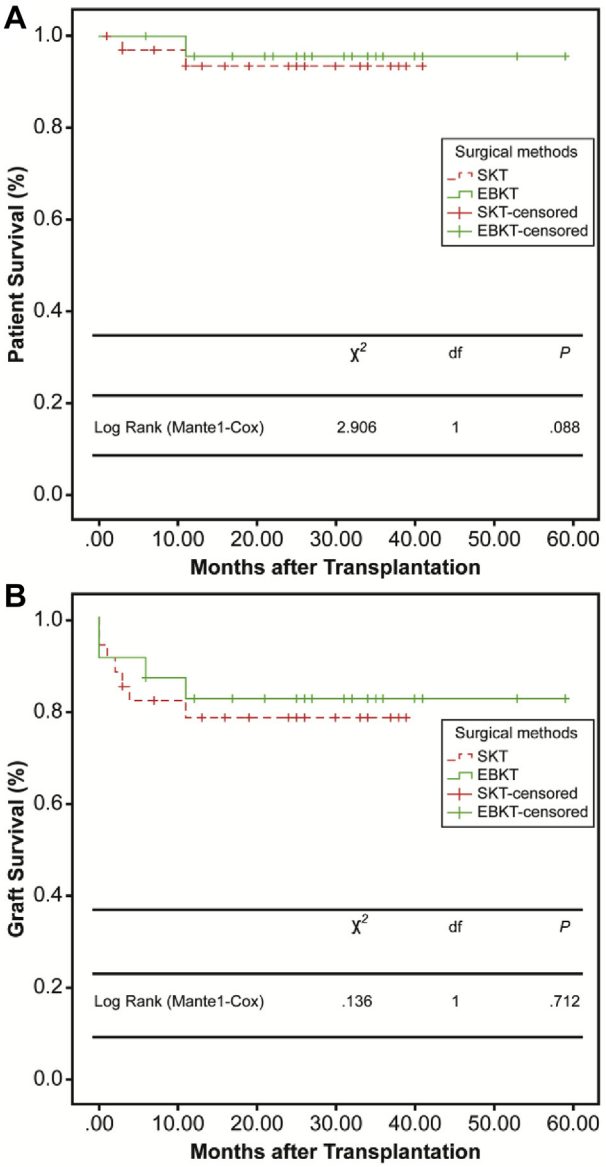

Fig 5. Kaplan-Meier Estimates of Graft Survival. **(A)** patient overall survival, **(B)** graft overall survival. The data are shown in Figure 5.

was statistically significant. The postoperative 1-year patient and graft survival rates were 94.1% and 79.4%, respectively, in the SKT group and 95.6% and 82.6%, respectively, in the EBKT group, with no significant between-group differences.

Among patients with complications, 3 died of septic shock associated with severe pneumonia and ensuing multiple organ failure. The most common causes of kidney loss were graft infarction caused by renal arterial thrombosis followed by graft rupture and bleeding. Most urinary fistulas achieved favorable outcomes after conservative treatments or proactive repairs. Moreover, no significant between-group differences were observed in patient or graft overall survival, noted in Fig 5.

DISCUSSION

In this study, we compared the results of infant donor kidney transplantation using 2 different surgical methods: SKT and EBKT. The results showed that when the donor was aged between 4 and 18 months, although the recovery of renal function in the early postoperative period was slower than that in EBKT, in the end, satisfactory short-term effects were obtained and the prognoses were basically the same. Our study provides supporting evidence for providing recipients with kidneys from low-age donors using SKT.

In fact, there is not currently a guide for the use of donor kidneys in infants and young children [11]. Transplants are largely dependent on the comprehensive decisions of surgeons. The prevailing view is that a weight $\geq$ 15 kg or kidney length $\geq$ 6 cm is an indication for SKT [5,12–15], where weight is used for the determination, perhaps considering that weight is more reflective of infant development than age. In this study, in the SKT group, the weight of the largest donor was 15 kg, and the average donor weight in kilograms $\pm$ SD was only 9.031 $\pm$ 2.8, which is much lower than the current consensus. Studies have found that the number of kidney units is fixed at birth and development only matures it [16], so we believe that age differentiation is sufficient. Surgical procedures and postoperative management of recipients were more likely to affect the prognoses. In addition, the use of EBKT was mainly based on the small size of the donor kidneys, insufficient renal units, and an inability to meet the needs of adults, which did exist in this study. The specific manifestation was a higher incidence of DGF and a slower rate of early creatinine reduction in the SKT group compared to the EBKT group; however, we believe that this "risk" is only temporary. In this study, in the SKT group, the eGFR (mean eGFR [mL/min per 1.73 m^2] $\pm$ SD) was 37.5 $\pm$ 23.0 noted 1 week after the operations and 82.9 $\pm$ 37.3 after 1 year. A study by Denic et al [17] showed that the average single-kidney eGFR was 80 $\pm$ 40 in normal subjects. Thus, we believe that even in a case of a unilateral kidney donation from a low-age infant, it is possible to meet the normal needs of an adult after going through the recovery period. Uemura et al [12] found that the donor kidney length and glomerular diameter reached the level of a normal adult 1 year after SKT, which confirmed the potential of SKT. However, there are other researchers who believe that EBKT is still the first choice for low-weight, low-age donors [3,18]. Our data showed that the incidence of DGF in the SKT group was significantly higher than that of the EBKT group (44.1% vs 17.3%, P = .03), but there was no significant difference in the incidence of complications between the 2 groups. This is consistent with the results of Dharnidharka et al [4], but they found that the survival rates of the grafts at 1, 3, and 5 years was significantly higher than for SKT, which was attributed to the occurrence of postoperative DGF. For this study, sufficient follow-up time is still needed to account for these possible differences, including long-term hyperperfusion injury and chronic rejection.

Vascular thrombosis is the leading cause of donor kidney loss in infants and young children. The reported incidence rate is 10% to 25% [14,19–21], which is much higher than the rate among adult donors (3.3%) [22]. In our data, 2 recipients of SKT and 2 recipients of EBKT experienced thrombosis (5.8% and 8.6%, respectively), which is close to the values reported above. Age is generally considered to be negatively correlated with the incidence of vascular complications, especially for donor kidneys under 1 year of age [20]. However, there was no indication in this study of the effect of different surgical procedures on the incidence of thrombotic complications, and our data show that, regardless of the surgical procedure, vascular thrombosis most often occurs within 3 days after surgery. In this study, 3 of the 4 recipients with renal loss due to vascular thrombosis were diagnosed by ultrasonography within 2 days of their operations, and all were excised. Renal graft stenosis is another cause of renal loss. Compared with vascular thrombosis, it occurs later. In this study, the first case of it occurred 2 months after the operation, and the second occurred 11 months after the operation. The first patient was cured through the placement of vascular stents, and the other patient died of severe pneumonia, although the same stent was placed. It is worth noting that the 2 cases of vascular stenosis in this study were in the SKT group, which is not fully consistent with some previous studies [23] that suggest that bilateral renal grafts are more easily angled and torsional, leading to stenosis. For these vascular complications, we believe that intraoperative intrarenal transplantation of papaverine can alleviate vasospasms, and we routinely use low-molecular-weight heparin to reduce the risk of thrombogenesis.

The occurrence of urinary fistulas is also worth noting. Although the outcomes following their occurrence are better than those of vascular thrombosis, they significantly increase the length and costs of hospitalizations. In our study, 3 recipients of SKT and 3 of EBKT had urinary fistulas. Among them, 3 patients were cured after repairs were performed and 2 patients were cured through conservative treatments. One patient lost the transplanted kidney due to a secondary perirenal infection. All of the patients were hospitalized for more than 1 month. We believe that it is very important to observe the blood supply to the ureter after the blood vessel is opened during the operation. If the surgeon thinks that the blood supply at the end of the ureter is poor, he or she can amputate part of the ureter and anastomose with the bladder and guarantee the tension state of the anastomotic stoma as far as possible. The placement of ureteral stents is one of the acceptable methods for this.

Study Limitations

The data were mainly focused on the short-term survival rates and prognoses of the patients. Since most of the patients were followed up for less than 2 years, we were not able to perform long-term analyses and comparisons of renal survival rates. At the same time, high perfusion injuries and long-term complications, such as chronic rejection, also need to be followed up on for a long period of time. Despite the inclusion of exact descriptions of volume changes in kidney transplantation in many studies, this study did not record it. As a multicenter retrospective control study, although the treatment protocols at each center in our study remain consistent, there are still differences in the specific applications of the treatments at each center. Furthermore, our research needs higher sample numbers to enhance its persuasive value.

CONCLUSIONS

In general, we found that the short-term curative effect of SKT is positive compared with that of EBKT, and the long-term prognoses of both is still need to be further followed up and observed. For infants aged 4 to 18 months, SKT can obtain good short-term effects, and it can effectively increase the number of kidney donations and alleviate the current tense situation around kidney donation.

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