https://doi.org/10.23873/2074-0506-2022-14-4-452-461

Influence of alprostadil on the dynamics of blood flow resistance index and renal graft function in the early postoperative period

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Abstract

Aim. *To evaluate the effect of continuous intravenous infusion of alprostadil solution on the dynamics of the peripheral resistance to arterial blood flow and renal graft function in the early postoperative period.*

Material and methods. *From June 2018 to May 2022, 278 kidney transplants from a deceased donor were performed at the City Clinical Hospital n.a. S.P. Botkin. In 179 recipients operated from June 2018 to May 2021, we evaluated the significance of the intraoperatively determined resistance index of blood flow in the segmental arteries of the renal graft as a predictor of the development of its delayed function. The study of the effect of alprostadil included 32 patients divided into 2*

groups comparable in patient age, gender, body mass index. The resistance index in both groups was more than 0.85. In the second group patients received a continuous intravenous infusion of alprostadil solution in the first 3 days after surgery.

Results. *Retrospectively we found that in patients with a high resistance index (more than 0.85), the risk of developing delayed graft function was 6.9 times higher, that was statistically significant (p=0.001). In the alprostadil group, a delayed graft function developed in 5 of 18 patients (27.8%), compared with the control group, where delayed graft function developed in 9 of 14 (64.3%) patients, however, without reaching the level of statistical significance (p=0.072). The median time to normalization of graft function in group II was 4 (interquartile range: 3-4) days, while in group I it was 7 (interquartile range: 5-8) days (p=0.05). The median hospital length of stay in the alprostadil group was significantly lower than in the control group and amounted to 13 (interquartile range: 8-15) versus 17 (interquartile range: 15-19) days (p=0.032).*

Conclusion. *The use of continuous intravenous infusion of alprostadil solution after kidney transplantation in patients with a high intraoperative resistance index can safely and effectively lead to a decrease in resistance index to normal rates, accelerate the recovery of graft function and significantly reduce the incidence of delayed graft function. However, further research is needed.*

Keywords: kidney transplantation, delayed renal graft function, resistance index, alprostadil

Conflict of interests Authors declare no conflict of interest

Financing The study was performed without external funding

For citation: Drozdov PA, Nesterenko IV, Makeev DA, Zhuravel OS, Astapovich SA, Solomatin DA, et al. Influence of alprostadil on the dynamics of blood flow

resistance index and renal graft function in the early postoperative period. *Transplantologiya. The Russian Journal of Transplantation.* 2022;14(4):452–461. (In Russ.). https://doi.org/10.23873/2074-0506-2022-14-4-452-461

BMI, body mass index
C_0, tacrolimus concentrations
CI, confidence interval
CRF, chronic renal failure
CTIN, chronic tubulointerstitial nephritis
DRGF, delayed renal graft function
IPRI, ischemic-preservation-reperfusion injury
IQR, interquartile range
KT, kidney transplantation
OR, odds ratios
RI, resistance index
SWI, second warm ischemia
US, ultrasonography

Introduction

Kidney transplantation (KT) is currently the "gold standard" of renal replacement therapy for patients in the end-stage renal disease without absolute contraindications, as it demonstrates the best medical, social and economic efficiency [1]. At the same time, the incidence of complications that can statistically significantly reduce graft survival, the quality of life of recipients, and increase the cost of their postoperative treatment is still high. One of the most frequent complications of the early postoperative period is the delayed renal graft function (DRGF), which, according to the world literature, develops in 10–50% of cases of KT [2–5]. Clinically, it manifests itself as acute renal failure, which morphological basis is the acute tubular necrosis due to ischemic-preservation-reperfusion injury (IPRI) of the kidney graft. The developing spasm of the glomeruli afferent arterioles, leading to impaired intraorgan

microcirculation, is the main link in the pathogenesis of DRGF [6]. Factors that aggravate the severity of IPRP include inadequate graft perfusion with a preservative solution at the explantation stage, long periods of static cold preservation, the use of high doses of catecholamines in the donor, graft characteristics that may lead to an increase in the time of forming anastomosis and, accordingly, an increased time of second warm ischemia, atherosclerosis, intraoperative hypotension, high body mass index (BMI) of the recipient, and others [7–8].

Doppler ultrasound (US) is the main instrumental method that allows a non-invasive determination of the qualitative and quantitative characteristics of blood flow in the kidney graft in the early postoperative period. In particular, the index of peripheral resistance (resistance index − RI) of arterial blood flow is the most informative and convenient parameter for a dynamic assessment, which increase indicates an impaired microcirculation in the graft [9]. Elevated RI (>0.7) in the early postoperative period can be seen in acute rejection, renal vein thrombosis, urological complications, and other circumstances. In addition, RI is affected by central hemodynamic parameters and the age of the recipient. Many studies have also proven the significance of RI as one of the early predictors of delayed renal graft function [10–12].

The high incidence of delayed renal graft function prompts the need to introduce new therapies that can reduce the consequences of IPRP, and thereby accelerate the recovery of the transplanted kidney function in the recipient's body. One of the most promising drugs to achieve this goal is alprostadil (Vazaprostan), a synthetic analogue of prostaglandin E 1. When administered systemically, alprostadil causes relaxation of smooth muscle fibers, produces a vasodilating effect, reduces total peripheral vascular resistance without a significant effect on

the blood pressure, and improves blood rheology. The use of alprostadil to improve microcirculation and reduce the severity of IPRI is actively used in the clinical practice of KT [13–16], while only a few publications in the Russian and world literature speak of its possible efficacy after kidney transplantation [17]. This is probably due to the predominantly renal route of elimination of this drug from the body, which makes the specialists to approach its administration to patients with end-stage chronic renal disease (ESRD) with increased caution. However, to date, in the course of reviewing the literature, we have not found a single randomized study on the efficacy and safety of this drug in kidney transplant recipients in the early postoperative period.

In this regard, this study is aimed at investigating the effect of alprostadil on the dynamics of the decrease in RI as the main parameter characterizing the peripheral resistance to arterial blood flow in the kidney graft, and its function in the early postoperative period.

Material and methods

From June 2018 to May 2022, 278 kidney transplants from a posthumous donor were performed at the City Clinical Hospital named after S.P. Botkin. Donor kidney removal, cold storage, KT, postoperative management, and immunosuppressive therapy were performed in conformity with the standard protocols developed according to the National Clinical Guidelines. Doppler ultrasound to determine the main Doppler characteristics of the arterial blood flow of the renal graft was performed intraoperatively, and then on the 1st, 2nd, 3rd, and 5th days. Intraoperative ultrasound of the graft was performed with a sterile probe after suturing the aponeurosis. The development of DRGF was defined as the need for renal replacement therapy in the first week after surgery.

At the first stage, in 179 consecutive recipients operated from June 2018 to May 2021, we assessed the significance of intraoperatively determined the blood flow RI_0 in the renal graft segmental arteries as a predictor of the DRGF development. Based on our own experience, we consider the values of RI_0 over 0.85 (extremely high) as requiring increased alertness after surgery. Thus, of 179 patients, 165 (92.2%) had RI_0 values of 0.85 or lower, while in 14 (7.8%) RI_0 values exceeded 0.85. Patients with elevated RI (over 0.85) made up the first (retrospective) group of this study. The second group consisted of 18 patients operated on in the period from March 2021 to May 2022. In this group, the intraoperative RI was also higher than 0.85 in all cases, and therefore they were administered alprostadil at a dose of 120 mcg/day for the first three days. The drug was administered by continuous intravenous infusion using an infusion pump: the daily dose of the drug was diluted with saline to 50 ml and administered at a rate of 5 μg/h (2 ml of alprostadil solution per hour). During the hemodialysis sessions, the infusion of alprostadil solution was not performed. The criteria for exclusion of patients from both groups of the study were: primary renal graft non-function, the development of surgical complications that required emergency revision and transplantectomy in the first 7 days after surgery, and the use of hypothermic oxygenated perfusion preservation.

Group characteristics

The first (retrospective) group included 14 kidney transplant recipients that consisted of 9 men (64.3%) and 5 women (35.7%). The median age of recipients was 50 (interquartile range [IQR]: 46–54) years, median BMI 28.5 (IQR: 25.0–30.5) kg/m^2. The causes of the end-stage kidney disease were chronic glomerulonephritis in 6/14 (42.9%), chronic tubulointerstitial nephritis (CTIN) in 4/14 (28.6%), autosomal dominant

polycystic kidney disease in 2/14 (14.3%), and condition after bilateral nephrectomy in 2/14 (14.3%) (Fig. 1A). The kidney graft was obtained from a donor with a confirmed brain death in 13 of 14 cases, and from a donor with effective blood circulation arrest in 1 case.

The second group consisted of 18 patients to whom an intravenous continuous infusion of an alprostadil solution was administered at a daily dose of 120 μg for 3 days after surgery in order to reduce the blood flow RI in the renal graft segmental arteries. There were 10 men (55.6%), and 8 (44.4%) women. The median age of the recipients was 48 (IQR: 44–55) years, the median BMI was 29.0 (IQR: 27.0–31.0) kg/m^2. The cause of ESRD was chronic glomerulonephritis in 11/18 patients (61.1%), the condition after bilateral nephrectomy in 3/18 (16.7%), chronic tubulointerstitial nephritis in 2/18 (11.1%), and diabetic nephropathy in 2/18 (11.1%) (Fig. 1B). The kidney graft was obtained from a donor with a confirmed brain death in 16 of 18 cases, from a donor with effective circulatory arrest in 2 cases.

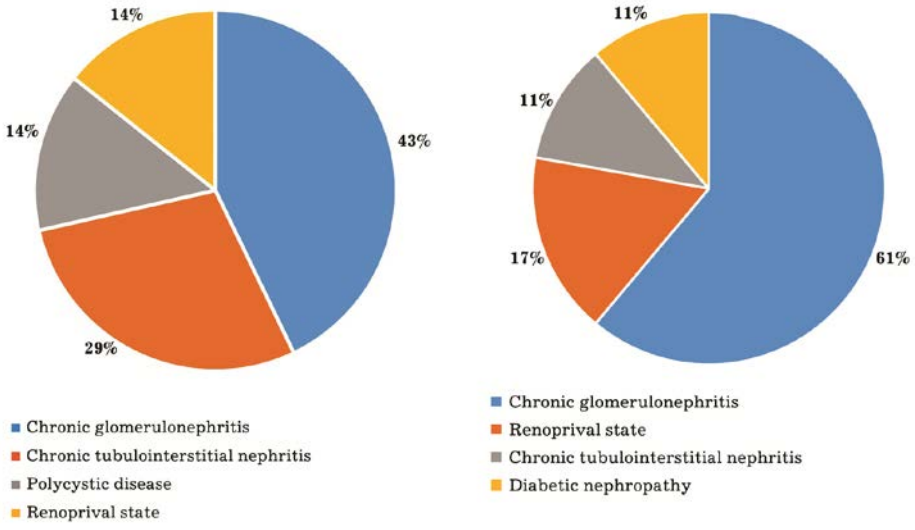

Figure. Etiological structure of end-stage chronic renal failure in kidney transplant recipients. A: group I; B: group II

Depending on the use of alprostadil after surgery, the authors analyzed changes in the blood flow RI in the segmental arteries of the renal graft from the moment of intraoperative measurement and on the following 3 postoperative days. Also, in both groups, the incidence of delayed renal graft function was assessed and the time required for its function normalization (defined as plasma creatinine normalization and no indications for hemodialysis) was comparatively analyzed. There were no significant differences between the groups in age and gender, and the etiology of end-stage renal disease, as well as in potential risk factors and predictors of the DRGF development, including recipient BMI (p=0.553), donor age (p=0.456), donor BMI (p=0.671), the highest value of the minimal concentration of tacrolimus (C_0) in the first 4 days after transplantation (p=0.733), the time of cold preservation (p=0.836), the second warm ischemia time (p=0.73), RI_0 (p=0.398) and other parameters. A detailed description of the compared groups is presented in Table 1.

Table 1. Characteristics of groups by the presence of potential risk factors and predictors of delayed renal graft function

Potential risk factors for the DKGF development	Characteristics of the group				p-value
	Group I (without alprostadil) n=14		Group II (with alprostadil) n=18		
	Me	IQR	Me	IQR	
Recipient's age, years	50	46–54	48	44−55	0.749
Recipient's BMI, kg/m^2	28.5	25.0–30,5	29,0	27.0–31.0	0.553
Donor's age, years	48	43−52	44	41−51	0.456
Donor's BMI, kg/m^2	29.5	26.0–33.0	28.0	25.5–31.0	0.671
Cold preservation time, min	600	500−800	650	500−750	0.836
SWI time, min	40	30−45	40	35−45	0.73
Residual diuresis before surgery, ml	200	0−400	300	0−350	0.557
Maximum C_0 of tacrolimus in the initial 4 days after KT, ng/mL	23.2	20.0–26.4	24.6	22.1–26.2	0.733
Intraoperative blood loss, ml	150	50−150	200	100−250	0.199

Notes: BMI, body mass index, SWI, second warm ischemia

Statistical analysis. Statistical processing and data analysis were performed using the IBM SPSS Statisticsб 26 version for Microsoft Windows (USA). To compare quantitative parameters between two groups, given the small sample size, the Mann-Whitney U-test was used regardless of the type of distribution. Comparison of qualitative data was performed using Pearson's χ^2-test or Fisher's exact test with the determination of the odds ratio (OR) and 95% confidence interval (CI), as well as the strength of association between the studied characteristics by Cramer's V. Differences were considered statistically significant at $p<0.05$, the trend towards statistical significance was defined as $p<0.1$.

Results

In the course of a retrospective analysis, it was found that an increase in intraoperatively determined RI (RI_0) had a statistically significant relationship with the development of DRGF (p=0.004) in a group of 179 consecutive kidney transplant recipients. The incidence of DRGF in patients with RI_0 0.85 or lower (n=165) was 20.6% (34/165), and 64.3% (9/14) in patients with RI_0 higher than 0.85 (n=14), who subsequently formed the control (retrospective) group of the study. In the presence of RI_0 over 0.85, the risk of developing DRGF was 6.9 times higher (95% CI: 2.18–22.05) than with its normal values. The differences were statistically significant (p=0.001) and there was a medium strength association between the values (Cramer's V=0.275).

Hospital mortality and the development of severe surgical complications of kidney transplantation (Clavien-Dindo more than II) in the early postoperative period were not recorded in any of the groups. Also, in none of the 18 cases in the second group, the administration of alprostadil solution did not lead to the development of any side effects.

The median values of the resistance indices (RI_3) determined on the 3rd postoperative day were 0.82 (IQR: 0.80–0.83) in the control group, and 0.73 (IQR: 0.71–0.75) in the alprostadil group. The differences were statistically significant (p=0.021). A detailed comparison of RI indices between the groups in the early postoperative period is presented in Table 2.

Table 2. Dynamics of changes in the arterial blood flow resistance index of the renal graft in the early postoperative period

Resistance index in the early postoperative period	Group I (without alprostadil use) n=14		Group II (with using alprostadil) n=18		p-value
	Me	IQR	Me	IQR	
RI_0	0.91	0.88–0.93	0.89	0.86–0.91	0.398
RI_1	0.90	0.87–0.92	0.87	0.84–0.90	0.587
RI_2	0.85	0.83–0.88	0.81	0.80–0.85	0.213
RI_3	0.82	0.80–0.83	0.73	0.71–0.75	***0.021**

Notes: RI_1, arterial blood flow resistance index of the renal graft on the 1st day after surgery; RI_2, arterial blood flow resistance index of the renal graft on the 2nd day after surgery

In the alprostadil group, DRGF developed in 5 (27.8%) of 18 patients, which was lower compared to 9/14 (64.3%) patients in the control group, but only with a trend towards statistical significance (p=0.072). As for the number of hemodialysis sessions performed in 2 weeks of the postoperative period until the normalization of the graft function, the hemodialysis sessions were required to 5 patients with DRGF in group II (one session each in 3 patients, and two sessions each in 2 patients), while in 9 patients with DRGF in the control group, 3 hemodialysis sessions each were required to 4 patients each, 2 sessions each to 3 patients and 1 session to 2 patients each. Thus, the mean time to normalization of the graft function in group II was 4 (IQR: 3–4) days,

while in group I, it was 7 (IQR: 5–8) days (p=0.041). The mean hospital length of stay in the alprostadil group was statistically significantly shorter than in the control group and amounted to 13 (IQR: 8–15) bed-days versus 17 (IQR: 15–19) (p=0.032) (Table 3).

Table 3. Comparative analysis of data from the early postoperative period with regard to using alprostadil

Study parameter	Group I (without using alprostadil) n=14	Group II (with using alprostadil) n=18	p-value
Time to renal graft function normalization, day	7 (IQR: 5−8)	4 (IQR: 3−4)	**0.041**
Hospital length of stay, bed-days	17 (IQR: 15−19)	13 (IQR:8−15)	**0.032**
Incidence of DKGF	9/14 (64.3%)	5/18 (27.8%)	0.072
Hospital mortality	0	0	1
Complications (Clavien-Dindo > II)	0	0	1

Discussion

Analyzing the data of the world literature and our own experience, we can confidently say that the delayed function of the kidney graft is a common complication and has a large number of risk factors, both on the part of the donor and the recipient [18–20]. In our study, an increased resistance index once again demonstrated its significance as an important predictor of the DRGF development (p=0.001). In more than half of patients with extremely high RI values (over 0.85), DRGF complicated the early postoperative period. A slow decrease in RI during follow-up was associated with a slow normalization of graft function and, accordingly, an increase in the hospital length of stay and the number of hemodialysis sessions.

Alprostadil administration protocol we described here for patients with an extremely high peripheral resistance index made it possible to

reduce the DRGF incidence from 64.3 to 30.7% in groups comparable in terms of major risk factors, but without reaching the level of statistical significance (p=0.072). This is probably due to the small number of patients in the study groups and the heterogeneity of risk factors for this complication. However, we obtained data that statistically significantly confirmed a faster recovery of graft function with using alprostadil (p=041), which was associated with a lower need for repeated hemodialysis sessions in patients.

Based on analyzing the RI dynamics in the first few days after the transplant surgery, we have proved the direct effect of alprostadil on the improvement of microcirculation in the renal graft. Patients receiving continuous infusion of alprostadil solution, had had significantly lower RI values by the 3rd day compared to the control group (p=0.021). We considered the improvements of RI values to 0.75 or lower as a criterion for discontinuing the drug; and in most cases it was done on the 4th postoperative day.

Based on the foregoing, we believe that the administration of alprostadil according to the protocol described by us to patients with a high risk of DRGF can, if not radically reduce its incidence, then, at least statistically significantly accelerate the recovery of kidney graft function. Reducing the mean hospital length of stay and the need in repeated sessions of hemodialysis for these patients can significantly improve the recovery of recipients and reduce their treatment costs in the early postoperative period.

Limitations

The authors primarily consider the main limitations of this study to be its retrospective design, using the data from a single center, a small number of cases, and the using a retrospective group as a control.

Perhaps, not all risk factors for DRGF were analyzed in our study; and their differences were not assessed between the groups.

Conclusions

1. The use of alprostadil according to the method we have described is safe for the kidney transplant recipients with an increased risk of developing a delayed graft function, provided that regular clinical and laboratory monitoring is performed.

2. The use of continuous intravenous infusion alprostadil in recipients with extremely high values of intraoperatively determined arterial blood flow resistance index (over 0.85) is associated with significantly shorter time to the normalization of graft function (p=0.041) and the decreased need for hemodialysis, however, further studies are needed.

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The article was received on April 28, 2022;
approved after reviewing June 16, 2022;
accepted for publication September 28, 2022