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Original Article

A Retrospective Post-Marketing Surveillance Study on TGlobulin25®, the First Rabbit Anti-Thymocyte Globulin (r-ATG) Biosimilar Worldwide, as Induction Therapy in Adult Kidney Transplant Recipients

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What's Known

- TGlobulin25® is the first rabbit anti-thymocyte globulin (r-ATG) biosimilar in the world.
- r-ATG is widely used in solid organ transplantations, including kidney transplants.

What's New

- The findings of this study indicated no significant difference between TGlobulin25® and Thymoglobulin® in preventing acute rejection, delayed graft function (DGF), and organ loss. The incidence of leukopenia was higher in the TGlobulin25® group, although this difference was not statistically significant.

Abstract

Background: Post-marketing surveillance studies are essential to establish a realistic assessment of TGlobulin25®, the first rabbit anti-thymocyte globulin (rATG) biosimilar approved in Iran, for the prevention of acute kidney transplant rejection. This study aimed to conduct a post-marketing surveillance investigation comparing TGlobulin25® with the originator product regarding efficacy and safety in adult kidney transplant recipients.

Methods: A comparative study of recipients who received either TGlobulin25® or Thymoglobulin® was conducted at the Abu-Ali Sina Transplant Center, Shiraz, Iran, from 21/03/2022 to 21/11/2022. Key outcomes, such as delayed graft function (DGF), biopsy-proven acute rejections, deaths, and adverse events, were assessed over a 1-year follow-up period. A multiple regression model was adjusted for confounding risk factors, and the normal distribution of continuous variables was evaluated using the Kolmogorov-Smirnov test.

Results: A total of 247 patients were enrolled (118 received TGlobulin25® and 129 received Thymoglobulin®). Except for the number of kidney transplantations, no statistically significant demographic differences were observed between the two groups. By the end of the study, DGF occurred in 19 patients (16.10%) in the TGlobulin25® group and 19 (14.72%) in the Thymoglobulin® group (P=0.76). Severe thrombocytopenia was reported in 3 (2.54%) patients in the TGlobulin25® group and 5 (3.88%) in the Thymoglobulin® group (P=0.55), while severe leukopenia was reported in 15 (12.71%) and 7 (5.43%) patients, respectively (P=0.07). No significant difference was observed in biopsy-proven acute rejections (P=0.39), and no statistically significant risk factor for rejection was identified. Four patients in each group died (3.38% and 3.12%, respectively), and three cases of allograft nephrectomy were reported in the Thymoglobulin® group. No significant difference was found in serum creatinine and calculated eGFR, except for eGFR at the end of the 12th month (P=0.013). The risk of viral infections was also non-significant.

Conclusion: Overall, no statistically significant differences were observed in major efficacy and safety outcomes. However, eGFR at 12 months was higher in the TGlobulin25® group. The incidence of Leukopenia was non-significantly higher in the TGlobulin25® group.

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Keywords ● Product surveillance ● Postmarketing ● Thymoglobulin ● Kidney transplantation

Introduction

Kidney transplantation is one of the major and most promising treatment options for end-stage renal failure. According to the reports of the United Network for Organ Sharing (UNOS), 42,887 solid organ transplantations (SOTs) were performed in the United States in 2022, of which 25,498 cases were kidney transplants.[1] A key factor in maintaining transplanted organ function is the design and implementation of an appropriate and efficient immunosuppressive regimen that prevents organ rejection while avoiding over-immunosuppression and its associated consequences. The immunosuppressive regimen employed in SOT comprises the two phases of induction and maintenance. Immunosuppressants historically used in the induction phase of kidney transplantation include monoclonal antibodies (mAbs) such as OKT3 (Muromonab), which targets CD3 (cluster of differentiation 3); alemtuzumab, an anti-CD-52 (cluster of differentiation 52) antibody; and anti-interleukin-2 receptor antagonists such as basiliximab. However, induction therapy with lymphocyte-depleting agents, such as anti-thymocyte globulin (ATG), has become more prevalent in kidney transplant centers worldwide due to its capacity to reduce immunological risk.[2-4] In a meta-analysis by Lee and others, most kidney transplant centers used induction therapy, and among the prescribed agents, ATG demonstrated greater success in preventing antibody-mediated rejection (AMR).[5]

ATG has been used in kidney transplant recipients as a T cell-depleting antibody since 1999 for the prevention and treatment of acute rejection.[6] Two types of ATG have been introduced to the market. One is produced in rabbits (r-ATG), and the other is a purified gamma globulin solution derived from the immunization of horses with human thymocytes (ATGAM®). ATGAM® is associated with lower efficacy and greater side effects than r-ATG and is therefore less commonly used in transplant centers today. Currently, two commercial r-ATG products are available in addition to TGlobulin25®. One is Thymoglobulin®, also known as ATG-Genzyme (Sanofi Genzyme, Cambridge, MA, USA), and the other is ATG-Fresenius (ATG-F), also known as ATG-Grafalon, Fresenius (Biotech GmbH, Munich, Germany). The difference between these two products lies in their preparation methods, which confer different characteristics. Thymoglobulin® is derived from rabbits immunized with fresh human thymocytes, whereas ATG-F is produced using the Jurkat T lymphoblastic cell line. Retrospective analyses demonstrated that induction therapy with Thymoglobulin® is superior to ATG-F in preventing acute kidney transplant rejection, while patients treated with ATG-F reported fewer cases of infection or malignancy than those receiving Thymoglobulin®.[7–10] Given these findings, both agents continue to be used in the prevention and treatment of kidney transplant rejection.

In developing countries, the use of generic drugs has become a common cost-saving strategy. Generic drugs typically cost between 40% and 60% of the reference drug's price.[11] However, despite the increasing use of generic formulations worldwide, concerns remain regarding the use of generics for medications with narrow therapeutic indices, such as immunosuppressants.[12] Numerous studies have compared generics and brand-name calcineurin inhibitors (CNIs) and antimetabolites.[12, 13] Finocchietti and others concluded that the rate of generics use in transplant patients is increasing, with generic tacrolimus use rising from 14.2% to 40.5% and generic mycophenolate sodium from 18.2% to 94.7%. Nonetheless, concerns remain regarding their efficacy compared with the reference drugs, which should be addressed through further evaluations.[13]

In response to these considerations, the Iranian pharmaceutical industry has prioritized the provision of generic and biosimilar immunosuppressants for use within the country and the Middle East region, supported by rigorous clinical studies to generate evidence of their safety and efficacy. TGlobulin25® is the first commercially available biosimilar of Thymoglobulin® worldwide, produced by Kawsar Biotech Company (Tehran, Iran), and was approved by Iran's Food and Drug Administration in 2020. It has been used in transplant centers in Iran since 2021. Shiraz Transplant Center, as the first solid organ transplantation (SOT) center in the Middle East and one of the major users of TGlobulin25®, has performed kidney transplantation since 1967 and is one of the largest SOT centers in the world, conducting over 700 SOTs annually.[14, 15] This study aimed to evaluate, as a post-marketing surveillance investigation, the efficacy and safety of TGlobulin25® compared with Thymoglobulin® in preventing organ rejection among kidney transplant recipients a year after kidney transplantation.

Materials and Methods

Study Settings and Design

This retrospective study was conducted from 21/03/2022 to 21/11/2022 at Abu-Ali Sina Transplant Center, Shiraz, Iran, one of the major transplant centers in the world, performing over 700 SOTs annually.

All patients received r-ATG with a cumulative dose of 4-6 mg/Kg as induction therapy. The medication was infused over 4 hours, primarily via a central line and, in some cases, through a peripheral line. Pre-medication with hydrocortisone and acetaminophen was prescribed for all patients before r-ATG administration. The patients also received 1 g of methylprednisolone intraoperatively. Subsequently, oral prednisolone was prescribed according to a standard corticosteroid taper, aiming to reduce the dose of prednisolone or its equivalent to 5 mg by 6 months post-transplantation. This immunosuppressive regimen was accompanied by a calcineurin inhibitor (CNI), either tacrolimus (0.08 mg/Kg/day, trough level 8-12 ng/mL) or cyclosporine (5 mg/kg/day, trough level 150-300 ng/mL), initiated the day after surgery and maintained for the first 3 months post-transplantation. The dose of CNIs was adjusted based on the plasma levels and the patient's clinical status. Mycophenolate mofetil (1.0 g orally twice daily) or mycophenolate sodium was also prescribed as an antimetabolite. All patients received valganciclovir for 3 months as cytomegalovirus (CMV) prophylaxis. Additionally, prophylaxis against Pneumocystis jirovecii pneumonia with trimethoprim-sulfamethoxazole was mandatory for all patients for at least 6 months. The study was approved by the Ethics Board of Shiraz University of Medical Sciences (IR.SUMS.REC.1401.208).

Eligibility Criteria

Kidney transplant candidates aged between 18 and 65 years who were admitted to Abu-Ali Sina Transplant Center and received either TGlobulin25® (KBC, Tehran, Iran) or Thymoglobulin® (Sanofi Genzyme, Cambridge, MA, USA) as part of an immunosuppressive regimen to prevent organ rejection were included. The exclusion criteria were as follows: any simultaneous transplantation of other organs, such as pancreas, heart, or liver; or receipt of r-ATG for the treatment of rejection episodes. Recipients with a panel-reactive antibody (PRA) level of 30% or more were also excluded.

Participants

Donors and recipients underwent HLA typing (A, B, and DRB1) and flow cross-match. Patients with a positive complement-dependent cytotoxicity (CDC) crossmatch were not transplanted, while those with a positive flow-cytometry crossmatch underwent further evaluation with the Luminex single-antigen bead assay to detect anti-human leukocyte antigen (HLA) antibodies.

Variables

Predefined clinical outcomes were collected for all patients over a 1-year follow-up period after enrollment. These outcomes included biopsy-proven acute rejections (BPARs) with Banff score and results, patient vital status, organ loss status, and viral infections with pathogens such as CMV (cytomegalovirus), BK virus, or Epstein–Barr virus (EBV), confirmed with a positive quantitative polymerase chain reaction (PCR) result or clinical evidence of infection. CMV viral load monitoring was performed by real-time PCR every 15 days during the first 90 days post-transplantation. Serum BK viral load was monitored monthly in all recipients during the 1-year post-transplantation by real-time PCR.

Additionally, hematologic adverse events, including severe anemia, thrombocytopenia, leukopenia, or any related adverse event related to r-ATG administration, were evaluated in both groups.

Data Sources

All demographic information and laboratory data of the patients were extracted from their electronic health records. These data included age, sex, cause of kidney failure, comorbid diseases, donor type, pre-transplant electrolytes such as serum creatinine, and estimated glomerular filtration rate (eGFR) according to CKD-EPI2021, number of prior kidney transplants, HLA typing report, and PRA. Data regarding r-ATG administration, including cumulative dose, route of administration (central or peripheral line), infusion reaction, and any related adverse drug reactions, were also collected.

Bias

The research associates who retrospectively extracted raw data from the electronic health records (EHR) into the study database were blinded to the primary study hypothesis and group comparisons. They followed a standardized data collection form that did not highlight the intervention comparison.

Study Size

The sample comprised all eligible consecutive patients treated during the specified period. To assess the sensitivity of the comparative analyses, a *post hoc* power calculation was conducted. For the key efficacy outcome of 1-year biopsy-proven acute rejection (BPAR), with an overall observed incidence of 10.9%, alpha set at 0.05, and the achieved group sizes (n=118 and n=129), this study had approximately 80% power to detect an absolute difference

in BPAR rates of 12-13% between the groups (using a two-sided Z-test for proportions). This power calculation confirmed that the cohort provided adequate power to detect clinically substantial differences in the primary outcomes.

Statistical Analysis

The normal distribution of continuous variables was assessed using the Kolmogorov-Smirnov test. Categorical variables were presented as numbers and percentages and compared using the Chi squared test or Fisher's exact test. Continuous variables were presented as mean±SD unless otherwise stated and compared by Student's *t* test. A multiple regression model was adjusted for confounding risk factors, including age, sex, PRA (<50% vs. >50%), the presence of complete HLA mismatch (yes or no), the incidence of delayed graft function (DGF), and cold ischemic time (CIT) more than 4 hours for the acute rejection analysis. Variables with P<0.20 in univariate analyses were entered into the multivariable logistic regression model. A P<0.05 was considered statistically significant. All analyses were performed using SPSS software (version 26.0; SPSS Company, Chicago, IL, USA).

Results

Descriptive Data

Throughout the study, 247 eligible patients were enrolled, of whom 129 patients (52.22%) received Thymoglobulin®, and 118 (47.77%) received TGlobulin25®. A total of 172 patients (69.63%) were male, and 75 patients (30.36%) were female. Among the enrolled patients, 41.39% had a history of hypertension, and 21.9% had a history of diabetes. The demographic characteristics of the patients in both groups are compared in table 1.

While 243 (98.4%) donors were deceased, four organs were harvested from living donors. The majority of the participants (236 patients) were receiving a graft for the first time, and 11 had a history of at least one prior transplantation. Of these 11 patients, one received TGlobulin25®, and 10 received Thymoglobulin®.

The immunosuppressive drug regimen at the end of the 12-month follow-up included tacrolimus (243 patients) or cyclosporine (4 patients) as CNIs, prednisolone (247 patients), and mycophenolate sodium (239 patients) or mycophenolate mofetil (8 patients) as anti-metabolites (P=0.48). None of the patients were prescribed mammalian target of rapamycin (mTOR) inhibitors as part of an immunosuppressive regimen.

Outcome Data

r-ATG administration data: The mean total administered dose of r-ATG as induction therapy was 5.072±0.98 mg/Kg in the TGlobulin25® group and 5.13±0.88 mg/Kg in the Thymoglobulin® group (P=0.56). Of all patients, 64% received r-ATG via a central line and 36% via a peripheral line. All patients in both groups received their first r-ATG in the operating room. During the 1st week after transplantation, three patients (2.54%) in the TGlobulin25® group and 5 (3.88%) in the Thymoglobulin® group developed severe (grade III) thrombocytopenia (P=0.55). Severe leukopenia occurred in 15 (12.71%) patients in the TGlobulin25® group and 7 (5.43%) in the Thymoglobulin® group (P=0.07). There was also one case (0.85%) of severe ecchymosis in the pelvic area of a patient in the TGlobulin25® group. All of these adverse events were assessed as related to r-ATG administration according to the Naranjo Adverse Drug Reaction Probability Scale.

Delayed Graft Function Occurrences: In this study, the need for dialysis during the 1st week after transplantation was considered indicative of DGF. Accordingly, 19 patients (16.10%) in the TGlobulin25® group and 19 (14.72%) in the Thymoglobulin® group developed DGF (P=0.76).

Organ Rejections

Biopsy-Proven Acute Rejection (BPAR): All instances of acute rejection confirmed by positive biopsy are reported in table 2. Totally, 27 patients (10.93%) developed BPAR, of whom 15 (12.71%) patients were in the TGlobulin25® group, and 12 patients (9.30%) were in the Thymoglobulin® group (P=0.39). Overall, 22 patients (8.91%) experienced T-cell-mediated rejection, four patients (1.62%) experienced AMR, and one patient (0.4%) experienced both types of T-cell-mediated rejection and AMR. The timeline of BPAR occurrences is reported in table 2, demonstrating that the majority of cases occurred during the 1st month after transplantation in both groups.

Patient and Organ Loss Status at the End of Follow-Up

At the end of the follow-up, 8 (3.23%) patients died, of whom 4 (3.38%) received TGlobulin25®, and 4 (3.12%) received Thymoglobulin®. The cause of death in three patients (one in the TGlobulin25® and two in the Thymoglobulin® group) was complications of graft dysfunction, such as bleeding from the transplant artery and uremia. The cause of death in the remaining five patients was sepsis and septic shock (three in the TGlobulin25®

and two in the Thymoglobulin® group). The 1-year Kaplan–Meier survival analysis (figure 1) showed a non-significant difference between the two groups regarding mortality at the end of the follow-up period (log-rank P=0.90).

Throughout the study, three patients underwent allograft nephrectomy, all of whom were in the Thymoglobulin® group. One of those cases was surgery-related, and two were graft-related.

Table 1: Demographic and laboratory data of the kidney transplant patients administered with r-ATG (n=247)

Variables		TGlobulin25® (n=118)	Thymoglobulin® (n=129)	Total (n=247)	P value
Recipient age (years, mean±SD)		42.03±12.76	44.68±14.61	43.42±13.80	0.13
Donor age (years, mean±SD)		32.54±13.16	35.96±16.23	34.33±14.91	0.07
Sex n (%)	Male	86 (72.88)	86 (66.66)	172 (69.6)	0.28
	Female	32 (27.11)	43 (33.33)	75 (30.4)	
Underlying kidney disease, n (%)	Glomerulonephritis	43 (36.44)	54 (41.86)	97 (39.27)	0.30
	Autosomal dominant polycystic kidney disease	11 (9.32)	21 (16.28)	32 (12.96)	0.61
	Diabetes	23 (19.49)	31 (24.03)	54 (21.86)	0.38
	Large vessel disease	16 (13.56)	14 (10.85)	30 (12.15)	0.17
	Undefined cause	25 (21.19)	9 (6.98)	34 (13.77)	0.09
Comorbidities					
Diabetes mellitus, n (%)		23 (19.49)	31 (24.03)	54 (21.86)	0.38
HTN, n (%)		83 (70.33)	89 (68.99)	102 (69.63)	0.17
IHD, n (%)		8 (6.78)	10 (7.75)	18 (7.29)	0.76
Hypothyroidism, n (%)		3 (2.54)	3 (2.33)	6 (2.43)	>0.999
Others, n (%)	CVA	1 (0.85)	2 (1.55)	3 (1.21)	0.51
	SVC syndrome	1 (0.85)	0 (0)	1 (0.4)	
	AF	0 (0)	1 (0.78)	1 (0.4)	
Prior transplant (first vs. second or more), n (%)	First	117 (99.15)	119 (92.25)	236 (95.55)	<0.001
	Second	1 (0.85)	10 (7.75)	11 (4.45)	
Types of donor, n (%)	Deceased	116 (98.31)	127 (98.45)	243 (98.38)	0.92
	Living	2 (1.69)	2 (1.55)	4 (1.62)	
HLA mismatch, n (%)	None	101 (85.59)	110 (85.27)	211 (85.43)	0.19
	1-2	8 (6.78)	15 (11.63)	23 (9.31)	
	>2	8 (6.78)	5 (3.88)	13 (5.26)	
PRA, percentile groups, n (%)	0-10	87 (73.72)	83 (64.34)	170 (68.82)	0.13
	10-20	16 (13.55)	24 (18.60)	40 (16.19)	
	20-30	15 (12.71)	22 (17.05)	37 (14.97)	
CIT more than 4 hours, n (%)		56 (47.46)	46 (35.66)	102 (41.3)	0.06
BMI (Kg/m^2, mean±SD)		23.60±3.48	23.83±3.93	23.72±3.72	0.62
Recipient serum creatinine at transplant day (mg/dL, mean±SD)		6.57±2.19	6.76±2.59	6.67±2.41	0.53
Positive CMV IgG pre-transplant, n (%)		79 (66.94)	88 (74.57)	167 (67.611)	0.17
Positive EBV IgG pre-transplant, n (%)		55 (42.63)	61 (42.28)	116 (46.96)	
HBsAg-positive, n (%)		12 (10.16)	9 (6.97)	21 (8.50)	0.97
anti-HCV antibody–positive, n (%)		8 (6.77)	3 (2.32)	11 (4.45)	0.10
CBC on transplant day, mean±SD	Hb (g/dL)	10.06±2.03	10.45±1.99	10.40±1.91	0.23
	PLT (1000/µL)	125.50±86.25	229±164.14	175.82±136.99	0.14
	WBC (1000/µL)	7.76±7.84	7.92±3.24	7.16±4.53	0.92
Donor serum creatinine (mg/DL, mean±SD)		1.25±0.44	1.10±0.42	1.16±0.43	0.14
Tacrolimus trough level at the 3rd month of follow-up (ng/dL, mean±SD)		10.85±4.90	11.25±3.65	11.06±4.29	0.11
Mycophenolate mofetil dose at the end of follow-up (g/day, mean±SD)		1.59±0.50	1.33±0.11	1.21±0.43	0.76
Prednisolone dose at the end of follow-up (mg/day, mean±SD)		6.00±2.17	5,42±3.11	5.76±2.15	0.91

HTN: Hypertension; IHD: Ischemic heart disease; CVA: Cerebro vascular accident; SVC: Superior vena cava; AF: Atrial fibrillation; CBC: Complete blood count; PLT: Platelet; WBC: White blood cells; HLA: Human leukocyte antigens; PRA: Panel reactive antibody; CIT: Cold ischemia time; BMI: Body mass index; eGFR: Estimated glomerular filtration rate; EBV: Epstein–Barr virus; CMV: Cytomegalovirus; IgG: Immunoglobulin G; HBsAg: Hepatitis B surface antigen; HCV: Hepatitis C cirus; P values were calculated from independent *t* test (continuous) and Chi-square tet, and Fisher's exact (categorical) test. P<0.05 was considered statistically significant.

Table 2: Types and frequencies of rejection one year after transplantation in kidney transplant recipients

Outcomes		TGlobulin25® (n=118)	Thymoglobulin® (n=129)	Total (n=247)	P value
Biopsy-proven rejection, n (%)		15 (12.71)	12 (9.30)	27 (10.93)	0.39
Type of biopsy-proven rejection, n (%)	Cellular rejection	14 (11.86)	8 (6.2)	22 (8.91)	0.18
	Humoral rejection	1 (0.85)	3 (2.33)	4 (1.62)	
	Both	0 (0)	1 (0.78)	1 (0.4)	
Grade of T-cell-mediated rejection, n (%)	IA	3 (2.54)	2 (1.55)	5 (2.02)	0.76
	IB	3 (2.54)	3 (2.33)	6 (2.43)	
	IIA	6 (5.08)	2 (1.55)	8 (3.24)	
	IIB	2 (1.69)	2 (1.55)	4 (1.62)	
	III	0 (0)	0 (0)	0 (0)	
Grade of antibody-mediated rejection, (n=5), n (%)	C4d-1	1 (0.85)	2 (1.55)	3 (1.21)	0.65
	C4d-2	0 (0)	1 (0.78)	1 (0.4)	
	C4d-3	0 (0)	1 (0.78)	1 (0.4)	
Time of biopsy-proven rejection	The 1st month after Tx	9 (7.63)	7 (5.43)	16 (6.48)	0.39
	1-3 months after Tx	4 (3.39)	2 (1.55)	6 (2.43)	
	3-6 months after Tx	0 (0)	2 (1.55)	2 (0.81)	
	6-12 months after Tx	2 (1.69)	1 (0.78)	3 (1.21)	
Borderline changes for T cell rejection		11 (9.32)	16 (12.40)	27 (10.93)	0.43
Time of borderline changes for T cell rejection after kidney Tx	The 1st month after Tx	7 (5.93)	13 (10.08)	20 (8.1)	0.14
	1-3 months after Tx	3 (2.54)	0 (0)	3 (1.21)	
	3-6 months after Tx	0 (0)	1 (0.78)	1 (0.4)	
	6-12 months after Tx	1 (0.85)	2 (1.55)	3 (1.21)	

Tx: Transplant; Independent *t* test (continuous) and Chi square/Fisher's exact (categorical) tests were used. P<0.05 was considered statistically significant.

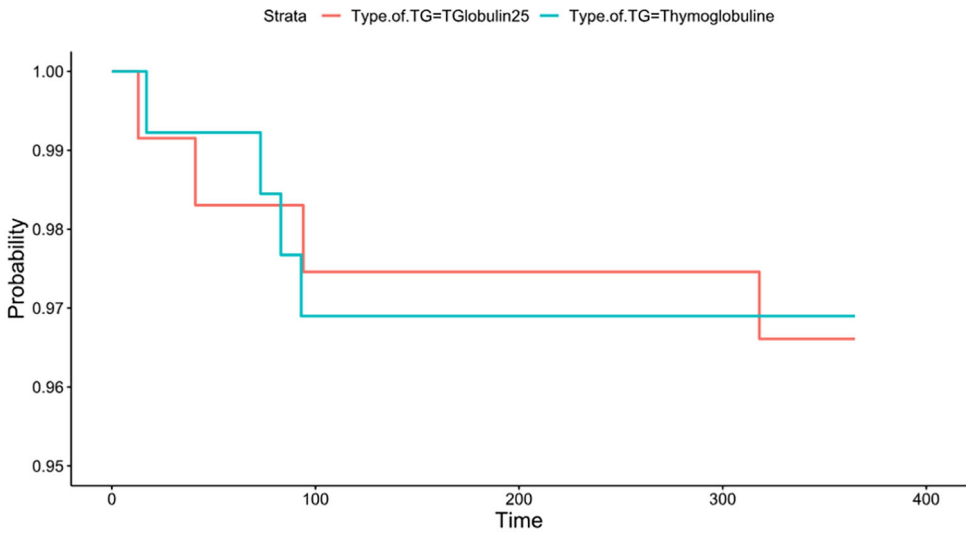

Figure 1: One-year Kaplan–Meier survival analysis of the SOT patients receiving TGlobulin25® or Thymoglobulin® is depicted in this figure. Time is measured in days.

Laboratory Findings

Table 3 presents the laboratory findings of the two groups during the follow-up period. No statistically significant differences were observed between the groups in serum creatinine or eGFR at discharge or at the end of the 1st, 3rd, and 6th months post-discharge. However, eGFR was significantly higher in the TGlobulin25® group than in the Thymoglobulin® group at the end of the 12th month (P=0.01).

Viral Infections

No significant differences in viral infections, including CMV or BK virus infections, were observed between the two groups throughout the study. Of the five patients with positive serum

Table 3: Comparison of the different levels of laboratory indices in kidney transplant patients receiving r-ATG in different periods

Laboratory tests		TGlobulin25® (n=118)	Thymoglobulin® (n=129)	Total (n=247)	P value
Serum creatinine (mg/dL, mean±SD)	Discharge	1.53±0.5	1.68±1.29	1.61±0.99	0.26
	End of the first month after Tx	1.47±0.53	1.62±1.27	1.54±0.99	0.25
	End of the third month after Tx	1.44±.036	1.68±1.29	1.59 ±1.03	0.22
	End of the sixth month after Tx	1.45±0.28	1.64±1.14	1.56±0.88	0.42
	End of the twelfth month after Tx	1.47±0.57	1.54±0.37	1.51±0.47	0.69
eGFR (mL/min/1.73m^2, mean±SD)	Discharge	59.09±19.02	58.15±22.55	58.60±20.90	0.72
	End of the first month after Tx	61.71±17.22	59.26±20.53	60.43±19.01	0.32
	End of the third month after Tx	63.34±17.91	59.09±21.90	60.87±20.44	0.27
	End of the sixth month after Tx	62.13±14.92	56.40±19.40	58.87±17.69	0.22
	End of the twelfth month after Tx	69.86±24.85	54.96±14.89	61.81±21.17	0.013
Mean serum concentration of tacrolimus at the time of discharge (ng/dL, mean±SD)		10.85±4.90	11.25±3.65	11.06±4.29	0.47
Mean serum concentration of cyclosporine at the time of discharge(ng/dL, mean±SD)		231.70±80.00	286.40±88.55	242.64±80.49	0.61

Tx: Transplant; eGFR: estimated glomerular filtration rate. Independent *t* test was used. P<0.05 was considered statistically significant.

Table 4: Multivariate analysis of the acute rejection risk factors among kidney transplant recipients

Variables	Adjusted OR (95% CI)	P value
Recipient age	1.09 (0.96–1.05)	0.67
Second kidney transplant	2.77 (0.91–1.05)	0.09
DGF	2.44 (0.66–9.04)	0.17
HLA mismatch	0.55 (0.09–3.23)	0.90
CIT more than 4 hours	0.41 (0.14–1.11)	0.08
Donor serum Cr	2.23 (0.60–8.29)	0.23

DGF: Delayed graft function; HLA: Human leukocyte antigen; CIT: Cold ischemia time; Cr: Creatinine; The multiple regression model was adjusted for confounding risk factors. Variables with P<0.20 in univariate analyses were entered into the multivariable logistic regression model. P< 0.05 was considered statistically significant.

CMV PCR results, four were in the TGlobulin25® group, and one was in the Thymoglobulin® group (P=0.19). Moreover, 17 patients had confirmed positive serum PCR for BK infection, of whom eight were in the TGlobulin25® group, and nine were in the Thymoglobulin® group (P=0.95).

Risk Factors for Rejection

The results of the univariate analysis of risk factors associated with BPAR showed that factors such as CIT greater than 4 hours, HLA mismatch, deceased donor, DGF during the 1st week after transplantation, and donor serum creatinine had P<0.2. The multivariate logistic regression analysis of these variables identified no statistically meaningful risk factors (table 4). Notably, the type of r-ATG administered (TGlobulin25® or Thymoglobulin®) was not a significant risk factor for acute rejection (P=0.33).

Discussion

The results of this study, which represents the first post-marketing surveillance investigation of TGlobulin25®, a biosimilar of Thymoglobulin®, demonstrated that there were no statistically significant differences between the two brands in terms of 1-year efficacy and safety.

Induction therapy with lymphocyte-depletion or non-depletion agents to prevent T-cell activation and acute rejection is widely employed in kidney transplantation worldwide, and extensive studies have therefore been conducted to assess their efficacy. Among these agents, rATG, as a T-cell-depleting antibody, holds a prominent place in induction therapy for the prevention of acute rejection in kidney transplant recipients. Although recent studies have favored the use of non-depleting strategies, such as interleukin-2 (IL-2) receptor antagonists, over ATG in patients with mild to moderate immunological risk to decrease long-term adverse events, the majority of transplant centers continue to use ATG as induction therapy.[5, 16] As mentioned earlier, r-ATG is currently available in two commercial forms, Thymoglobulin® and ATG-F.[17] The comparison of the effects of these two forms on the lymphocytes indicated that Thymoglobulin® exerted a more potent inhibitory effect on T lymphocytes than ATG-F.[17]

The results of different studies comparing the effects of these two formulations on the prevention of organ rejection were contradictory,[17, 18] and more extensive studies are warranted to clarify this issue.

Given the substantial costs associated with the transplantation process, the incorporation of scientific and rational transplant stewardship could moderate expenses to some extent.[19] One such strategy is the use of appropriate biosimilar agents in induction therapy. Considering the high importance and sensitivity surrounding transplantation, proving the comparable efficacy and safety of biosimilars relative to the originator products is of crucial importance.[20] According to the European Medicines Agency (EMA), a "highly similar quality profile" should be established in the development and clinical assessments of such products.[20]

To date, several biosimilars for monoclonal antibodies, including infliximab, adalimumab, rituximab, and trastuzumab, have been introduced to the market, and their efficacy and safety profiles have been evaluated in multiple studies.[21–25] To the best of our knowledge, TGlobulin25® is the only approved biosimilar of Thymoglobulin® worldwide and is currently administered in several transplant centers in Iran, as one of the leading countries in the Middle East in the field of transplantation.

The results of this study revealed an 11% rate of 1-year organ rejection rate among the patients, which aligned with the findings of a similar published study from the same transplant center, as well as those from other SOT centers worldwide.[26] The efficacy of the two discussed products in the induction therapy of organ rejection prevention was comparable. Multivariate regression analysis showed that the administered brand of r-ATG, whether TGlobulin25® or Thymoglobulin®, was not among the significant risk factors for organ rejection. This lack of association was also observed for DGF occurrence and mortality in both groups. Although the rates of graft loss and nephrectomy were higher in the Thymoglobulin® group, as mentioned earlier, the most important cause of nephrectomy was surgery-related. According to the results of this study, eGFR at the end of the 12th month of follow-up was significantly higher in the TGlobulin25® group (69.86±24.85 vs. 54.96±14.89 mL/min/ 1.73 m^2). There is still debate among researchers as to whether eGFR constitutes a suitable primary endpoint in kidney transplant studies. Some randomized controlled trials on this topic used eGFR as an efficacy endpoint, and certain studies concluded that a 20-40% reduction in eGFR between the 3rd and 24th months post-transplantation has a significant correlation with graft loss 2-5 years after kidney transplant.[27–29] A review article argued that eGFR could not serve as an ideal surrogate endpoint in kidney transplant patients, particularly when calculated using serum creatinine-based formulas, as the use of medications such as corticosteroids, which may induce muscle atrophy, or the initiation or discontinuation of drugs such as angiotensin-converting enzyme inhibitors, angiotensin receptor blockers (ARBs), or CNIs can bias the results of eGFR calculations.[30] Therefore, these studies have proposed more comprehensive strategies, namely, the combined assessment of eGFR and proteinuria, for graft efficacy.

Concerning the rate of hematologic adverse events, the incidence of severe leukopenia (grade 3) was higher in the TGlobulin25® group than in the Thymoglobulin®group. However, this difference was not statistically significant. This finding warrants further attention and should be considered in future studies due to the potential impact of leukopenia-related adverse events on mortality, diverse infections, and acute rejection rates.[31] This observation aligned with the findings of the most recent comparative study, which also reported a trend towards higher leukopenia rates with another rabbit ATG biosimilar than Thymoglobulin, without a corresponding increase in thrombocytopenia.[32] This shift toward relatively more leukopenia and less thrombocytopenia was consistent with possible subtle differences in anti-lymphocyte antibody composition, specificity, or potency between the biosimilar and the originator product. Similar differential hematologic effect profiles have been documented when comparing other ATG preparations, such as Grafalon (rabbit ATG) versus Thymoglobulin®, which are known to exhibit variations in their antibody spectra and resultant clinical effects. This observation does not constitute a safety signal strong enough to contraindicate the use of TGlobulin25®, as overall rates of severe cytopenias remained low and clinically manageable in both groups. However, it underscored the importance of monitoring complete blood counts during induction therapy and acknowledged that even highly similar biological agents might exhibit nuanced profiles in clinical practice. There was no report of infusion- related syndrome in either group, which might be attributable to the appropriate pre-medication protocol administered before r-ATG infusion in all recipients. According to the product's summary of product characteristics (SmPC), the infusion should be filtered through a 0.22-µm filter into

a high-flow vein and administered for at least 6 hours for the first dose and at least 4 hours for subsequent doses. The SmPC does not provide any guidelines for the administration of r-ATG through a peripheral vein. However, 36% of our patients received their r-ATG infusion through the peripheral veins. None of these patients exhibited signs or symptoms of phlebitis or thrombosis, which might be due to the addition of heparin and hydrocortisone to their infusion bottles, a method employed in prior studies reporting the administration of r-ATG through a peripheral vein to reduce the risk of thromboembolic events.[33]

The incidences of CMV and BK viral infections were 3% and 7%, respectively, during the follow-up period, which were broadly consistent with the findings of similar studies.[34, 35] There was no significant difference between the groups in this regard. However, the 1-year course of this study addressed early infections rather than late infections, which require longer follow-up periods.

While this study provides robust 1-year comparative data, the potential long-term consequences of the observed trends warrant consideration. The non-significant trend towards increased severe leukopenia with TGlobulin25® merits attention beyond the immediate risk of infection. Prolonged or profound lymphopenia following induction therapy has been associated in some studies with a higher incidence of late-onset viral infections, impaired immune reconstitution, and a potentially altered risk profile for post-transplant lymphoproliferative disorder (PTLD), although our 1-year follow-up precludes assessment of this latter outcome. Conversely, it is also essential to monitor whether the numerical imbalance in leukopenia could influence long-term infection-related morbidity or mortality. Therefore, while our primary one-year efficacy and safety endpoints are reassuring, definitive conclusions regarding the long-term equivalence of these agents in preserving graft function and ensuring durable patient safety will require prospective studies with extended follow-up periods of 3 to 5 years or more.

Although this study is the first 1-year postmarketing surveillance (PMS) comparison of Thymoglobulin® and TGlobulin25® as its biosimilar, it was subject to several limitations. One such limitation was its retrospective nature, which restricted the assessment of several factors. Accordingly, retrospective multicenter studies are essential for this issue. This was a single-center study, and further multicenter studies are required to increase the statistical power of the subject population. Another challenge was the 1-year follow-up period, which did not permit the assessment of several important outcomes, such as PTLD, chronic allograft nephropathy, or chronic rejection. Therefore, future studies should adopt longer follow-up periods. Another limitation of this study was that *de novo* donor-specific antibodies (DSA) were not evaluated, along with certain parameters of kidney function assessment, such as urine protein-to-creatinine ratio (UPCR) or urine albumin-to-creatinine ratio (UACR). Furthermore, a cost-effectiveness analysis was not performed for this study.

Conclusion

According to the results of this study, and considering all the limitations inherent to retrospective research, the administration of TGlobulin25®, as induction therapy, in kidney transplant patients demonstrated comparable efficacy to Thymoglobulin® in preventing acute rejection, DGF, and organ loss. Additionally, no significant differences were observed in the incidence rates of adverse events and viral infections, such as CMV or BK virus, between the two groups. It is essential to note that, given the retrospective nature of this study, prospective, multicentre studies are required to further evaluate the efficacy and safety of TGlobulin25®.

Authors' Contribution

M.S.: Conceptualization, methodology, formal analysis, resources, data curation, writing, visualization, supervision and project administration, funding acquisition; S.N.: Conceptualization, methodology, formal analysis, resources, writing, visualization, supervision and project administration, funding acquisition; M. A.J And J.R.: Methodology, software, formal analysis, data curation, writing, visualization; Z.Z.: Methodology, software, formal analysis, resources, writing, visualization; S.M.: Methodology, formal analysis, data curation, writing, visualization; M.D.: Methodology, formal analysis, data curation, writing, visualization; F.S.: Software, formal analysis, data curation, writing, visualization; S.G.: Software, formal analysis, data curation, writing, visualization. All authors have reviewed, read, and approved the final manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declaration of AI

The authors declare that no AI tools were used in the preparation of this manuscript.

Conflict of Interest: None declared.

References

1 Organ Procurement and Transplantation Network. 2022 organ transplants again set annual records; organ donation from deceased donors continues 12-year record-setting trend [Internet]. Richmond (VA): OPTN; 2022 [cited 2025]. Available from: https://optn.transplant.hrsa.gov/news/2022-organ-transplants-again-set-annual-records-organ-donation-from-deceased-donors-continues-12-year-record-setting-trend/

2 Brennan DC, Daller JA, Lake KD, Cibrik D, Del Castillo D, Thymoglobulin Induction Study G. Rabbit antithymocyte globulin versus basiliximab in renal transplantation. N Engl J Med. 2006;355:1967-77. doi: 10.1056/NEJMoa060068. PubMed PMID: 17093248.

3 Hardinger KL, Brennan DC, Klein CL. Selection of induction therapy in kidney transplantation. Transpl Int. 2013;26:662-72. doi: 10.1111/tri.12043. PubMed PMID: 23279211.

4 Custodio LFP, Martins SBS, Viana LA, Cristelli MP, Requiao-Moura L, Chow CYZ, et al. Efficacy and safety of single-dose anti-thymocyte globulin versus basiliximab induction therapy in pediatric kidney transplant recipients: A retrospective comparative cohort study. Pediatr Transplant. 2024;28:e14713. doi: 10.1111/petr.14713. PubMed PMID: 38553819.

5 Lee JH, Lee H, Kim K, Lee SW, Song JH, Hwang SD. The Effect of Induction Therapy on Antibody-Mediated Rejection in Kidney Transplantation: A Network Meta-Analysis Using Recent Data. Transplant Proc. 2024;56:530-3. doi: 10.1016/j.transproceed.2024.01.021. PubMed PMID: 38490831.

6 Stevens RB, Wrenshall LE, Miles CD, Farney AC, Jie T, Sandoz JP, et al. A Double-Blind, Double-Dummy, Flexible-Design Randomized Multicenter Trial: Early Safety of Single- Versus Divided-Dose Rabbit Anti-Thymocyte Globulin Induction in Renal Transplantation. Am J Transplant. 2016;16:1858-67. doi: 10.1111/ajt.13659. PubMed PMID: 26696251; PubMed Central PMCID: PMC5069643.

7 Zuckermann AO, Grimm M, Czerny M, Ofner P, Ullrich R, Ploner M, et al. Improved long-term results with thymoglobuline induction therapy after cardiac transplantation: a comparison of two different rabbit-antithymocyte globulines. Transplantation. 2000;69:1890-8. doi: 10.1097/00007890-200005150-00026. PubMed PMID: 10830228.

8 Opelz G, Naujokat C, Daniel V, Terness P, Dohler B. Disassociation between risk of graft loss and risk of non-Hodgkin lymphoma with induction agents in renal transplant recipients. Transplantation. 2006;81:1227-33. doi: 10.1097/01.tp.0000219817.18049.36. PubMed PMID: 16699447.

9 Xuan D, Chen G, Wang C, Yao X, Yin H, Zhang L, et al. A Cost-effectiveness Analysis of Rabbit Antithymocyte Globulin Versus Antithymocyte Globulin-fresenius as Induction Therapy for Patients With Kidney Transplantation From Donation After Cardiac Death in China. Clin Ther. 2018;40:1741-51. doi: 10.1016/j.clinthera.2018.08.017. PubMed PMID: 30243768.

10 Jha PK, Rana A, Kher A, Bansal SB, Sethi S, Nandwani A, et al. Grafalon(R) vs. Thymoglobulin(R) as an Induction Agent in Renal Transplantation - A Retrospective Study. Indian J Nephrol. 2021;31:336-40. doi: 10.4103/ijn.IJN_205_20. PubMed PMID: 34584347; PubMed Central PMCID: PMC8443089.

11 Hernandez I, San-Juan-Rodriguez A, Good CB, Gellad WF. Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018. JAMA. 2020;323:854-62. doi: 10.1001/jama.2020.1012. PubMed PMID: 32125403; PubMed Central PMCID: PMC7054846.

12 Taube D, Jones G, O'Beirne J, Wennberg L, Connor A, Rasmussen A, et al. Generic tacrolimus in solid organ transplantation. Clin Transplant. 2014;28:623-32. doi: 10.1111/ctr.12336. PubMed PMID: 24750309.

13 Finocchietti M, Marino ML, Rosa AC, Bellini A, Masiero L, Cardillo M, et al. Immunosuppression with Generics in Liver and Kidney Transplantation: A Real-World Evidence Study. Drug Des Devel Ther. 2024;18:53-69. doi: 10.2147/DDDT.S431121. PubMed PMID: 38229916; PubMed Central PMCID: PMC10790661.

14 Malekshahi A, MortezaNejad HF, Taromsari MR, Gheshlagh RG, Delpasand K. An evaluation of the current status of kidney transplant in terms of the type of receipt among Iranian patients. Ren Replace Ther. 2020;6:45. doi: 10.1186/s41100-020-00314-8.

15 Malek-Hosseini SA, Habibzadeh F,

Nikeghbalian S. Shiraz Organ Transplant Center: The Largest Liver Transplant Center in the World. Transplantation. 2019;103:1523-5. doi: 10.1097/TP.0000000000002581. PubMed PMID: 31348432.
16 Ali H, Mohamed MM, Sharma A, Fulop T, Halawa A. Outcomes of Interleukin-2 Receptor Antagonist Induction Therapy in Standard-Risk Renal Transplant Recipients Maintained on Tacrolimus: A Systematic Review and Meta-Analysis. Am J Nephrol. 2021;52:279-91. doi: 10.1159/000514454. PubMed PMID: 33887727.
17 Gharekhani A, Entezari-Maleki T, Dashti-Khavidaki S, Khalili H. A review on comparing two commonly used rabbit anti-thymocyte globulins as induction therapy in solid organ transplantation. Expert Opin Biol Ther. 2013;13:1299-313. doi: 10.1517/14712598.2013.822064. PubMed PMID: 23875884.v
18 Song T, Yin S, Li X, Jiang Y, Lin T. Thymoglobulin vs. ATG-Fresenius as Induction Therapy in Kidney Transplantation: A Bayesian Network Meta-Analysis of Randomized Controlled Trials. Front Immunol. 2020;11:457. doi: 10.3389/fimmu.2020.00457. PubMed PMID: 32318057; PubMed Central PMCID: PMC7146975.
19 Jorgenson MR, Descourouez JL, Brady BL, Chandran MM, Do V, Kim M, et al. A call for transplant stewardship: The need for expanded evidence-based evaluation of induction and biologic-based cost-saving strategies in kidney transplantation and beyond. Clin Transplant. 2021;35:e14372. doi: 10.1111/ctr.14372. PubMed PMID: 34033140.
20 European Medicines Agency. Guideline on similar biological medicinal products [Internet]. London: EMA; 2014 [cited 2025]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/10/WC500176768.pdf
21 Shin D, Kim Y, Kim YS, Kornicke T, Fuhr R. A Randomized, Phase I Pharmacokinetic Study Comparing SB2 and Infliximab Reference Product (Remicade((R))) in Healthy Subjects. BioDrugs. 2015;29:381-8. doi: 10.1007/s40259-015-0150-5. PubMed PMID: 26577771; PubMed Central PMCID: PMC4684585.
22 Shin D, Lee Y, Kim H, Kornicke T, Fuhr R. A randomized phase I comparative pharmacokinetic study comparing SB5 with reference adalimumab in healthy volunteers. J Clin Pharm Ther. 2017;42:672-8. doi: 10.1111/jcpt.12583. PubMed PMID: 28675520.
23 Song NK, et al. Safety and efficacy comparisons of rituximab biosimilars to the reference product in patients with cancer: a systematic meta-analysis review. J Pharm Pract Res. 2022;52:234-45. doi: 10.1002/jppr.1827.
24 Yin D, Barker KB, Li R, Meng X, Reich SD, Ricart AD, et al. A randomized phase 1 pharmacokinetic trial comparing the potential biosimilar PF-05280014 with trastuzumab in healthy volunteers (REFLECTIONS B327-01). Br J Clin Pharmacol. 2014;78:1281-90. doi: 10.1111/bcp.12464. PubMed PMID: 25041377; PubMed Central PMCID: PMC4256618.
25 Ishii-Watabe A, Kuwabara T. Biosimilarity assessment of biosimilar therapeutic monoclonal antibodies. Drug Metab Pharmacokinet. 2019;34:64-70. doi: 10.1016/j.dmpk.2018.11.004. PubMed PMID: 30600193.
26 Roozbeh J, Malekmakan L, Monavarian M, Daneshian A, Karimi Z. Survival of Kidney Retransplant Compared With First Kidney Transplant: A Report From Southern Iran. Exp Clin Transplant. 2018;16:386-90. doi: 10.6002/ect.2016.0130. PubMed PMID: 27855590.
27 Budde K, Rath T, Sommerer C, Haller H, Reinke P, Witzke O, et al. Renal, efficacy and safety outcomes following late conversion of kidney transplant patients from calcineurin inhibitor therapy to everolimus: the randomized APOLLO study. Clin Nephrol. 2015;83:11-21. doi: 10.5414/cn108444. PubMed PMID: 25512099.
28 Tedesco-Silva H, Peddi VR, Sanchez-Fructuoso A, Marder BA, Russ GR, Diekmann F, et al. Open-Label, Randomized Study of Transition From Tacrolimus to Sirolimus Immunosuppression in Renal Allograft Recipients. Transplant Direct. 2016;2:e69. doi: 10.1097/TXD.0000000000000579. PubMed PMID: 27500260; PubMed Central PMCID: PMC4946511.
29 Sommerer C, Duerr M, Witzke O, Lehner F, Arns W, Kliem V, et al. Five-year outcomes in kidney transplant patients randomized to everolimus with cyclosporine withdrawal or low-exposure cyclosporine versus standard therapy. Am J Transplant. 2018;18:2965-76. doi: 10.1111/ajt.14897. PubMed PMID: 29722128.
30 Hilbrands L, Budde K, Bellini MI, Diekmann F, Furian L, Grinyo J, et al. Allograft Function as Endpoint for Clinical Trials in Kidney Transplantation. Transpl Int. 2022;35:10139. doi: 10.3389/ti.2022.10139. PubMed PMID: 35669976; PubMed Central PMCID:

PMC9163811.
31 Henningsen M, Jaenigen B, Zschiedrich S, Pisarski P, Walz G, Schneider J. Risk Factors and Management of Leukopenia After Kidney Transplantation: A Single-Center Experience. Transplant Proc. 2021;53:1589-98. doi: 10.1016/j.transproceed.2021.04.011. PubMed PMID: 34020796.
32 Shafiekhani M, Esmaeili A, Emami FS, Heidari K, Saberi Moghadam N, Badri S, et al. Comparing the noninfectious adverse effects of two rabbit anti-thymocyte globulin immunosuppression in kidney transplantation: a multicenter, retrospective study. Expert Opin Biol Ther. 2025;25:799-806. doi: 10.1080/14712598.2025.2512127. PubMed PMID: 40438907.
33 Wolf M, Descourouez JL, Hager DR, Djamali A. Peripheral administration of antithymocyte globulins: a review of current literature. Transplant Rev (Orlando). 2013;27:17-20. doi: 10.1016/j.trre.2012.11.002. PubMed PMID: 23276645.
34 Radtke J, Dietze N, Fischer L, Achilles EG, Li J, Scheidat S, et al. Incidence of BK polyomavirus infection after kidney transplantation is independent of type of immunosuppressive therapy. Transpl Infect Dis. 2016;18:850-5. doi: 10.1111/tid.12611. PubMed PMID: 27639176.
35 Raval AD, Kistler KD, Tang Y, Murata Y, Snydman DR. Epidemiology, risk factors, and outcomes associated with cytomegalovirus in adult kidney transplant recipients: A systematic literature review of real-world evidence. Transpl Infect Dis. 2021;23:e13483. doi: 10.1111/tid.13483. PubMed PMID: 33012092.